Universidade do Minho
Escola de Medicina

Fernando Emanuel Dias Correia

Validation of a Novel Intervention Based on Digital Biofeedback for Home-based Rehabilitation after Hip or Knee Replacement

setembro de 2020

Validation of a Novel Intervention Based on Digital Biofeedback for Home-based Rehabilitation after Hip or Knee Replacement
Fernando Emanuel Dias Correia
UMinho | 2020

Universidade do Minho
Escola de Medicina

Fernando Emanuel Dias Correia

Validation of a Novel Intervention Based on Digital Biofeedback for Home-based Rehabilitation after Hip or Knee Replacement

Tese de Doutoramento em Medicina

Tese auto-proposta

setembro de 2020

Ackowledgments

To my parents, for everything that can be put into words, particularly for being my role models of hard work, dedication and resilience, but also – and especially - for everything that cannot.

To my wife, Sandra, for being a safe harbor in every moment, and whose infinite comprehension has allowed me to reach this far.

To my son, Eduardo, to whom I wish this thesis serve as inspiration for trying to aim higher and make a mark in the world.

To Virgilio Bento, for his brilliance and creativity, for being the lighting spark and guiding light behind SWORD, and for pushing me ever harder.

To all collaborators at SWORD Health, *primus inter pares*, who have effectively made all this work possible, especially to the members of the clinical team.

To all of those who helped me bring this strenuous task, spanning several years, to fruition.

To all the team from Hospital da Prelada, who believed in the potential of this new technology, and supported us from day one, in particular to the Clinical Lead, Dr. Varejão Pinto, and the Director of Orthopaedics, Dr. Rosmaninho Seabra.

To João Chaves, my mentor, whose romantic vision of life helped me discover the art and charm behind medicine and neurology.

To Ricardo Taipa, for being an example, both professionally and personally, of what great men are made of, and for guiding me through all these years.

And to Joana Domingos, who left us too soon, for teaching me, as a colleague and as a friend, that greatness, humility and kindness can co-exist in the same person.

Financing

The work herein presented was largely financed by the European Commission, through the H2020 Project SME Instrument Phase 2 – grant agreement 672814.

SWORD Health, SA- the manufacturer of the medical device SWORD Phoenix® – was the entity responsible for the execution of the project conducting to the work herein presented, and acted as sponsor of the clinical trials.

STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

University of Minho, 30/09/2020

Full name: Fernando Emanuel Dias Correia

Signature: _____

Resumo

A artroplastia total da anca (ATA) e do joelho (ATJ) é a abordagem terapêutica indicada em doentes com osteoartrose da anca/joelho com sintomas e incapacidade não controláveis com tratamento conservador. A fisioterapia permite maximizar os resultados clínicos após ATA/ATJ. Contudo, as abordagens convencionais obrigam a uma logística pesada por parte dos prestadores e/ou utentes. Soluções de tele-reabilitação têm demonstrado resultados clínicos semelhantes a fisioterapia convencional, mas continuam a depender de forma muito direta da disponibilidade de fisioterapeutas.

São, por isso, necessárias soluções que permitam a realização de programas de reabilitação domiciliários controlados remota e assincronamente pelas equipas clínicos, mas a maioria está numa fase embrionária e a validação clínica é escassa. O SWORD Phoenix® é um dispositivo de biofeedback digital, baseado em sensores de movimento inercial, que pretende responder a esta necessidade.

O objetivo desta tese foi o de comparar os resultados clínicos de ATA/ATJ seguida de um programa de reabilitação digital, realizado através do sistema SWORD Phoenix, com os de cirurgia seguida de fisioterapia convencional. Adicionalmente, pretendeu-se também avaliar a usabilidade do sistema, e comparar os custos do um programa digital com os da fisioterapia convencional.

Nesta tese são apresentados dois ensaios clínicos, prospetivos, uni-cêntricos, não randomizados, de grupo paralelo, com um desenho semelhante. Os doentes foram recrutados antes da cirurgia, seguindo-se cirurgia eletiva e alocação a um de dois grupos aquando da alta hospitalar: doentes que residiam fora dos limites administrativos da cidade foram alocados ao programa digital; os outros foram alocados a fisioterapia convencional. Ambos os grupos tiveram 8 semanas de reabilitação após cirurgia. Os doentes foram avaliados antes da cirurgia, 4 e 8 semanas após cirurgia, e depois 3 e 6 meses após cirurgia. O outcome primário foi a evolução do teste Timed up and Go (TUG) entre a avaliação inicial e a das 8 semanas. Foram adicionalmente considerados os scores TUG, bem como as amplitudes articulares da anca/joelho e ainda escalas auto-reportadas – Hip Osteoarthritis Outcome Score (HOOS) e Knee Osteoarthritis Otucome Score (KOOS)- nos vários pontos de avaliação (e evolução desde a avaliação inicial). Foram ainda avaliados parâmetros de aceitação e usabilidade, assim como os eventos adversos.

No ensaio clínico focado na ATA, foram incluídos 66 doentes: 35 foram alocados ao grupo cirurgia seguida de programa digital (grupo digital) e 31 ao grupo cirurgia seguida de fisioterapia convencional (grupo convencional). Na avaliação inicial, o grupo digital tinha pontuações mais baixas na subescala de qualidade de vida da HOOS. Não foram constatadas outras diferenças entre os grupos nesta avaliação. No total, 59 doentes terminaram o programa (30 grupo digital vs 29 grupo convencional) e 57 a avaliação dos 6 meses (30 vs 27). Foram observados resultados superiores – particularmente na análise "per protocol" (PP)- no grupo digital não só para o outcome primário ($p<0.001$) mas também para os valores de TUG em todos os pontos de avaliação, bem como na variação desde a avaliação inicial. Observamos, contudo, tendência para convergência entre os dois grupos após a

avaliação das 8 semanas, com diferença não clinicamente significativa aos 6 meses para o TUG. Em relação às amplitudes articulares, os resultados foram também superiores no grupo digital em todos os pontos de avaliação, excetuando para a flexão da anca em pé. Foi também notada convergência nestes parâmetros após as 8 semanas. Relativamente à escala HOOS, na análise PP foram observados resultados favorecendo o grupo digital nae variação desde a avaliação inicial até às 8 semanas, 3 e 6 meses, bem como melhores resultados nas avaliações das 8 semanas, 3 e 6 meses. Na análise "intent-to-treat" (ITT), as diferenças foram menos evidentes, mas os scores às 8 semanas e 6 meses ns subescalas de Actividades da vida diária (ADL) e Qualidade de vida (QoL) também favorecem o grupo digital. Não houve diferenças na taxa de eventos adversos – 14.3% digital e 22.6% convencional (p=0.525). Em termos de usabilidade, no grupo digital, 91.4% classificaram a satisfação com 10/10. Os doentes deste grupo tiveram uma média de 0.6 (intervalo 0-2) visitas e de uma mediana de 4 chamadas adicionais (intervalo 0-7), e 37.1% necessitaram de ajuda de um cuidador na interação com o sistema.

No ensaio clínico focado na ATJ, foram incluídos 69 doentes: 38 grupo digital vs 31 grupo convencional. Na avaliação inicial, o grupo digital tinha pontuações mais baixas em todas as subescalas da KOOS. Não foram constatadas outras diferenças entre os grupos. No total, 59 doentes terminaram o programa e concluíram a avaliação dos 6 meses (30 vs 29). Na análise PP, foram observados resultados superiores no grupo digital não só para o outcome primário (p<0.001), mas também para o TUG em todos os pontos de avaliação e variação desde avaliação inicial. Na análise ITT, constataram-ser resultados superiores no grupo digital às 8 semanas, 3 e 6 meses mas não na variação desde avaliação inicial. Foram observados resultados superiores no grupo digital para a extensão do joelho sentado, e na análise PP também na variação desde a avaliação inicial até às 8 semanas em todas as amplitudes articulares. Foi observada tendência para convergência entre os dois grupos para TUG e ROM depois das 8 semanas. Em relação à KOOS, na análise PP, os resultados no grupo digital foram superiores em todas as subescalas, em todos os pontos de avaliação e na variação desde avaliação inicial. Na análise ITT, foram observados scores superiores na variação desde a avaliação inicial até às 8 semanas, 3 e 6 meses, em todas as subescalas excepto Sports. A taxa de eventos adversos foi superior no grupo convencional - 22-6% vs 2.6% no grupo digital (p=0.02). Em relação à usabilidade, no grupo digital, 73.7% classificaram a satisfação com 10/10. Os doentes deste grupo tiveram uma média de 0.4 (intervalo 0-2) visitas e uma mediana de 2.5 (intervalo 1-12) chamadas adicionais, e 58% necessitaram de ajuda de um cuidador na interação com o sistema.

Em conjunto, estes dois ensaios clínicos demonstram que a THA/TKA seguida de reabilitação digital é uma abordagem fazível, permite maximizar os resultados clínicos em comparação com cirurgia seguida de fisioterapia convencional, oferecendo uma solução escalável que maximiza a conveniência do doente e minimiza a dependência de recursos humanos, resultando em potenciais reduções no custo da prestação de cuidados.

Palavras-chave: artroplastia, anca, biofeedback, joelho, reabilitação

Abstract

Total hip (THA) or knee arthroplasty (TKA) are the mainstay treatment in patients with hip/knee osteoarthritis with severe symptoms or functional limitations despite optimized conservative care. Rehabilitation maximizes outcomes after THA/TKA. Conventional physical therapy (PT) poses considerable logistic difficulties to patients and/or providers, and while tele-rehabilitation has demonstrated similar outcomes to conventional approaches, it remains very demanding in terms of therapist time.

Technological solutions that enable home-based rehabilitation programs under remote and asynchronous monitoring from clinical teams are therefore necessary. However, many are still on the early stages of development and clinical validation is still poor. SWORD Phoenix® is a novel digital biofeedback system based on inertial motion trackers that seeks to fulfill these needs.

The aim of this thesis was to compare the clinical outcomes of THA/TKA followed by a digital rehabilitation program using this system against those of surgery plus conventional rehabilitation. Additionally, we sought to asses system usability, and to compare the costs of the delivery of a digital program versus those of conventional rehabilitation.

The thesis presents two single-center, prospective, non-randomized, parallel-group clinical trials, with a similar design. In both, patients were recruited before surgery and then allocated to one of two groups after discharge, according to geographical criteria: patients residing outside city limits were allocated to the digital program and the others were allocated to conventional PT. Both groups went through elective surgery plus 8 weeks of post-surgical rehabilitation. Patients were assessed at baseline (pre-surgery), and then at 4 weeks 4, 8 weeks, 3 months and 6 months after surgery. The primary outcome was the evolution in the Timed up and Go test (TUG) between baseline and 8 weeks. TUG scores in the other timepoints (and their evolution from baseline) were also considered, as well as hip/knee range of motion (ROM) and patient-reported outcome measures – Hip Osteoarthritis Outcomes Scale (HOOS) and Knee Osteoarthitis Outcomes Scale (KOOS) – in all timepoints. Acceptance and usability parameters were also assessed, as well as adverse events.

In the THA study, 66 patients were included: 35 surgery plus digital program (digital group) versus 31 surgery plus conventional rehabilitation (conventional group), and 59 completed the program (30 vs 29). There were no differences at baseline between groups except for lower HOOS quality of life (QoL) subscale scores in the digital PT group. Overall, greater benefits were observed in the digital group not only for the primary outcome ($p<0.001$), as well for the TUG score in all timepoints and change from baseline, particularly evident in the per protocol (PP) analysis. As to hip ROM, results also favor the digital group in all timepoints, except for standing hip flexion. We did observe convergence between groups after the 8 week assessment, leading to a non-clinically significant difference at the 6M assessment for TUG. Convergence was also noted for ROM. As to HOOS, results in the PP analysis were also in favor of the digital group, showing not only greater changes from baseline to 8 weeks and 6 months, as well as higher results at 8 weeks and 6 months in all subscales except Pain. In the intent-to-treat

analysis (ITT), differences between groups are less evident, but scores in the Activities of Daily Living (ADL) and Quality of Life (QoL) at 8 weeks and 6 months favor the digital group.
There was no difference in terms of adverse events in both groups – 14.3% in the digital group vs 22.6% in the conventional group (p=0.525).
In terms of usability, in the digital group, 91.4% rated their satisfaction as 10/10. Patients in this group required an average of 0.6 (range 0-2) extra contacts and a median of 4 extra calls (range 0-7) for technical assistance. Also, 37.1% required the assistance of a caregiver to interact with the system.

In the TKA study, 69 patients were included: 38 digital group versus 31 conventional group, and 59 completed the program and follow up assessments (30 vs 29). The digital group had lower KOOS scores (in all subscales) at baseline, with no other differences noted between groups.
In the PP analysis, greater benefits were observed in the digital group not only for the primary outcome ($p<0.001$), as well for the TUG score in all timepoints and change from baseline. The ITT analysis shows better outcomes in the digital group for TUG at 8 weeks and 6 months, but not in change from baseline. Regarding knee ROM, better outcomes were noted in the digital group for sitting knee extension, and in the PP analysis in terms of change from baseline to 8 weeks in all movements assessed. We did observe convergence between groups after the 8 week assessment, in both TUG and ROM. Regarding KOOS, in the PP analysis, scores in the digital group were higher for all subscales at all timepoints and also considering change from baseline. In the ITT analysis, higher scores in the digital group were found when considering change from baseline to 8 weeks and 6 months in all subscales except Sports.
The adverse event rate was higher in the conventional group – 22-6% vs 2.6% In the digital group (p=0.02).
In terms of usability, in the digital group, 73.7% rated their satisfaction as 10/10. Patients in this group required an average of 0.4 (range 0-2) extra contacts and a median of 2.5 extra calls (range 1-12) for technical assistance. Also, 58% required the assistance of a caregiver to interact with the system.

Taken together, these two trials demonstrate that THA/TKA followed by a digital rehabilitation program is feasible, safe and capable of maximizing clinical outcomes in comparison to surgery plus conventional rehabilitation, while being far less demanding in terms of human resources and therefore resulting in lower costs of care.

Key words: arthroplasty, biofeedback, hip, knee, rehabilitation

Contents

List of Figures

List of Tables

List of Abbreviations

6MW- 6-minute walking test

ACL- Anterior Cruciate Ligament

ADL- Activities of Daily Living

ASA- American Society of Anesthesiology

ATA- Artroplastia Total da Anca

ATJ- Artroplastia Total do Joelho

ANOVA- Analysis of Variance

BMI- Body Mass Index

CES-D10- Centre for Epidemiological Studies Depression Scale

CJR- Comprehensive Joint Replacement

CI- Confidence Interval

CONSORT- Consolidated Standards of Reporting Trials

CT- Computerized Tomography

EMG- electromyography

EU- European Union

FAS- Functional Ability Score

FEDMER- French Federation of Physical Rehabilitation Medicine

FTSST- Five Times Sit to Stand Test

GDP- Gross Domestic Product

HOOS- Hip Osteoarthritis Outcome Score

IMU- Inertial Motion Unit

ITT- Intent-to-treat

KOOS- Knee Osteoarthritis Outcome Score

KOOS-PS- Knee Osteoarthritis Outcome Scale Physical Function Short Scale

MCID- Minimal Clinically Important Difference

MDC- Minimal Detectable Change

MRI- Magnetic Resonance Imaging

NHS- National Health Service

NSAIDs- Non-Steroid Anti-Inflammatory Drugs

OA- Osteoarthritis

OADR- Old-age Dependency Ratios

OECD- Organization for Economic Cooperation and Development

POADR- Prospective Old-age Dependency Ratios

PP-Per-protocol

PROM- Patient Reported Outcome Measures

QoL- Quality of Life

ROM- Range of Motion

SDD- Smallest Detectable Difference

SF-36- Short Form Questionnaire-36

SOFMER- French Physical and Rehabilitation Medicine Society

SWORD- Stroke Wearable Operative Rehabilitation Device

THA- Total Hip Arthroplasty

TJA- Total Joint Arthroplasty

TKA- Total Knee Arthroplasty

TUG- Timed up and Go Test

UK- United Kingdom

UKA- Unicompartmental Knee Arthroplasty

USA- United States of America

WMFT- Wolf Motor Function Test

WOMAC- Western Ontario and McMaster University Arthritis Index

YLD- Years Lived with Disability

Original contributions and awards

The work herein presented resulted in the following publications in peer reviewed international scientific journals:

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V. **Home-based Rehabilitation With A Novel Digital Biofeedback System versus Conventional In-person Rehabilitation after Total Knee Replacement: a feasibility study.** Sci Rep. 2018. doi:10.1038/s41598-018-29668-0 (Impact Factor: 4.011; Q1 in Multidisciplinary Journals) (**Annex 1**)

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V. **Medium-Term Outcomes of Digital Versus Conventional Home-Based Rehabilitation After Total Knee Arthroplasty: Prospective, Parallel-Group Feasibility Study.** JMIR Rehabil Assist Technol. 2019. doi:10.2196/13111 (Impact Factor: NA; sister journal of Journal of Medical Internet Research – IF 2018: 4.945) (**Annex 2**)

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Pires J, Seabra R, Lains J, Bento V. **Digital Versus Conventional Rehabilitation After Total Hip Arthroplasty: A Single-Center, Parallel-Group Pilot Study.** JMIR Rehabil Assist Technol. 2019;6(1):e14523. doi:10.2196/14523 (Impact Factor: NA; sister journal of Journal of Medical Internet Research – IF 2018: 4.945) (**Annex 3**)

The results of the work herein presented were also presented in the following international conferences:

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V. **Home-based rehabilitation with SWORD Phoenix versus standard of care after total knee replacement: a pilot study.** 12th International Society of Physical and Rehabilitation Medicine World Congress, Paris, 8-12 July 2018 (e-poster) (**Annex IV**)

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V. **Medium-term outcomes after Total Knee Replacement: follow up results of a feasibility study comparing digital versus conventional home-based rehabilitation.** 13th International Society of Physical and Rehabilitation Medicine World Congress, Kobe, 9-12 June 2019 (**Annex V**)

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Pires J, Seabra R, Lains J, Bento V. **Digital Biofeedback System versus Conventional Home-based In-person Rehabilitation**

for Total Hip Arthroplasty: a feasibility study. 13th International Society of Physical and Rehabilitation Medicine World Congress, Kobe, 9-12 June 2019 (**also Annex V**)

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Pires J, Seabra R, Lains J, Bento V. **Medium-term outcomes of a feasibility study comparing digital versus conventional home-based rehabilitation after Total Hip Replacement.** 13th International Society of Physical and Rehabilitation Medicine World Congress, Kobe, 9-12 June 2019 (**also Annex V**)

Additionally, in 2018, SWORD Phoenix® received the Best Innovation Award at the 12th International Society of Physical and Rehabilitation Medicine World Congress (**Annex VI**)

CHAPTER 1| INTRODUCTION

1.1. Thesis organization

This thesis is organized into six chapters. The present chapter - **Chapter 1** - provides an overview of the motivation behind the thesis, presents the specific objectives and outlines the thesis roadmap, including a brief description of the purpose of each chapter.

Chapter 2 provides an overview of the current state of the art, beginning with an epidemiological contextualization of the problem, followed by a review of current evidence on rehabilitation after THA/TKA and subsequently addressing current technological solutions and their clinical validation.

Chapters 3 describes the THA clinical trial, including methods, results and discussion. For the purpose of this thesis, the introduction part was omitted, since it is covered in chapter 2; original contributions were adapted and expanded to provide additional information that was not possible to convey in the published papers.

Chapter 4 describes the TKA clinical trial, including methods, results and discussion. For the purpose of this thesis, the introduction part was omitted, since it is covered in chapter 2; original contributions were adapted and expanded to provide additional information that was not possible to convey in the published papers.

Chapter 5 discusses common and contrasting aspects related to both trials, which merit a joint reflection, including not only clinical aspects but also those related to usability, as well as the discussion of trial limitations.

Chapter 6 presents a pos-hoc cost-comparison analysis between the two post-surgery interventions. For the purpose of this analysis, and given the similarity between the post-surgery interventions in the two clinical trials, they were both combined.

Chapter 7 presents the overarching conclusions and takes a look forward, expanding on future directions and lines of research created by the work herein presented.

1.2. Motivation

The world population is aging[1] and with this, the prevalence of osteoarthritis (OA) is rising.[2] OA affects mostly the hand, hip, knee and spine joints.[3] Clinically, hip and knee osteoarthritis are important causes of disability worldwide.[3]

In patients with severe symptoms or functional limitations associated with a reduced quality of life despite optimized conservative care, total hip (THA) or knee arthroplasty (TKA) remains the mainstay treatment.[4] In fact, the incidence of THA/TKA has been steadily increasing, and will continue to do so in the following decades.[5–7]

Rehabilitation maximizes outcomes after THA/TKA.[8–12] However, the provision of these services varies widely[13,14] and there are no universally accepted guidelines for rehabilitation after THA/TKA.[11,15–18] Access to rehabilitation is thus far from ideal, and the wide variation in program composition[14] does little to ensure all patients have access to effective rehabilitation.

Moreover, in the current context of increasing expenditure in healthcare systems worldwide and huge pressure to contain it,[19] the development of novel delivery models that are financially sustainable, is both a challenge and a priority.[19]

Most rehabilitation programs after THA/TKA are performed in an outpatient setting, whether at the hospital or at rehabilitation clinics.[13] This, however, poses considerable logistic difficulties to both patients and caregivers, which are amplified in remote areas.[20] Home-based supervised programs, conversely, are heavy on logistics on the provider side.[20] To circumvent this, tele-rehabilitation solutions have been developed, and these have demonstrated similar outcomes to conventional physical therapy following both THA and TKA.[21–25] However, these solutions remain very demanding in terms of therapist time, and still face multiple technical challenges, namely in terms of setup and need for technical support.[26] In recent years, more advanced technological solutions have emerged that further enhance patient autonomy and minimize real-time human supervision.[27–32] Crucially, these incorporate biofeedback systems with the intent of increasing both patient adherence and performance.

Promising as these may be, clinical validation is still poor, with very few randomized controlled trials against conventional physical therapy[28,30,33] and only one in the context of TKA, with a very short follow-up.[28]

SWORD Health has developed a novel digital biofeedback system (SWORD Phoenix®) based on inertial motion trackers, that enables independent home-based physical rehabilitation under remote monitoring from the clinical team, addressing the limitations of current systems.

This thesis aimed to explore how would the clinical impact of THA/TKA plus digital intervention compare to with that of surgery plus conventional physical therapy, and additionally assess the safety and usability of this system, in the context of home-based rehabilitation afeter THA/TKA.

The importance of this work lies in the fact that solutions like the one presented here, if effective, can hold the key to solve current constraints in the delivery of rehabilitation interventions, and unlock the potential of technology to democratize access to healthcare. This is especially important since innovations in medical technology are generally believed to be the primary driver of healthcare spending.[19,34]

1.3. Previous research

SWORD Phoenix® is a certified class I medical device (CE marking) since May 2016 (Registration number: ED 60110945 0001) and is the result of a research and development project that began in 2008, when Virgilio Bento initiated his PhD in electronics engineering.

The first prototype of the system was developed to explore the use of vibratory feedback in the rehabilitation of stroke patients. The safety and tolerability of this prototype was validated in a proof of concept clinical trial involving five patients with hemiparesis resulting from ischemic stroke.[35]

This clinical trial opened the door to further investigation and innovation. Recognizing the need for proper assessment of motor performance in neurorehabilitation, a three-dimensional motion quantification system was developed. A second proof-of-concept trial was then developed to compare the assessment of upper limb function between a trained therapist and an automated algorithm processing the information derived from the motion trackers. This algorithm included features inferred from the Functional Ability Score of the Wolf Motor Function Test (WMFT).[36] Five stroke patients were tested on both sides across five selected tasks. There was an agreement between both systems in four out of five patients, demonstrating that the prototype was able to automatically classify upper limb function with a high accuracy.[37]

The motion quantification system was then combined with the vibration module to create the SWORD system (Stroke Wearable Operative Rehabilitation Device). A pilot clinical trial was then performed to explore the utility of the solution in stroke rehabilitation. This pilot trial was performed in a hospital setting

and involved five patients with hemiparesis after ischemic stroke. This was a crossover trial where the traditional approach was tested against this system.[38] For comparison, a simple motor task was chosen - shoulder flexion with elbow flexed at 90 degrees - as a proxy of the hand-to-mouth task. All patients performed the exercise in both experimental conditions - using the movement quantification system with and without vibratory feedback. The results showed that, for four in five participants, the use of the SWORD device with active feedback promoted an increase in training intensity and quality, defined as the number of correct movements performed by the user during the duration of the session.[38]

Based on these results, a larger trial was performed.[39] This was a randomized controlled trial with a crossover design, involving 44 patients with hemiparesis after ischemic stroke (ClinicalTrials.gov Registry Number NCT01967290). This trial was performed in an inpatient setting, in the first rehabilitation session after stroke. Two patient groups were defined and randomly distributed between the intervention group (motion analysis plus vibratory feedback whilst performing the exercise) and the active comparator (motion analysis of the same exercise without feedback). The primary outcome was the number of correct movements per minute. In this trial, the vibratory feedback was able to modulate motor training, increasing the number of correct movements by an average of 7.2/minute (95%CI [4.9;9.4]; $p<0.001$) and reducing the probability of performing an error from 1:3 to 1:9.[39]

This trial confirmed the results obtained in the previous pilot trial and not only stimulated further research, but ultimately led to the creation of SWORD Health, in order to bridge the gap between bench and bedside and transform the system into a medical device that could be used in the field.

However, this implied a profound change in the nature of the feedback provided - the vibratory module was abandoned and exchanged for visual and auditory feedback provided through a patient dedicated app. This decision was influenced by several factors, arising both from research in neurorehabilitation and from pragmatical observations: a) neurobiological data shows increased functional activity in several cortical areas after stroke[40]; b) a multimodal approach implies activation and coordination of several cortical regions, stimulating neuroplasticity[41]; c) research findings suggest that visual and auditory feedback may enhance patient performance[42]; d) vibratory feedback has intrinsic limitations in patients with sensory impairment; e) vibratory feedback is not sufficient to relay all the required kinetic information to the patient; f) the vibratory interferes with the motion tracking system accuracy. From the above stated reasons, the last two – pragmatical in nature – were the main drivers for this paradigm change and a clear example of the sometimes profound changes that translation from an academic/investigational context to the real-world implies.

When the motion tracking system and the vibratory modules were combined in the previous clinical trial, the movement that was performed by the patients was purely in the vertical plane, requiring only inputs from the gyroscope and accelerometer. However, to adequately track motion on the horizontal plane, the magnetometer is necessary to correct the accumulated drift of the gyroscope.[43]The vibratory module generates a magnetic field that interferes with the magnetometer, and therefore with the accuracy of the system, rendering it unreliable for use in a clinical scenario.

Furthermore, in the previous context where the system was studied, the patient was either under direct supervision of a clinician (or physical therapist) and/or had been given specific instructions in person regarding the movements he was expected to perform. However, without a visual interface displaying a video and audio description of the exercises, it was not possible to reduce (much less eliminate) the need for either direct human supervision or close proximity to the clinical team. In other words, it would never be possible to devise a system that could be potentially used by the patient at home, without direct clinical supervision, in the absence of a visual interface.

A follow-up clinical trial, with a similar methodology to the previous one, was then planned to test the new feedback on the motor performance of patients after stroke. It was hypothesized that this new feedback would have a positive impact on motor performance and that the magnitude of the effect would be at least similar to the vibratory feedback tested in the previous trial. This was a single-center, prospective, randomized, cross-over trial (NCT03032692) involving 30 patients, which were recruited in an outpatient clinic setting (therefore, in a post-acute setting). Patients were allocated to two groups. Both groups performed one exercise with the affected upper limb with and without biofeedback, in reverse order. The primary outcome was the number of correct movements, defined as those starting at the baseline and reaching the target joint angle, without violating movement or posture constraints. In this trial, the number of correct movements was higher in the sessions with feedback by an average of 13.2 movements/session (95% CI [5.9; 20.4]; $P<0.01$) and movement error probability was decreased from 1:1.3 to 1:7.7.[44]

Collectively, these clinical trials validated the positive impact on performance of the biofeedback provided by the SWORD system, and formed the basis for the application to an SME Instrument Phase 2 Grant, to further develop the system and bring it to market.

1.4. Thesis research in context

The project funded by the European Commission, which started in July 2015, brought about further improvements to all system components (hardware and software) and also the development of a web-based Portal to allow the clinical teams to monitor patient performance and evolution remotely.

The work performed under that project culminated in the certification of the system – under the commercial designation SWORD Phoenix® - as a class I medical device for use in rehabilitation, in May 2016.

Crucially, the ethos behind the development of such a system was never one of providing a digital tool to be used as part of the rehabilitation program, but one of re-defining care by enabling digital rehabilitation programs to be delivered and executed independently by the patients under remote (asynchronous) monitoring from the clinical teams.

To this effect, and given the innovative nature of this approach, with little research published in the area, producing clinical evidence that such a system could form the mainstay of rehabilitation programs, was a necessity.

Of note, at this point in time, preliminary evidence of the utility of this system for rehabilitation after stroke had been produced, both in inpatient and outpatient settings, but no validation existed for home-based use, and no evidence of whether such a system could bring about meaningful outcomes had been produced.

Concurrently, while the application of SWORD Phoenix® In the rehabilitation of neurological disorders was underway, namely through partnerships with public hospitals (Centro Hospitalar de Entre Douro e Vouga and Centro de Medicina Física e Reabilitação da Região Centro- Rovisco Pais) and private outpatient clinics, its application in musculoskeletal disorders was also being considered.

This resulted from the combination of several factors: a) musculoskeletal disorders (MSD) are the single largest cause of disability worldwide;[45] b) exercise is the mainstay in the treatment of musculoskeletal conditions;[46–49] c) very promising initial field experience with patients suffering from musculoskeletal disorders receiving care at the institutions using SWORD Phoenix®, both in terms of patient acceptability and clinical impact.

Within MSDs, osteoarthritis, in particular of the hip and knee, are important causes of disability worldwide[3], thus posing a natural interest as investigation targets. Also, biomechanically, both joints are much less complex than the shoulder joint, reinforcing their appeal as initial targets.

In addition to this, the prevalence of OA – including of the hip and knee- is rising.[2], and so is the incidence of THA/TKA[5–7] which are the largest cost drivers in OA care.[50] This has led countries to develop programs to support better and more efficient care to these patients, namely through programs like the Comprehensive Joint Replacement (CJR) program in the United States of America (USA) [51] This program is intended to test bundled payment (ie, payment of a fixed amount per patient, including surgery and post-surgical rehabilitation within a 90 day period) and quality measurement to encourage providers to work together in improving quality of care.

Within this context, and given the conjunction of all the factors discussed above, pursuing the validation of SWORD Phoenix® in the rehabilitation of MSD in general, and after THA/TKA in particular, became particularly attractive.

1.5. Objectives

The research questions that supported this thesis were:

Question 1: Is there any difference between the clinical outcomes of THA/TKA plus digital rehabilitation versus surgery plus conventional rehabilitation?

Question 2: Is the digital intervention well accepted, easily usable and engaging for patients undergoing rehabilitation after THA/TKA independently at home?

Question 3: Is the digital intervention associated with potential cost savings versus conventional rehabilititation?

CHAPTER 2 | STATE OF THE ART

2.1. Global socio-economical context

The world population is aging[1] and this is true both for developed and developing countries. In fact, the rate at which the population is aging is even greater in developing countries.[1] In 2017, estimates point to 962 million people aged 60 years or over, twice the number of 1980, an number which is expected to reach nearly 2.1 billion people in 2050.[1]

This has led to marked increases in Old-Age Dependency Ratios (OADR) across the globe, and to milder increases in Prospective Old Age Dependency Ratios (POADR), which take into account the years of life remaining as a proxy for dependency rather than years of life already lived.[1] Both are expected to continue increasing,[1] translating into a heavier burden of care for future societies.

The corollary of this is an increase in healthcare expenditure. In the European Union (EU), for example, the total cost of ageing (including pensions, healthcare, long-term care, education and unemployment benefits) is expected to increase by 1.7% to 26.7% of Gross Domestic Product (GDP) between 2016 and 2070.[52] Importantly, long-term care and healthcare costs are expected to contribute the most for this rise, increasing by 2.1% in the same period.[52]

This accrues to the problem of increasing healthcare spending throughout the Organization for Economic Cooperation and Development (OECD)[19], which, despite the recent slowdown since the global financial crisis, is expected to consume an additional 2% of GDP over the next 20 years.[19] Four main factors are cited as reasons for this increase even in developed countries: a) rising incomes lead to greater expectations on the quality of care; b) institutional characteristics of healthcare systems, with more regulated systems being more cost-saving; c) changing demography and d) new technologies.[19] The impact of changing demography in healthcare spend has been much debated.[53] While it seems obvious that age relates to a decrease in health status, it is not so clear that an increased life expectancy directly increases healthcare costs.[53] Still, evidence suggests that population aging moderately increases expenditures on acute care and strongly increases expenditures on long-term care.[53] What seems clearer is that innovations in medical technology is the primary driver of healthcare spending.[19,34,53]

In this current context, of increasing healthcare expenditure and the need to contain it, to ensure sustainability[19], new models of healthcare delivery are a necessity, and technology needs to become part of the solution, instead of part of the problem.

2.2. Epidemiology and burden of Osteoarthritis

Osteoarthritis (OA) is the most prevalent chronic joint disease.[54] It can involve any joint, but most frequently involves the hands, knees and hips, with knee and hip OA being the major drivers of OA-associated disability.[3]

The prevalence of OA is difficult to estimate, as it depends on the precise definition used, the age, sex, geographical area studied and the site of interest.[3,54] It is, however, clear, that OA becomes more common with age, and that after the age of 50, it is more prevalent in women than in men.[3,54,55] A study published in 2003, by Woolf & Pfleger, presents an estimated prevalence of 10% in men and 18% in women after age 60.[2] The EpiReumaPT, the only study on the epidemiology of rheumatological disorders in Portugal, reports a much higher prevalence in the 50-64 age group, with a combined prevalence of 29.7% (16.2% in men and 43.5% in women).[55] The magnitude of the difference between these two reports is significant. Still, if we factor in the fact that the prevalence of OA is increasing, mainly due to the aging population and the obesity epidemics,[54] and take into account that the first study was published in 2003 and the latter in 2018, then it seems likely that the current global prevalence is closer to the figure reported by the Portuguese study. In regards to the increase in OA prevalence, a study on the prevalence of doctor-diagnosed arthritis in the US estimates a prevalence of almost 25% in the adult population by 2030.[56]

Regarding hip OA, a study published in 2014 by Kim *et al.*[57] reported a prevalence of radiographic and symptomatic OA of 19.6% and 4.2%, respectively, in the Framingham Study Community Cohort.[57] The EpiReumaPT study reports a 2.9% prevalence of hip OA in the adult population.[58]

Regarding knee OA, a Swedish study reported a prevalence of 25.4% for radiographic OA and of 15.4% for symptomatic OA.[59] The EpiReumaPT study reports a 12.4% prevalence of knee OA in the adult population.[58] These values are significantly higher than the 7% reported in the Framingham Osteoarthritis study published in 1987,[60] probably related to an increase in prevalence since then. In fact, the most recent report of the Global Burden of Disease points to an increase in the prevalence of hip and knee OA between 2007 and 2017 of 21.6% for females and 16.7% for males, affecting more than 300 million people worldwide.[45]

Hip and knee OA are a leading cause of disability in adults,[61] particularly in the elderly.[62] The most recent report of the Global Burden of Disease points to more than 9.6 million Years Lived with Disability (YLD) caused by these two disorders – a number which increased 31.4% between 2007 and 2017.[45]

The resulting socio-economic impact is brutal, with direct and indirect costs amounting to between 1.0% and 2.5% of the GDP in developed countries, driven mainly by knee and hip OA.[63]

2.3. Clinical aspects of hip and knee osteoarthritis

A detailed review of the clinical aspects of hip and knee OA is out of the scope of this thesis. Still, a contextualization of these disorders is important to understand the work herein presented, and therefore a brief reference will be made to the most relevant clinical aspects of hip and knee OA.

2.3.1. Pathophysiology

Osteoarthritis was once viewed as a process involving mainly cartilage degradation resulting from biomechanical stress.[54,64] However, recent evidence points towards an involvement of several joint structures, especially the synovium and the subchondral bone.[54,64] Synovial inflammation happens in both early and late stages of OA, and is thought to be secondary to cartilage debris and catabolic mediators entering the synovial cavity.[54] Regarding the subchondral bone, subchondral sclerosis, osteophyte formation and bone remodeling are hallmarks of the disorder and crucial for radiological diagnosis.[54] However, these may occur early in the disorder, and it has even been postulated that they may be one of the drivers of cartilage damage.[54]

2.3.2. Risk factors for hip and knee osteoarthritis

There are several known risk factors for OA, which can be divided in systemic and local factors. Regarding systemic factors, age, female gender, obesity and osteoporosis are well established risk factors.[3,54] Intriguingly, for reasons yet unknown, obesity has a much greater impact on the risk of knee OA than in hip OA.[65] There also appears to be a strong genetic basis for susceptibility to OA, as determined by both family-based and genome-wide association studies.[54]

As to local factors, traumatic knee injuries are one of the main risk factors for knee OA, as well as prolonged kneeling or squatting.[3] Abnormal mechanical alignment of the knee and quadriceps weakness are also two established is an independent risk factors for knee OA development and progression.[54,66] Evidence regarding the association between sporting activities and knee or hip OA is conflicting.[3]

2.3.3. Clinical features and diagnosis

Pain is the main symptom associated with OA.[3,54,64,67] Pain in OA typically follows a mechanical pattern, worsening with movement and weight bearing, and is often associated with short-lasting stiffness after significant inactivity periods.[54] Movement limitation is another important feature of the disorder.[3,54,64,67] Together with pain, these two features lead to increasing disability as the disease progresses.

Other features of the disorder are joint effusion, which can be present both in initial and later stages, as well as variable degrees of joint inflammation.[54,64,67]

Physical examination enables a thorough characterization of joint involvement, with crepitus being a frequently encountered sign.[54]

The diagnosis of hip[68] or knee[69] osteoarthritis depends upon clinical and imaging criteria. The main radiographic features supporting the diagnosis are osteophytes and a reduction in joint space.[68,69] Given the widespread availability, simplicity and low cost of plain radiography, the role of other imaging techniques, namely Computerized Tomography (CT), echography and Magnetic Resonance Imaging (MRI) in the diagnosis of OA is unclear and they are not routinely used.[54]

2.3.4. Management of hip and knee osteoarthritis

According to the position paper of the Osteoarthritis Research Society International (OARSI) on recommendations for the management of hip and knee OA, optimal patient management requires a combination of pharmacological and non-pharmacological modalities.[4]

Regarding non-pharmacological interventions, patient education, maintaining regular aerobic/strengthening exercises and weight management are those with the highest level of evidence (class Ia).[4]

Regarding pharmacological interventions, oral analgesics are recommended as the first line of therapy against pain (class Ia) and non-steroid anti-inflammatory drugs (NSAIDs) should be used only if necessary, in the lowest effective dose, and long-term use should be avoided (class Ia).[4] Topical NSAIDs are an effective alternative (class Ia). In patients with refractory pain, intra-articular administration of corticoids or hyaluronate can be considered (class Ia). The use of other analgesics, such as weak opioids, can be considered in case of ongoing pain. (class Ia).[4]

For patients with significant pain and disability refractory to these treatment modalities, surgery needs to be considered. In hip OA, osteostomy and joint preserving procedures can be considered in young patients, especially in the presence of hip dysplasia (class IIb).[4] Likewise, in young patients with unicompartmental knee OA, high tibial osteostomy can be considered to delay the need for total joint replacement (class IIb).[4] Surgical lavage and debridement in knee OA is not more effective than placebo and is, therefore, not advised.[70] Total hip and knee replacement are discussed below.

2.4. Total hip and knee replacement

2.4.1. Epidemiology and costs

THA is a very common procedure, with more than 1 million procedures undertaken worldwide each year.[71] As a consequence of the aging population, the rates of primary and revision THA have been increasing globally.[71]

In the United Kingdom, data from the 2017 report from the National Joint Registry shows a 214% increase in the number of primary THA procedures between 2004 and 2017 and a 297% increase in the number of revision THA over the same period, totaling almost 100,000 procedures.[72] In the USA, estimates point to a 174% increase in primary THA between 2005 and 2030, and to a 237% increase in revision THA.[5] This will translate into around 572,000 primary procedures per year and into 96,700 revision procedures in 2030.[5]

Like THA, TKA is also a very common surgical procedure. The number of THA procedures has been increasing every year and will continue to do so in the next decades. Data from UK´s National Joint Registry shows a 524% increase in the number of primary TKA procedures between 2004 and 2017 and a 510% increase in the number of revision THA over the same period, totaling almost 110,000 procedures.[72] In the USA, it has been estimated that by 2030, the demand for primary TKA will increase by 673% and for revision TKA by 601% compared to 2005.[5] This will translate into around 3.48 million primary and 268.000 revision procedures.[5]

The costs associated with THA and TKA are substantial. A study published in 2012, by Murphy & Helmick, estimated costs due to hospital expenditures of THA and TKA in the USA, presenting a total figure of $42.3 billion.[73] Little data exists for cost estimations outside the USA. Still, a study published by Dakin *et al.* in 2012 reports an average cost of £7458 (circa 8633€) per primary TKA and five years of

subsequent care.[74] Extrapolated to the number of surgical procedures in 2017, this would place costs with TKA and subsequent care in the UK above £750 million (circa 870 million €).

Despite the huge costs associated with these procedures, a systematic review conducted by Daigle *et al.*, which included several high-quality studies, demonstrates that they are highly cost-effective.[75] Still, the numbers presented above, especially for the US, clearly highlight the need to optimize outcomes after surgery, aiming to further improve cost-effectiveness.

2.4.2. Indications for surgery

No international consensus exists regarding surgical indications for THA or TKA, and there is wide variation between surgeons.[71,76] In general, though, surgery is considered for patients with refractory pain after a trial of non-operative interventions, with substantial disability and significant radiographic changes.[71,76]

Regarding knee OA, indications for partial knee arthroplasty are the same as for TKA, but the disease should be isolated to one compartment.[76] In good candidates, this procedure may have a better functional outcome than TKA, at the expense of a high rate of revision procedures.[76]

2.4.3. Types of prosthetics

For THA, there are four main types of fixation options: cemented, uncemented, hybrid (cemented stem and uncemented cup) and reverse hybrid (uncemented stem and cemented cup). Alternative bearing surfaces (eg ceramic, metal) can be used. Therefore, multiple combinations exist, with an even greater variability depending on the specific brand/design.

For TKA, the variability is even greater, with both cemented, uncemented and hybrid designs; fixed-bearing (tibial component attached firmly to the metal implant beneath) or mobile-bearing; with or without ligament preservation (posterior and/or anterior cruciate ligament preserving).

In both cases, head-to-head comparison of the different types of prosthetics was and still is almost inexistent, and the decision is mostly based on specific patient characteristics, as well as on surgeon preferences.[71,76] This was one of the reasons behind the creation of prospective national registries.[71,76]

As a result of these registries, evidence favoring certain types of prosthetics, or certain brands, are starting to appear.[77,78] Regarding THA, a recent cost-effectiveness study that gathered data from the UK

and Swedish registries showed that small-head (<36mm in diameter) cemented metal-on-polyethylene implants were the most cost-effective for adults >65 years old in contrast with ceramic-on-polyethylene for <65 years old, and that uncemented or hybrid were not cost effective.[77] Regarding TKA, a study with data from the UK registry compared five brands of cemented, unconstrained (ligament-sparing), fixed-tibial bearing prosthetics – which are the most used type – showed a superiority of the Nexgen brand.[78]

2.4.4. Outcomes after surgery

Traditionally, surgical outcomes in both THA and TKA have been measured by survival analysis, with revision surgery as an endpoint.[71,76] Based on these criteria, excellent implant survivorship has been reported for THA, with 10-year survivorship rates of 95% and 20-year rates >80%.[71] For TKA, the 10 year risk of revision is situated between 4 and 6%.[76]

However, this approach does not address clinical or functional outcomes, nor patient satisfaction with the procedure, and therefore is not acceptable as the only measure of surgical outcome.

On the other hand, while range of motion is a frequent concern for patients and clinicians alike, it is, at least for TKA, considered a poor marker of implant success,[79] with little relation to functional performance[80] and may not reflect patient satisfaction adequately.[81]

Self-reported outcome scores, also called Patient Reported Outcome Scores (PROMs) provide relevant data on function, symptoms and activity from a patient perspective. There is no agreement about what constitutes a good PROM though,[76] and there is no clear superior outcome measure.[18] For THA studies, the most commonly used PROMs are the Western Ontario and McMaster University Athritis Index (WOMAC), the Oxford Hip Score and the Hip Osteoarthritis Outcome Score (HOOS).[18] For TKA studies, WOMAC, the Oxford Knee Score and the Knee Osteoarthritis Outcome Score (KOOS) are the most commonly used.[16]

Several authors, however, conclude that PROMs are heavily influenced by pain and that, as a result, they should be combined with performance-based measures. [16,82–86] For studies on THA or TKA, the Osteoarthritis Research Society International recommends that the 30 second chair rise test, 4×10m fast-paced walk test, a timed stair climbing test, Timed up and Go Test (TUG) and 6-minute walking test (6MW) be included as outcome measures.[87]

Based on performance measures and on PROMs, THA and TKA are associated with clinically significant improvements in a vast majority of patients.[88–91] Still, results after THA appear to be slightly superior to

those after TKA – the RESTORE study, involving 263 patients submitted to THA and TKA, reported significant improvements in about 90% of patients after THA and 70% of those after TKA[88], whereas the results of a 20-year Dutch registry involving 2089 patients report significant improvements in 91.5% of THA patients at 12 months and 79% for TKA.[89]

On a different aspect, a recently published Finnish[92] study, involving 408 employees from the public sectors that underwent THA, reported that 94% returned to work after THA on average after three months.

2.4.5. Impact of surgery on quality of life

A systematic review on health-related Quality of Life (QoL) after THA and TKA, by Ethgen *et al.*, published in 2004, which included a total of 74 studies, concluded that THA and TKA were quite effective in terms of improvement in health-related QoL, with some exceptions regarding social dimensions.[93]

Subsequently, a study, by Bruyère *et al.*, followed 39 patients prospectively for seven years (22 THA; 17 TKA) and reported a significant improvement in both generic health-related QoL, measured through the Short Form 36 (SF-36), and in specific health-related QoL, measured through the WOMAC, over a short term period of follow-up (six months), which were maintained for seven years.[94]

A more recent study, performed by Dailiana *et al.* on patient-reported QoL after primary major total joint arthroplasty (TJA), which involved 378 patients (174 THA and 208 TKA) reported significant improvements in the WOMAC and in the Centre for Epidemiological Studies Depression Scale (CES-D10) one year after surgery, as well as an 88% satisfaction rate.[95]

In spite of these promising results, a recent Iranian study[96] involving 217 patients after THA, compared with a matched reference population, reported significantly lower health-related QoL measures in the patient group. This indicates that, despite a beneficial impact of these procedures, achieving near-normal outcomes remains an elusive goal.

2.4.6. Risk factors for adverse events and sub-optimal outcomes after surgery

Regarding factors associated with adverse events, a study performed by Keswani *et al.*,[97] compared adverse events after discharge from Total Joint Arthroplasty (TJA) by discharge destination (home, skilled nursing facility or inpatient rehabilitation) to identify risk factors for inpatient discharge and adverse events after discharge. This was a large study involving 106,360 patients submitted to TJA, and found the

following factors associated with adverse events after discharge: a) severe adverse event before discharge; b) age; c) operative time; d) male gender; e) functional status; f) Body Mass Index (BMI)>40; g) history of smoking; h) hypertension; i) steroids for chronic condition within 30 days of procedure; j) bleeding disorder; K) American Society of Anesthesiology (ASA) class 3/4.[97] Additionally, the following factors were associated with unplanned 30-day admission: a) diabetes; b) pulmonary disease; c) cardiac disease. Interestingly, this study also demonstrated that non-home discharge was associated with an increase in the risk of adverse events, even after adjusting for patient risk levels, and this was true for all patients except for those at very high risk of adverse events.[97]

Another study, by Paxton *et al.*[98] analyzed the factors associated with the change in physical activity levels one to two years post-operatively.[98] This study, which evaluated 5678 THA and 11084 TKA procedures, identified female gender, obesity and certain comorbidities (psychosis, renal failure, neurological disorders) as predictors of a limited increase in physical activity following TJA.[98]

2.5. Rehabilitation after total hip and knee replacement

Rehabilitation maximizes outcomes after THA/TKA[8–12] and, as such, is widely prescribed after surgery. However, there are no universally accepted guidelines for rehabilitation after THA or TKA.[11,12,15–18] In fact, surprisingly, clinical evidence on this matter is limited, with variable quality and sometimes inconsistent.[11,15–18] This is particularly evident for rehabilitation after THA, where two systematic reviews, performed by the same authors, published in 2009[15] and 2015[18] pointed out that, while the narrative review supported the benefits of physiotherapy exercise in terms of function, walking and muscle strengthening, the quality of the available studies was insufficient to draw definitive conclusions. The main issues reported by these papers were design flaws in early studies, small sample sizes and short follow-up times.[15,18] A more recent meta-analysis, published in 2019,[99] on the efficacy of exercise for improving functional outcomes after THA, which included ten studies with a total of 441 patients, reported that, in comparison with the control group, post-operative exercise has better pain relief and clinical outcomes.

Other methodological issues, such as insufficient information on the intervention (timing, dosage, specific program), were reported by Pozzi *et al.* in their systematic review of physiotherapy following TKA.[16] Importantly, the latter systematic review also notes that trials that suggested physical therapy is not necessary after TKA lack methodological control and subjects in all groups appeared under-rehabilitated.[16]

In this context of unknown ideal timings, composition and duration of physical therapy programs, it is not surprising that programs vary widely between different centers[14]. Still, even in the face of these limitations, the picture presented by Artz *et al.* on the provision of physiotherapy following THA and TKA is dim.[13] This study, published in 2012, analyzed routine practices at 24 high-volume National Health Service (NHS) Hospitals in England and Whales. After THA, no high-volume orthopedic centers offered routine physiotherapy unless patients were considered to be in clinical need of additional physiotherapy support.[13] Referral for physiotherapy after TKA was more routinely performed, but still 26% of hospitals failed to refer patients routinely.[13] This is particularly worrisome since the rehabilitation program may influence both short- and long-term results.[100–105]

Notwithstanding, studies suggest that intensive and progressive rehabilitation translates into better results,[16] also maximizing patient's adherence to therapy and overall satisfaction.[106] There is also evidence stating that therapeutic exercise should be a primary component of post-operative care, that programs should include strengthening exercises, and that the exercise programs should be supervised and progressed as the patients meet clinical and strength milestones.[16,100] Other authors also state that a more functional approach to rehabilitation, including weight-bearing exercises, appears to be more effective.[15]

According to an expert consensus on best practices for post-acute rehabilitation after THA and TKA, which involved a Delphi panel of USA and Canadian experts, rehabilitation should start within three weeks of discharge[17]. Despite the absence of consensus on specific dose parameters of duration, frequency, and number of treatment sessions, the greatest support for rehabilitation after THA was for four to eight weeks of supervised rehabilitation, two to three times per week and, for TKA, of four to 12 weeks.[17] The panel also recommended that interventions should be based on therapeutic exercise.[17]

The only European guidelines on rehabilitation after THA and TKA are those developed in collaboration between the French Physical and Rehabilitation Medicine Society (SOFMER) and the French Federation of Physical Rehabilitation Medicine (FEDMER). These recommend, as standard for rehabilitation after THA or TKA, a nine week program consisting of three weekly sessions in the first six weeks and two to three weekly sessions in the last three weeks.[107,108]

Regarding the rehabilitation setting, physical therapy delivered in an outpatient setting requires that patients travels to the clinic, which poses considerable logistic difficulties to both patients and caregivers, which are amplified in an elderly population and in remote areas.[16,20] In this sense, home-based programs could facilitate access to rehabilitation and increase patient uptake and adherence, which are important issues in rehabilitation.[109] Both for THA and for TKA, evidence shows that home-based and clinic-based

rehabilitation protocols have generated similar improvements.[10,11,15,16,18]

Home-based programs, conversely, are heavy on logistics on the provider side.[20] To circumvent this, telerehabilitation solutions have been developed and these have demonstrated similar outcomes to conventional physical therapy following both THA and TKA.[21–25] Telerehabilitation also enhances therapy uptake, while allowing professionals to remotely adjust rehabilitation programs.[110–112] However, these solutions remain very demanding in terms of therapist time, and still face multiple technical challenges, namely in terms of setup and need for technical support.[26]

In lieu of the limitations faced by both conventional and tele-rehabilitation, the need for supervised rehabilitation has been recently challenged, especially after THA. Coulter *et al.*, for example, in a study involving 98 patients, reported no differences between a supervised versus unsupervised program at the six month follow-up assessment, but the program duration was only 4 weeks, and the supervised group only had one session per week.[113] Mikkelsen *et al.* also performed a study comparing supervised versus unsupervised rehabilitation after THA, which involved 68 patients, and reported no differences at one year after surgery.[114] Even if the latter study was methodologically more refined, the patients in the unsupervised program were instructed to perform pre-structured sessions that had been developed by a clinical team, while patients in the supervised program had two supervised sessions per week plus five unsupervised sessions. Therefore, it can be argued that this study demonstrates the benefit of some form of structured exercise after THA, and points to the relevance of intensity as a very important component of the recovery process.

A more recent study, published by Klement *et al.*,[115] which included 941 patients, compared the outcomes of an unsupervised, web-based self-directed physical therapy program after THA (646 patients) with those of a combined unsupervised program together with outpatient physical therapy (295), and reported better outcomes in the unsupervised program. However, the authors note that, from the patients who were prescribed a combined program, 88.2% were due to perceived need for outpatient rehabilitation by the attending physician. The authors therefore conclude that the unsupervised program may be suited for less disabled but not all patients.

Finally, a recent systematic review and meta-analysis of randomized controlled trials investigating the effect of supervised exercise compared to non-supervised home-based exercise after THA, which included seven studies and a total of 389 participants, reported a small and non-significant difference in favor of the supervised groups for patient-reported function, hip-related pain, health-related quality of life and

performance-based function at end of treatment and in patient-reported function at the six to twelve-month follow-up.[116] In conclusion, evidence in this field is still equivocal.

2.6. Novel technologies for rehabilitation after total hip and knee replacement

In the face of the challenges faced both by conventional outpatient or in-home rehabilitation and by telerehabilitation, technological solutions that enable home-based rehabilitation to take place without the need for real-time human supervision can be the key to facilitate access, improve effectiveness and lower costs.

In this sense, the term "novel technologies" is used here in relation to technological approaches that may fulfill these needs and that are *latu sensu* comparable to the solution presented in this thesis, and not in the broader meaning of the expression. This excludes, for example, robotic devices, which are expensive, heavy and not portable, as well as other technologies like large camera-based system for motion analysis (existing only in gait analysis laboratories) and fully immersive virtual reality systems.

In the context of the present thesis, four main categories of novel technologies are to be considered: a) systems based on electromyography (EMG); b) portable camera-based systems (such as Microsoft® Kinect®); c) systems based on the Nintendo® Wii® Fit console; d) systems based on inertial motion units (IMUs).

Crucially, all the above-mentioned systems incorporate biofeedback with the intent of increasing both patient adherence and performance. In fact, biofeedback has been used in rehabilitation for over 50 years, with most studies focused on EMG-based solutions.[117] Unfortunately, in this area, while there have been some advances in novel technologies for neurological rehabilitation[118,119] there is little validation on such solutions for musculoskeletal disorders, particularly for hip OA or THA, where only two studies were found.[27,120] Available evidence is discussed below.

A recent systematic review on the use of biofeedback devices in comparison to usual care after TKA found a total of eleven studies on the subject.[121] These studies involved a variety of biofeedback systems: three with Nintendo® Wii® Fit or Wii® balance[122–124] (one of them[124] combined with a leg press device and a motion capture laboratory); two with other balance boards[125,126]; two with EMG[127,128]; one with a Fitbit® activity monitor[129]; one with an instrumented treadmill and motion capture lab[130]; one with a pressure sensor embedded in a pillow[131] and another with a goniometer embedded in a knee orthesis.[132] From these studies, only one of those involving Wii® [122]and the one involving Fitbit® [129] were performed in a home-

based autonomous setting and another, also involving Wii®[123], was performed in a home-based setting under guidance from a home health professional. Importantly, three of these studies[128,131,132] had a very short follow-up time, limited to 1 week, and therefore only preliminary conclusions on patient acceptance and possible efficacy could be derived from them, and only four studies[122,124,129,130] had a follow-up time of four to six months. Still, this review concluded that training with biofeedback after TKA is a viable way to improve gait symmetry, reduce pain and increase activity level.[121]

Another recent systematic review addressing the efficacy of virtual reality tools for TKA,[133] included a total of six studies - three with solutions based on the Nintendo® Wii® Fit console (also incorporated on the previous systematic review); one based on Microsoft® Kinect®; [134] one based on IMUs[28] and one based on a dynamometric platform.[135] From those not based on Wii®, which were discussed in the paragraphs above, only the study based on an IMU solution was performed in a home-based setting, and this study is discussed below. This systematic review did not report any advantage of virtual reality tools over conventional training, while noting that more studies were necessary, in particular regarding the feasibility of continued in-home intervention.[133]

2.6.1 Electromyography-based solutions

Regarding EMG-based solutions, evidence was found for patellofemoral pain,[136,137] anterior cruciate ligament (ACL) reconstruction,[138–140] knee OA,[141,142] meniscal repair and minor arthroscopic knee surgeries.[143]

Some of these papers were included in a systematic review performed by Wasielewski *et al.* in 2011,[144] with the exception of the papers by Anwer *et al.*,[142] Christanell *et al.*,[140] Shanb *et al.*[127] and Wang *et al.*,[128] which were published afterwards.

That systematic review concluded that potential improvements in knee extension and functional outcomes were demonstrated for ACL reconstruction and meniscal repair, but with limited datasets to draw more definitive conclusions,[144] and that participants with patellofemoral pain and OA did not benefit from these interventions.[144]

The study by Anwer *et al.*[142] aimed to evaluate the effectiveness of EMG biofeedback as an add-on to isometric quadriceps training. The study involved 33 patients and concluded that, at the end of the five-week program, the group which performed the exercises with biofeedback had significantly greater quadriceps strength.[142]

The study by Christanell *et al.*, which involved 16 patients, demonstrated that EMG biofeedback in addition to conventional physical therapy could increase knee strength after ACL reconstruction, over a six-week program.[140]

The study by Shanb *et al.* involved 45 patients, who were divided into two groups; the experimental group had biofeedback training in addition to a conventional rehabilitation program, two sessions per week for four months.[127] The authors reported significant improvements in quadriceps torque, voluntary activation and knee functional activity in the experimental group in comparison to the control group.[127]

Finally, Wang *et al.* performed a study involving 66 patients, which were randomly assigned to one of two groups: no intervention or EMG-based biofeedback relaxation training twice a day for five days, concurrently with continuous passive-motion (CPM) therapy.[128] The authors reported significant less pain during CPM in the biofeedback group.[128]

Evidence on the efficacy of EMG-biofeedback based systems is therefore only preliminary, and these have yet to be incorporated in a fully functional solution that can be used independently by the patients at home.

2.6.2. Camera-based solutions

In relation to camera-based solutions, only three studies were found on the validation of Kinect®-based telerehabilitation systems, one on THA,[27] another on TKA/unicompartmental knee arthroplasty (UKA)[31] and a more recent one on both.[145]

The study on THA, by Antón *et al.*, was a small study, involving seven patients, in a total of 19 rehabilitation sessions.[27] This study reported that the system was well received by the patients and that it was able to identify exercises correctly, with some concerns regarding exercises performed with certain types of clothing, with external objects (eg. chairs) and in cluttered environments.[27]

The study on TKA, by Chughtai *et al.*, which enrolled 157 patients (14 TKA; 139 UKA) was a single-arm study aimed at evaluating patient adherence and compliance to a home-based rehabilitation program with the technology, system usability and clinical outcomes.[31] The authors reported high usability and patient adherence, as well as a marked improvement on the Knee Society Score (KSS) pain and function scores, the WOMAC and in the Boston University Activity Measure for Post Acute Care score.[31]

The third study, which involved 111 patients submitted to THA or TKA[145] compared the outcomes of tele-rehabilitation using a Kinect®-based versus usual care after a period of three weeks of inpatient

rehabilitation, and reported comparable results between the two groups in terms of functional testing, quality of life and pain.[145]

Despite these promising results, concerns on the real-world usability of camera-based solutions, such as those raised by Antón *et al* still remain.[27]

Furthermore, even though commercial solutions using this technology are available (eg. Reflexion Health), Kinect® was unfortunately discontinued as a stand-alone module and is now going to be made available only as a module for developers, which will likely cause setbacks in its incorporation in rehabilitation solutions.

2.6.3. Nintendo® Wii®- Based Solutions

In regards to solutions using the Nintendo® Wii® Fit console, there is preliminary validation of their acceptability after TKA[123,146] and anterior cruciate ligament (ACL) reconstruction.[32] Fung *et al.* compared conventional outpatient physiotherapy program with or without an extra period of 15 minutes of Wii® Fit gaming activities in 50 patients, and found it to be well accepted, although no clinical differences were found in clinical outcomes between groups.[123] Ficklscherer *et al.* used a similar design, in a study involving 17 patients submitted either to TKA or ACL reconstruction, and found similar conclusions.[146]

The exceptions to these preliminary studies are the RCTs performed by Baltaci *et al.* involving 30 patients submitted to ACL reconstruction, comparing a program performed with Wii® Fit against conventional physical therapy,[32] and by Christiansen *et al.*,[122] involving 26 patients, where the addition of weight bearing feedback to conventional physiotherapy was tested against physiotherapy alone. The first study found no differences in clinical outcomes between the two groups at the twelve-week assessment, in terms of isokinetic knee strength, dynamic balance and functional squat tests.[32] The latter study found no differences at 26 weeks regarding weight bearing symmetry or knee extension moments during the five times sit-to-stand test (FTSST), but did find increases in knee extension during gait, as well as improved FTSST times.[122]

Anecdotally, we found one study that combined both the Kinect® and the Wii® Fit devices with a dedicated software, and tested the system in a single patient after TKA, during a six-week inpatient rehabilitation program, in addition to conventional physiotherapy, concluding that such a approach was feasible.[147]

In addition to the little clinical validation available, there are no commercially available solutions based on this technology directed specifically at rehabilitation for lower limb musculoskeletal disorders, especially in an elderly population.

2.6.4. IMU-based solutions

A recent systematic review on interactive wearable systems for upper body rehabilitation, published in 2017, found only four studies on musculoskeletal disorders, all of which focused on usability aspects, and none of which was a clinical trial.[148] Interestingly, in this review, which included 45 papers, 84% of them used IMUs or accelerometers.[148]

For lower limbs, IMU-based solution have been mainly used in this field for movement characterization and not as rehabilitation tools. [149–157] The same conclusion was reported in a recent review on wearable motion tracking systems for rehabilitation after THA and TKA, published in 2018 by Bahadori *et al.*[158]

Regarding THA, only one study was found, by Raaben *et al.*,[159] which aimed to determine the effect of real-time visual feedback on weight bearing during in-hospital rehabilitation, versus no feedback, using a force sensor inside the insole of custom-made sandals. This study, which enrolled 24 patients, found higher peak loads in the biofeedback group at the 12 week assessment.[159] Still, this does not qualify neither as an IMU-based solution nor as a fully functional rehabilitation system.

Regarding TKA, we found two studies published on a solution based on inertial motion trackers.[28,160] One study included 142 patients, which were randomized to receive a two-week program after surgery (10 sessions) with this system versus conventional rehabilitation. The outcomes were similar in both groups, but the intervention duration was too short to draw definitive conclusions.[28] The other study, by Argent *et al.*,[160] published in 2019, was a smaller study, involving fifteen patients, and aimed at testing the usability of a prototype system. The authors reported a high degree of usability and a mean adherence of 79% (i.e. 79% of patients completed the recommended number of sessions).[160]

Additionally, we found two other studies with an IMU-based solution for chronic knee pain.[29,30] The first study, published in 2017, was a single-arm study which enrolled 41 patients with chronic knee pain.[29] Participants had a 12-week program consisting of: a) therapeutic exercise (led by a mobile application and two IMUs); b) education (articles presented through the mobile application); c) cognitive behavioral therapy-like sessions (four video sessions); d) group chatting mediated by a health coach; e) patient-led tracking of symptoms, weight and activity.[29] The authors report a mean improvement in KOOS Pain scores

of 16 points at 12 weeks, as well as a 10-point improvement in the KOOS-PS (physical function short scale), which were maintained at six months. Importantly, around one third of the patients included were doing "physiotherapy-like" exercises at the time of inclusion, and they were not asked to stop, which is a major confounding factor.

The second study, published in 2018, was an RCT involving 162 participants (treatment group n=101; controls n=61).[30] The intervention was the same as above for the intervention group; the control group only had access to three pieces of educational material (i.e. no active control). The authors reported a significantly greater reduction in KOOS pain and KOOS-PS in the intervention group.[30] However, the difference between groups was below the 10-point reported Minimal Clinically Important Difference (MCID) of 8-10 points reported for this scale.[161] Plus, again, around one third of the patients included were doing "physiotherapy-like" exercises at the time of inclusion, and they were not asked to stop, which is a major confounding factor.

In all, evidence backing IMU-based solutions is still lacking, but these appear to be promising solutions, especially in the light of the two studies presented above on knee OA.

2.7. SWORD Phoenix®

After discussing the emerging novel technologies for rehabilitation after total hip or knee replacement, and presenting IMU-based solutions as potentially promising solutions, a description of SWORD Phoenix® will be provided below, to allow adequate understanding of system components and how they are integrated. SWORD Phoenix® is a class I certified medical device composed of three components (**Figure 1A-E**): a) Internal motion trackers; b) mobile app; c) web-based Portal.

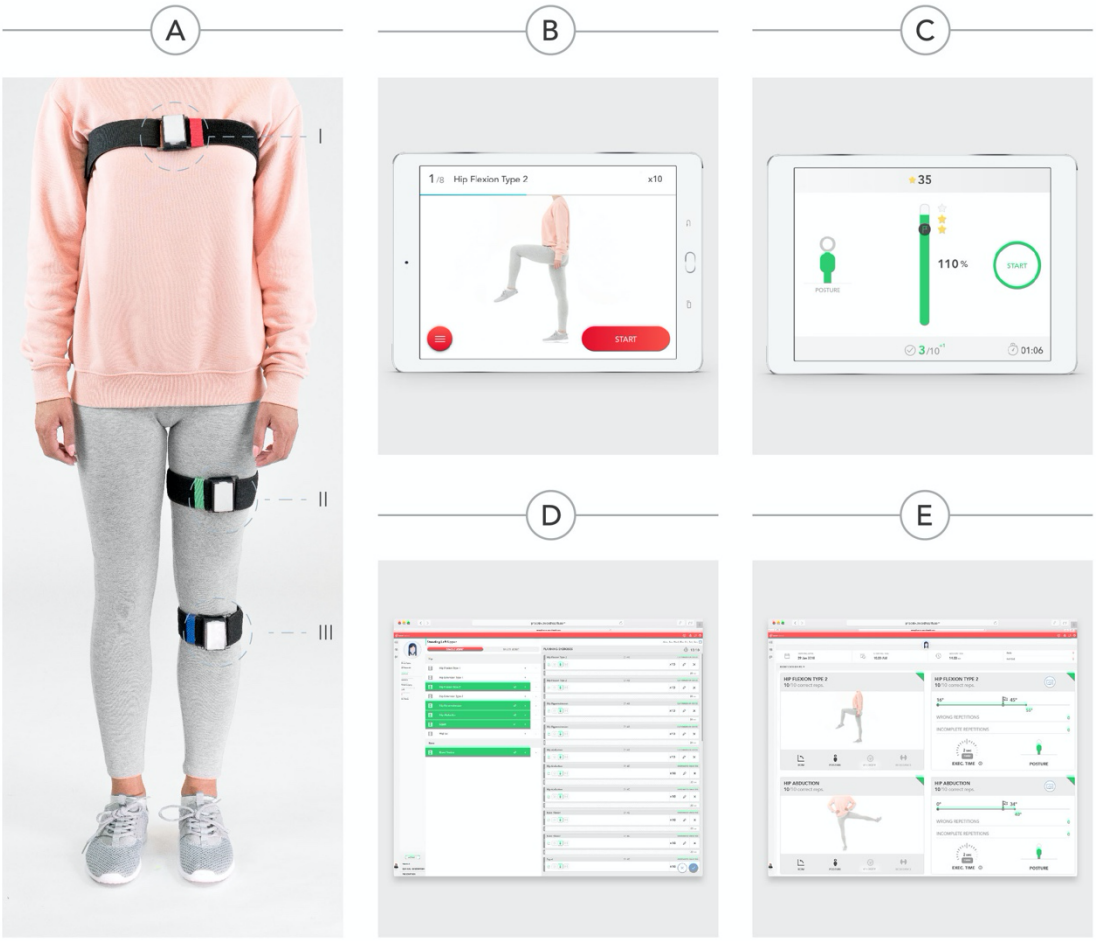


Figure 1. SWORD Phoenix® components. ***A - Motion Tracker Setup. B - Mobile App: preparation screen.*** *This screen is shown before each exercise, and displays a video of the exercise, as well as audio instructions.* ***C - Mobile App: execution screen.*** *This screen is shown during exercise execution, displaying: a) timer; b) progress bar; c) posture dummy; d) repetition counter; e) time left;* ***D - Web Portal - prescription screen.*** *This screen displays the available exercises on the left and the layout of the exercise session on the right.* ***E - Web Portal - results screen.*** *In this screen, the following information is presented: a) date and time of the session; b) session duration; c) pain and fatigue reported by the patient through the app; d) one card per exercise, showing baseline and target joint angles, wrong and incomplete repetitions, as well as posture errors.*

2.7.1. Inertial motion trackers

The trackers are placed on body segments using Velcro® straps, in specific positions (**Figure 1A**):

i. **Red tracker:** over the sternal manubrium
ii. **Green tracker:** anterior surface of the hip, midway between the trochanter and the knee
iii. **Blue tracker:** over the anterior tibial crest

Even if an in-depth review of how patient movement is estimated using IMUs is outside of the scope of this thesis, and also limited by proprietary company information which cannot be disclosed, a brief explanation of this topic will be provided below, to enable a better understanding of the system featured in this thesis.

Each tracker contains an IMU unit, which is composed of an accelerometer and a gyroscope. These components provide measurements of linear acceleration and angular velocity. The trackers also feature a magnetometer – which is not technically an inertial motion sensor - which provides measurements of magnetic field strength.

Data coming from each of the sensors is combined within the IMU, using a proprietary sensor-fusion algorithm. Even if specifics around the algorithm cannot be provided, IMU orientation is obtained by integrating the angular velocity measured with the gyroscope, and correcting drift around the pitch (y) and roll (x) axes with measurements from the accelerometer. The magnetometer is then used to correct heading drift- ie, drift around the gravitational axis (z).

The output of each IMU is a quaternion, which is a four-element vector that can be used to estimate the orientation of the IMU in relation to the Earth frame of reference. By strapping each IMU to a given body segment, the IMUs allow the estimating the orientation of that body segment.

Each sensor communicates with the mobile app on a tablet through Bluetooth Low Energy, at a frequency of 50Hz. To quantify the movement of a target joint, two crucial steps need to occur. First, the information packages sent by each tracker need to be synchronised – this is achieved through a proprietary and patented algorithm. Second, they need to be combined with a biomechanical model that depicts the kinetic chain of that body segment and the degrees of liberty of the involved joints. This process allows for the correction of movement estimation errors that are not coherent with the constraints imposed by the biomechanical model.

Further adjustments are necessary to then adapt the theoretical body frame represented by the model to the actual body frame of the patient. This is achieved through a calibration process at the beginning of each exercise session, where the following adaptations are made: a) chest tracker inclination is

compensated; b) inclinations and rotations of the hip and leg are compensated. This calibration also allows a mapping of the magnetic environment surrounding the patient. In-session calibrations are automatically triggered in the event of sustained incoherencies resulting from the accumulation of heading drift that cannot be compensated automatically through the algorithm.

Within this framework, joint angles and range of motion are calculated by means of the projection of spatial orientation vectors onto a 3D plane. In other words, each movement is defined as a specific configuration of vectors and plane, which are assessed using an algorithm whose output is an angle. Taking, as an example, standing hip flexion (**Figure 2),** the calculation of the flexion angle results from the projection of the orientation vectors of the chest tracker and the hip tracker onto the sagittal plane, and calculating the resulting angle (in degrees) between them - for joint angles- or the delta (in degrees) between two time-points (movement start and finish) – for range of motion.

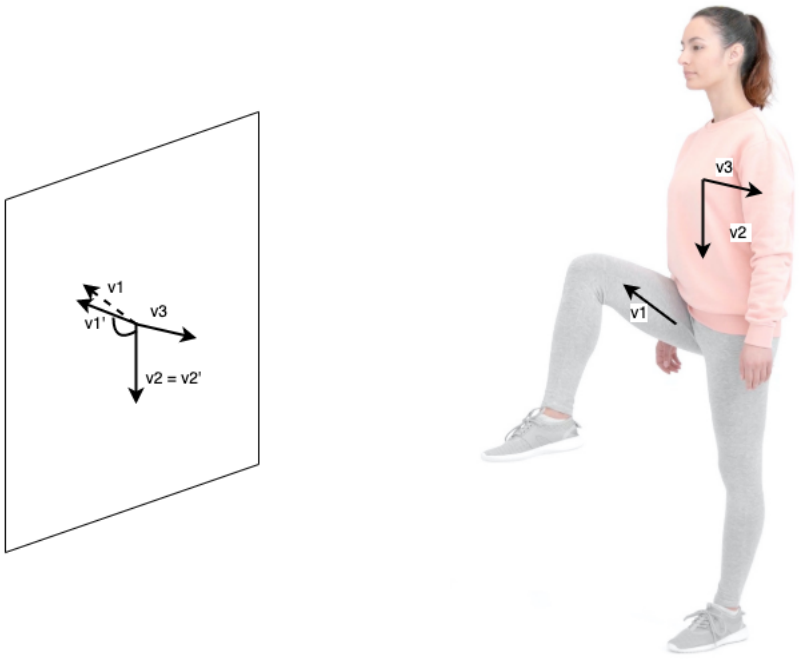


Figure 2. Example of joint angle/ range of motion calculation – hip flexion

2.7.2. Mobile App

Before each exercise, a video demonstration is presented to the patient (**Figure 1B**), complemented with an audio explanation. During execution, the patient is given real-time biofeedback through a dedicated interface (**Figure 1C**). Only repetitions assessed as correct contribute to reach the session´s goals. These are defined as movements starting at the baseline and reaching or surpassing the specified ROM without violating movement or posture constraints. If the patient violates a constraint, an error message is displayed, allowing the patient to correct the movement in the following attempts.

2.7.3. Web-based Portal

The Portal allows clinical teams to prescribe exercises, monitor results and edit prescriptions. To prescribe a session, the clinician selects the exercises, number of sets, number of repetitions and ROM for each exercise **(Figure 1D)**. Upon the performance of a session, the results are uploaded to the platform and available for review **(Figure 1E)**. Based on this information, the clinical team can edit the session remotely.

2.8. Cost analysis of new technological interventions

There is, unfortunately, a dearth of studies on this topic. A systematic review published in 2105 by Torrez-Diez *et al.* [162] on the cost-utility and cost-effectiveness studies of telemedicine, electronic and mobile health systems found a total of 35 articles, mostly on cost-effectiveness of telemedicine in general, with some demonstrating that telemedicine can reduce costs.[162] Another study, by Tousignant *et al.*[163] performed a cost analysis of in-home telerehabilitation after TKA in comparison with conventional home-visit rehabilitation. In this study, the cost for a single session of in-home telerehabilitation was lower or about the same as conventional rehabilitation, depending on the distance between the patient's home and health care center, with a favorable cost differential when the patient was more than 30km from the provider.[163] Another study, published in 2017 by Haines *et a.l*,[164] presented a cost-effectiveness comparison of motion-sensor biofeedback plus guidelines-based treatment of sub-acute or chronic low back pain against guidelines-based care only (consisting of advice on staying active, pain management and medical/physiotherapy care as deemed appropriate). These authors concluded that the motion-sensor intervention was more cost-effective over 12 months, given the increase in productivity and the reduction in medical/physical therapy treatment. As far as we are aware, these are the only studies published on this subject so far.

CHAPTER 3 | THA Clinical Trial

METHODS

3.1. Design

Single-center, non-randomized, parallel-group, clinical trial, designed to compare the clinical outcomes of THA plus digital home-based rehabilitation versus THA plus conventional rehabilitation, as well as to assess patient acceptance, usability and engagement with the system.

3.2. Investigation hypothesis

It was hypothesized that there would be no differences in the clinical outcomes of surgery plus digital rehabilitation versus surgery plus conventional rehabilitation after THA.

In terms of safety, it was hypothesized that the adverse event rate of the surgery plus digital intervention group would be similar to that of surgery plus conventional rehabilitation.

In terms of usability, it was hypothesized that the digital program would be well accepted by patients.

3.3. Outcomes

Several studies suggest that clinical outcomes should be measured not only in terms of range of motion, which is considered a poor marker of implant success and patient satisfaction, [16,109,165,166] but also using PROMs and performance tests.[16,82–86] As such, clinical outcomes were evaluated according to three outcome measures: **a)** a performance test; **b)** PROMs; and **c)** hip range of motion.

In regards to the performance test, we chose the Timed up ad Go Test (TUG). The TUG measures the time the patient takes to rise up from a chair, walk three meters, turn around, walk again towards the chair and sit down again. This test was chosen as it is simple and practical, quick and easy to administer, has excellent inter-rater reliability and very good test-retest reliability [167] and has been demonstrated to predict both short- [168] and long-term [80,169] function following hip and knee arthroplasty. Moreover, Podsiadlo and Richardson confirmed it's content validity in elder persons in that it evaluated a well-recognized series of maneuvers in daily life.[170]

In regards to PROMs, the HOOS[171] scale was used. This scale was validated for patients submitted to THA by Nilsdotter *et al.*[172] The HOOS scale (**Annex VII**) consist of 5 subscales: 1) Pain; 2) other Symptoms; 3) Activities of Daily Living (ADL); 4) Function in sport and recreation (Sport/Rec) and 5) hip/knee related QoL. The previous week is the time period considered when answering the questions. Standardized

options are given and each question is assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. Although there is no validated MCID for THA, Ornetti *et al.* reported a smallest detectable difference (SDD) of: 10.5 points for the HOOS-symptoms, 15.1 points for pain, 9.6 points for ADL, 15.5 points for sports and 16.2 points for QoL, in patients with hip OA.[173]

In regards to hip ROM, it was assessed in the following movements – lying flexion, lying abduction, standing flexion, standing abduction and standing hyperextension. Given that SWORD Phoenix® is a certified medical device with a joint angle measuring function, ROM was measured in all patients using this system. According to the technical specifications of the device, the measurement error in comparison to standard goniometry is of 5.5 degrees.

All clinical outcomes were assessed at baseline (pre-operatively), four weeks after initiating the rehabilitation program, at the end of the program (eight weeks), three months after surgery and finally six months after surgery.

3.3.1. Primary outcome

The primary outcome was the change in TUG score from baseline to the week 8 reassessment.

3.3.2. Secondary outcomes

The remaining clinical clinical outcomes (including other timepoints for TUG) were assessed as secondary outcomes. Hierarchically, changes from baseline to week 8 were given particular emphasis, followed by changes from baseline to 6 months and by changes from baseline to 3 months. Assessments at each of the timepoints were also considered, with the 4 week and 3 month assessment being given less relevance than the other timepoints.

Safety was measured through adverse event rates in both groups, divided in 3 periods: in-hospital; during rehabilitation program and after rehabilitation program.

Usability was measured through global enrollment rate, retention rate (drop-outs) in each of the groups and also, need for therapist contact in both groups. In the digital group, compliance to the program, independence of use, need for therapist contact and patient satisfaction were also measured.

3.4. Locations and timelines

This was a single-center clinical trial which was held at the Hospital da Prelada- Dr. Domingos Braga da Cruz, Porto, Portugal, in collaboration with the Orthopedics Department.

All consecutive patients admitted for THA between December 19th 2016 and January 16th 2018 were screened for eligibility by the two orthopedic surgeons that oversaw the trial- Joaquim Pires and Rosmaninho Seabra. Completion date for the assessment at the end of the eight-week active rehabilitation period was March 21st 2018 and for the six month follow-up was 16th July 16th 2018.

3.5. Sample size estimation

Sample size estimation calculations were performed taking into consideration the change in TUG score from baseline to 8 weeks. In the absence of a validated MCID for this scale in patients submitted to THA, calculations were based on the Minimal Detectable Change (MDC) of 2.49 seconds, as reported by Kennedy *et al*[174] on a longitudinal study evaluating outcomes following THA or TKA. The behavior of the variable of interest (TUG) at baseline was calculated based on that reported by Dayton *et al*[82] in a study on performance-based versus self-reported outcomes after THA (mean 8.80 seconds; standard deviation 3.27 seconds). The resulting computed effect size was of 0.76.

Considering this effect size, a power of 80% and a two-sided 0.05 significance level, 60 patients (30 in each group) would be necessary to detect a 2.49 second difference between the two groups. Considering a dropout rate of 15%, the target recruitment was 70 patients.

3.6. Inclusion & Exclusion Criteria

3.6.1. Inclusion Criteria

a) Patients over 18 years old;
b) Clinical and imaging evidence of hip osteoarthritis;
c) Indication for total hip replacement according to patient´s orthopedic surgeon;
d) Ability to walk unaided or requiring assistive device (unilateral or bilateral);
e) Availability of a carer to assist the patient after surgery.

3.6.2. Exclusion Criteria

a) Patients admitted for revision of total hip replacement;
b) Contralateral hip or knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program;
c) Aphasia, dementia or psychiatric comorbidity interfering with the communication or compliance to the rehabilitation process;
d) Respiratory, cardiac, metabolic or other condition incompatible with at least 30 minutes of light to moderate physical activity;
e) Major medical complications occurring after surgery that prevent the discharge of the patient within 10 days after the surgery;
f) Other medical and/or surgical complications that prevent the patient from complying with a rehabilitation program;
g) Blind and/or illiterate patients.

3.7. Patient enrollment

3.7.1. Patient identification and recruitment

Whenever a potential candidate was identified, the local investigator approached the candidate and explained the clinical trial in detail. The prospective candidate was given the patient information document and informed consent (see **Annex IX**) and sufficient time to consider whether he wished to participate in the trial. Subsequently, the prospective candidate was given opportunity to clarify any doubts, after which the informed consent form was signed and dated in duplicate by the patient and the investigator. Only then was the baseline assessment performed.

3.7.2. Patient allocation

Patient allocation to the digital or conventional rehabilitation group was performed upon hospital discharge using patient address as criterion. Subjects residing in areas outside the administrative limits of the city of Oporto were allocated to the digital PT group. Conversely, patients residing within the administrative limits of the city were allocated to the conventional rehabilitation group. Patient allocation was performed centrally by one investigator –Fernando Dias Correia.

3.7.3. Blinding

The nature of the trial did not allow blinding of the patients. Patient assessment was performed by two investigators- Joaquim Pires and Rosmaninho Seabra - blinded for allocation groups. Primary statistical analysis was performed by a blinded statistician – Laetitia Teixeira.

3.8. Intervention

Patients were admitted for elective surgery and proceeded to surgery as per the existing hospital protocols. Between day 1 post-op and hospital discharge, all patients were taught, as per the hospital protocol, how to safely get in and out of bed and were asked to perform alternate ankle flexion and extension exercises regularly. All patients performed initial gait training with canes.

After that, both groups received early-onset home-based rehabilitation immediately after discharge, for eight weeks.

3.8.1. Digital PT Group

In the digital PT group, patients received an initial visit from the physical therapist, to assess specific rehabilitation needs and to teach patients and/or caregivers how to set up and use the biofeedback system. After this initial visit, the digital PT group performed a rehabilitation program solely through the use of the biofeedback system, under remote monitoring from a physical therapist. Patients were instructed to perform sessions between five and seven days a week, but compliance to this frequency was not mandatory per protocol and patients were not excluded in case of lower adherence. The number of sessions, daily adherence and total training time was registered automatically by the system and was made available through the web Portal.

3.8.1.1. Face-to-face visits

Each patient in this group received three visits from the assigned physical therapist:

Visit 1: Initial deployment

In this visit, the physical therapist taught the patient how to operate the system, and adapted the exercise program based on the presented guidelines (see below) and adapted to the patient´s specific needs. The therapist performed an initial session with the patient, ensuring that the patient was able to perform each exercise and that he could operate the system, alone or with the help of a caregiver.

Visit 2: Interim visit (4 weeks ± 5 days)

In this visit, the physical therapist assessed patient progress and adjusted the rehabilitation program accordingly. This visit did not consist of a conventional face-to-face rehabilitation session.

Visit 3: Termination visit (8 weeks ± 5 days)

The purpose of this visit was to collect the equipment. This visit did not consist of a conventional face-to-face rehabilitation session.

3.8.1.2. Telephone calls

Each patient received two interim telephone calls per protocol, at weeks 2 and 6 (± 3 days) after initiation of the rehabilitation program. In these calls, the therapist ascertained more details on patient progress to help guide the treatment, and explicitly questioned the patients about adverse events.

3.8.1.3. Additional visits or telephone calls

When required, additional visits or telephone calls for technical assistance were performed by the physical therapist, and registered as such in the patient file (date, motive, duration).

3.8.2. Conventional Rehabilitation Group

The conventional rehabilitation group received a home-based supervised program provided by a physiotherapist, three times a week, for one hour. Patients were instructed by their physical therapist to perform additional unsupervised sessions in at least two other days of the week.

Specific instructions regarding exercises, sets and repetitions were laid out in paper for each patient.

Compliance to these unsupervised sessions was not mandatory and formal registry of these sessions were not kept.

3.8.3. Rehabilitation Protocols

In the absence of a gold standard, the rehabilitation protocols were designed taking into account a recent systematic review on the subject,[16] the results of a Delphi panel on best practices for rehabilitation after THA/TKA[17] and the protocol published by SOFMER.[107]

Detailed rehabilitation programs are presented in **Tables 1** and **2.** In any case, as can be seen in the tables, these protocols were tailored to the patient´s specific needs, according to the joint assessment between the orthopedic surgeon and the physical therapist.

Table 1. Rehabilitation protocol for THA (stage 1)

Stage 1 (weeks 0-5)	
Objectives	**Precautions**
Decrease pain and swelling Restore range of motion Strengthen hip flexors and abductors Restore fully load capacity on both legs	Avoid hip internal rotation and hip adduction beyond neutral Avoid hip flexion above 90° Ice pack application after each session and throughout the day as needed
Intervention	
Digital PT Group	**Conventional rehabilitation**
Open kinetic chain exercises without added resistance Lying: - Hip flexion (2x10 reps) - Hip abduction (2x10 reps) - Knee flexion (2x10 reps) - Hip flexion with knee flexion (2x10 reps) Sitting (high chair): - Hip abduction (2x10 reps) - Knee extension (2x10 reps) - Sit to stand (2x10 reps) Standing (initially with support): - Hip flexion (2x10 reps) - Hip abduction (2x10 reps) - Hip hyperextension (2x10 reps) - Knee flexion (2x10 reps) - Hip flexion with knee flexion (2x10 reps) - Mini-squats (2x10reps) **Note 1:** adjust sets, reps and total session duration according to patient tolerance (based on patient performance and on the pain and fatigue scores) **Note 2:** aim for at least 30 minutes in total **Note 3:** recommend two daily sessions as soon as tolerated	Soft tissue massage Active assisted mobilization of the hip to increase range of motion Gait training with bilateral support Isometric exercises: - gluteus contraction (3x10 sec) - quadriceps contraction (3x10 sec) - abductors contraction (3x10 sec) Progressing to open kinetic chain exercises without added resistance according to patient tolerance - Same exercises as the digital PT group **Note 1:** adjust sets, reps and total session duration according to patient tolerance **Note 2:** recommend additional sessions twice per week (write down exercises, sets and reps)

Table 2. Rehabilitation protocol for THA (stage 2)

Stage 2 (weeks 6-8)	
Objectives	**Precautions**
Strengthening of hip flexors and abductors Improve balance Independence on all activities of daily living	Identical to stage 1
Intervention	
Digital PTI Group	**Conventional rehabilitation**
Open kinetic chain exercises in the lying, sitting and standing positions Same exercises as above but with higher number of repetitions and added resistance Progression to closed kinetic chain exercises: - Squat (2x10) - Forward and lateral lunges (2x10) Stair climbing exercises: - Climb a step (2x15 steps) - Come down a step (2x15 reps) **Note 1:** adjust sets, reps and total session duration according to patient tolerance (based on patient performance and on the pain and fatigue scores attributed by the patient at the end of each session) **Note 2:** maintain recommendation of two sessions/day	Soft tissue massage Balance exercises with progression to one-leg support Gait training with progressive withdrawal of external support Open kinetic chain exercises in the lying, sitting and standing positions Same exercises as above but with higher number of repetitions and added resistance Progression to closed kinetic chain exercises - same exercises as the digital PT group **Note 1:** adjust sets, reps and total session duration according to patient tolerance

3.9. Patient Assessments

Patients were assessed at baseline (pre-operatively), on discharge (in-hospital), four weeks after initiating the rehabilitation program, at the end of the program (eight weeks), three months after surgery and finally six months after surgery. These assessments were performed in the ward or in the outpatient clinic by the patient orthopaedic surgeon. For each of the post-discharge visits, a timeframe of five working days before or after the date was allowed.

3.9.1. Baseline assessment (V1): pre-operative

Participant characterization consisted of:

a) Demographics (gender, age at enrollment);

b) Affected side

c) Comorbidities and risk factors for adverse events

- Body Mass Index
- Smoking

- Diabetes
- Cardiac disease
- Respiratory disease
- Hypertension
- Stroke
- Renal Disease
- Bleeding disorders
- American Society of Anesthesiologists physical status classification score
- Intake of steroids for chronic condition
- Previous hip replacement
- Previous knee replacement

d) Timed Up and Go test score

e) Hip Osteoarthritis Outcome Score

3.9.2. Assessment on discharge (V2)

An additional assessment on discharge was performed, with collection of the following information:

a) Data on hospitalization and surgical procedure

- Time between admission and surgery
- Surgical technique
- Type of prosthesis
- Type of anesthesia
- Operative time
- Length of stay

b) Complications before discharge

- Falls
- Infectious complications (urinary, respiratory, prosthesis)
- Thromboembolism (deep vein thrombosis, pulmonary embolism)

3.9.1. Subsequent assessments (V3, V4, V5)

These assessments consisted of:

a) Timed Up and Go test score
b) Hip Osteoarthritis Outcomes Scale score
c) Complications after discharge
    a. Falls
    b. Infectious complications
    c. Thromboembolism
    d. Readmissions

3.10. Safety and Adverse Events

As per the protocol, patients with serious medical/surgical complications not allowing discharge home within 10 days were excluded from the trial. Other adverse events during hospitalization were retrieved from medical records at the time of discharge.

During the rehabilitation period, patients in the conventional rehabilitation group were under regular monitoring by a physical therapist, enabling early detection and reporting of adverse events. In the digital PT group, safety was evaluated through pain and fatigue scores (graduated from 0 to 10) at the end of each session, which were available for remote monitoring through the web-based portal. Patients were also asked to report any adverse events to their physical therapist or to the investigator through a direct telephone contact.

In the follow-up period, adverse events were not proactively questioned to participants.

3.11. Statistical Analysis

To assess differences in clinical and demographic variables of the patients allocated to the two groups, independent samples T test or Mann–Whitney U test were used for quantitative variables. For categorical variables, Chi-squared test and Fisher's exact test were used.

Outcome analysis was performed using both an intent-to-treat (ITT) and a per-protocol (PP) analysis. Differences between the two groups were performed using independent samples T test or Mann-Whitney U test. For non-normally distributed variables, the magnitude of median difference was assessed using

Hodges-Lehman estimator.

Since outcomes were measured in different moments, a repeated measures analysis was also performed, using a repeated Analysis of Variance (ANOVA) with group as an independent factor and time as a within-subjects factor.

3.12. Data Protection & Ethics Approval of Research

This clinical trial was jointly approved, together (but not independently) with the TKA trial, by the National Data Protection Commission (authorization number 1476/2017) – see **Annex X**- and by the local ethics committee at Hospital da Prelada (Chair: Dr. Juiz Conselheiro Almeida Lopes)- see **Annex XI**. The methods were conducted in accordance with the approved guidelines. All patient data was anonymized and linked to the patient by a unique number that did not contain any personal identifiers.

3.13. Registration

This clinical trial was prospectively registered at www.clinicaltrials.gov with the following Unique identifier: NCT03045549. Date of registration: 7 February 2017.

3.14. Availability of data and materials

The protocol of this trial is available from www.clinicaltrials.gov. Individual patient data (in Excel format) that underlie the results reported in the paper was submitted as supplementary information, accessible through the online version.

3.15. Funding

This work was supported in part by the European Commission through the Project H2020 SME Instrument Phase 2 - Grant Agreement number 672814.

The manufacturer of the SWORD Phoenix medical device - SWORD Health, SA - was the sponsor of the trial and, in that capacity, provided financial and logistics support to the work herein presented.

RESULTS

3.16. Trial flow

One hundred and fifty-six patients were assessed for eligibility between 19th December 2016 and 16th January 2018. **Figure 2** shows the CONSORT diagram for the trial. Trial inclusion rate was of 42%. Between the eligibility screening and patient allocation, 46 patients refused to participate or withdrew consent, corresponding to 51% (46/90) of all screening failures.

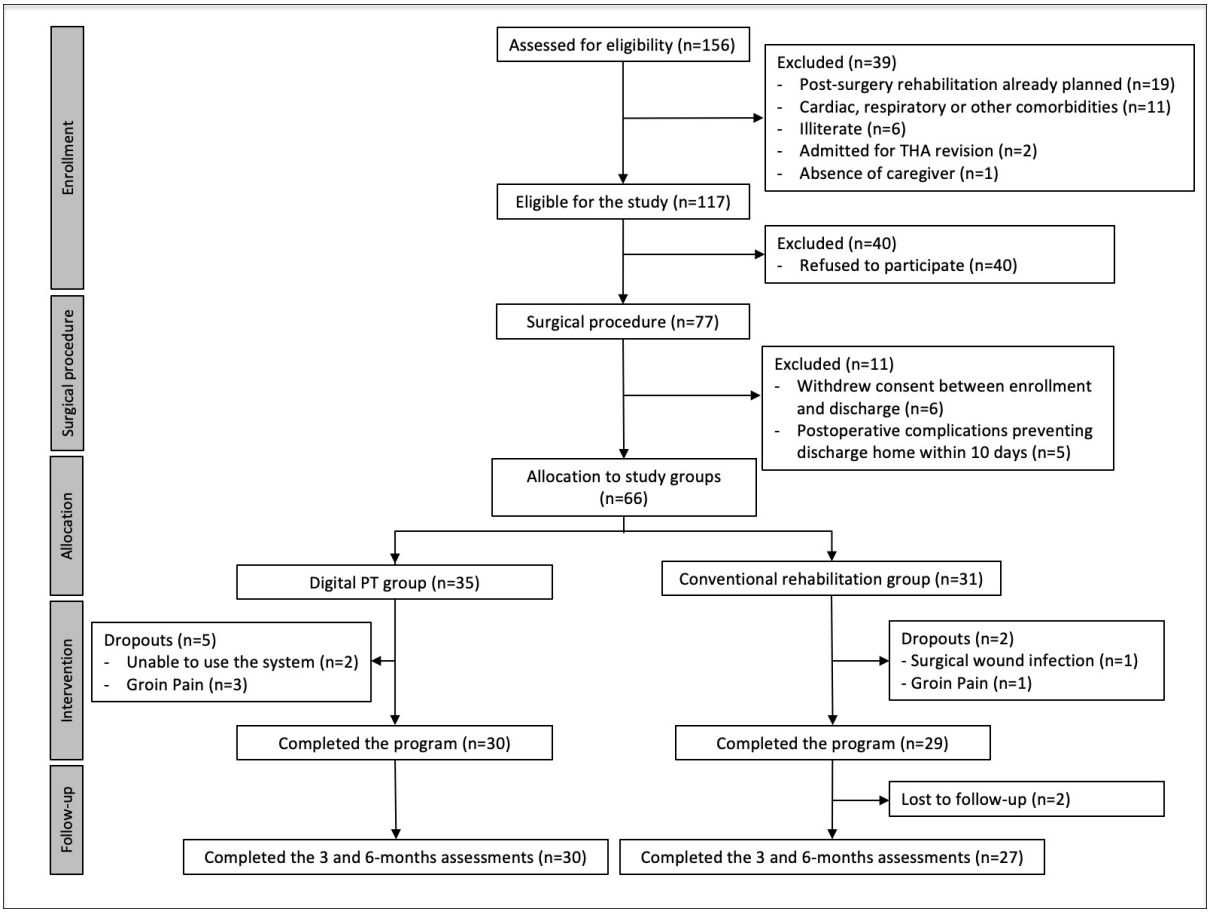


Figure 3. THA trial CONSORT diagram

Sixty-six patients were included (35 digital PT group *vs* 31 conventional rehabilitation). The dropout rate in the digital PT group was 14.3%: two patients did not adapt to the system and withdrew consent in the first week; three were excluded due to groin pain. The dropout rate in the conventional rehabilitation group was 6.5% - two patients were excluded, one patient was excluded due to a surgical wound infection requiring readmission, and another due to groin pain. In total, 59 patients completed the trial (30 *vs* 29)

and 57 completed the follow-up assessments - two patients in the conventional rehabilitation group were lost to follow-up between the three and six-month assessment. There were no differences between the dropout rates in the two groups (p=0.433)

3.17. Baseline population characterization

Baseline characteristics of trial participants regarding demographics, comorbidities and risk factors for adverse events, as well as data on hospitalization and surgery are summarized in **Table 3**. There were no differences at baseline between the two groups regarding any characteristics.

Table 3. Baseline characteristics of participants in the THA trial

	Digital PT Group (n=35)	Control Group (n=31)	*p* value
Demographics			
Age (years) mean (sd)	62.4 (8.4)	66.6 (10.1)	0.072#
Gender female (%)	42.9	51.6	0.642
Side right (%)	45.7	38.7	0.745
Comorbidities & Known risk factors for adverse events			
Body Mass Index mean (sd)	28.3 (2.8)	27.4 (4.3)	0.310#
Smoking (%)	5.7	22.5	0.072*
Hypertension (%)	40.0	38.7	1.000
Diabetes (%)	31.4	22.6	0.597
Pulmonary disease (%)	2.9	3.2	1.000
Cardiac disease (%)	8.6	16.1	0.459*
Stroke (%)	2.9	0.0	-
Renal disorders (%)	0.0	0.0	-
Bleeding disorders (%)	0.0	6.5	-
ASA€ class 3 or 4 (%)	22.9	32.3	0.563
Steroids for chronic condition (%)	0.0	0.0	-
Previous contralateral hip replacement (%)	20.0	16.1	0.931
Previous knee replacement (%)	2.9	0.0	NA
Hospital admission and surgical procedure			
Time between admission and surgery (hours)	<24 h	<24 h	-
Operative time (min) mean (sd)	63.7 (9.7)	59.9 (8.7)	0.099#
Uncemented prosthesis (%)	5.7	5.7	1.000
Length of stay (days) median (IQR)	6.0 (2)	6.0 (1)	0.426§

Legend: €American Society of Anesthesiology physical status classification system; *Fisher' Exact test; #independent sample t-test; §Mann-Whitney U test

Regarding outcome measures, there were no differences between the two groups except for the HOOS-QoL subscale, with the conventional group presenting higher median scores (p=0.032) (see **Table 4, 5**

and 6). The median difference between the TUG scores in the two groups was of 2.34 seconds (95% CI: -0.97;5.62) in favor of the conventional rehabilitation group. Taking into consideration the 2.49 seconds reported as MCD for this test,[174] this difference is neither statistically nor clinically significant.

3.18. Intent-to-treat analysis

For the intent-to-treat analysis all patients who enrolled in the trial were considered. For those who dropped out or were lost to follow-up, the last known assessment was carried forward.

The results of all the timepoints, as well as the difference between each of those timepoints and baseline, can be found in the Tables 4, 5 and 6 below and then discussed jointly.

Table 4.Primary outcome assessment in the THA trial: intent-to-treat

Primary outcome - Timed up and Go*					
Time-point	Digital PT Group (n=35)	Control Group (n=31)	P value#	Estimate difference between groups	95% confidence interval
Baseline	17.50 (6.33)	14.89 (9.42)	0.12	2.34	-0.69;5.17
4 Weeks	9.92 (5.45)	15.01 (8.20)	<0.001	-4.64	-7.01;-2.65
Change baseline- 4 weeks	-6.60(8.08)	0.53 (8.73)	<0.001	-7.90	-10.77;-4.66
8 weeks	7.26 (2.15)	11.03 (6.84)	<0.001	-3.34	-5.14;-1.70
Change baseline-8 weeks	- 10.50 (7.45)	- 2.90 (7.10)	<0.001	-6.33	-8.79;-3.42
3 months	6.17 (2.57)	9.63 (5.71)	<0.001	-2.50	-4.28;-1.23
Change baseline-3 months	-10.50 (7.73)	-4.62 (8.00)	0.001	-5.66	-8.30;-2.36
6 months	6.38 (2.30)	8.20 (4.22)	<0.001	-1.87	-3.02;-0.62
Change baseline-6 months	-10.50 (7.39)	-5.10 (6.94)	0.005	-4.79	-7.24;-1.70

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 5. Patient reported outcomes assessment in the THA trial: intent-to-treat

Patient Reported Outcomes Assessment- HOOS*					
Variable	Digital PT Group	Control Group	P value	Estimate difference between groups	95% confidence interval
Baseline					
Symptoms	35.0 (20.0)	40.0 (30.0)	0.12	-10.0	-20.0;0.0
Pain	33.0 (13.0)	33.0 (35.0)	0.50	-3.0	-13.0;5.0
Act. Daily Living	29.0 (15.0)	28.0 (28.0)	0.75	1.0	-6.0;7.0
Sports	0.0 (6.0)	0.0 (19.0)	0.34	0.0	0.0;0.0
Quality of Life	13.0 (13.0)	19.0 (25.0)	0.03	-6.0	-13.0;0.0
4 weeks					
Symptoms	90.0 (20.0)	90.0 (20.0)	0.94	0.0	-5.0;5.0
Pain	85.0 (35.0)	90.0 (15.0)	0.57	-3.0	-10.0;3.0
Act. Daily Living	78.0 (25.0)	75.0 (16.0)	0.59	1.0	-5.0;7.0
Sports	19.0 (25.0)	31.0 (19.0)	0.08	-6.0	-13.0;0.0
Quality of Life	56.0 (25.0)	50.0 (25.0)	0.73	0.0	-13.0;7.0
Change baseline- 4 weeks					
Symptoms	50.0 (30.0)	35.0 (35.0)	0.14	10.0	-5.0;20.0
Pain	53.0 (27.0)	43.0 (25.0)	0.91	0.0	-10.0; 12.0
Act. Daily Living	44.0 (24.0)	35.0 (27.0)	0.55	3.0	-9.0;12.0
Sports	19.0 (32.0)	25.0 (18.0)	0.43	-6.0	-12.0;6.0
Quality of Life	38.0 (31.0)	31.0 (31.0)	0.41	6.0	-6.0;13.0
8 weeks					
Symptoms	100.0 (5.0)	95.0 (20.0)	<0.01	5.00	0.0;10.0
Pain	100.0 (7.0)	98.0 (12.0)	0.24	0.0	0.0; 5.0
Act. Daily Living	93.0 (11.0)	82.0 (14.0)	<0.001	9.0	4.0;13.0
Sports	50.0 (18.0)	38.0 (19.0)	0.004	12.0	6.0;19.0
Quality of Life	81.0 (19.0)	69.0 (31.0)	0.08	6.0	0.0;18.0
Change baseline- 8 weeks					
Symptoms	60.0 (30.0)	45.0 (30.0)	0.06	10.0	0.0;20.0
Pain	60.0 (22.0)	60.0 (32.0)	0.75	2.0	-10.0;10.0
Act. Daily Living	56.0 (23.0)	57.0 (27.0)	0.63	-2.0	-10.0;6.0
Sports	44.0 (25.0)	38.0 (25.0)	0.26	6.0	-6.0;13.0
Quality of Life	63.0 (31.0)	50.0 (25.0)	0.46	6.0	-6.0;13.0
3 months					
Symptoms	100.0 (5.0)	95.0 (15.0)	0.08	5.00	0.0;10.0
Pain	100.0 (5.0)	98.0 (12.0)	0.10	0.0	0.0; 2.0
Act. Daily Living	94.0 (10.0)	87.0 (21.0)	<0.001	7.0	3.0;12.0
Sports	56.0 (19.0)	44.0 (25.0)	0.03	7.0	0.0;19.0
Quality of Life	81.0 (13.0)	75.0 (21.0)	0.004	12.0	6.0;19.0
Change baseline-3 months					
Symptoms	60.0 (25.0)	50.0 (35.0)	0.04	15.0	0.0;25.0
Pain	65.0 (22.0)	53.0 (33.0)	0.16	10.0	-3.0;20.0
Act. Daily Living	65.0 (16.0)	50.0 (25.0)	0.02	10.0	2.0;18.0
Sports	50.0 (19.0)	38.0 (25.0)	0.01	13.0	6.0;19.0
Quality of Life	69.0 (19.0)	50.0 (25.0)	<0.001	19.0	12.0;31.0
6 months					
Symptoms	100.0 (5.0)	95.0 (10.0)	0.20	0.0	0.0;5.0
Pain	100.0 (5.0)	100.0 (7.0)	0.75	0.0	0.0;0.0
Act. Daily Living	96.0 (11.0)	88.0 (19.0)	0.02	4.0	0.0;10.0
Sports	75.0 (32.0)	50.00 (32.0)	0.01	19.0	6.0;37.0
Quality of Life	94.0 (12.0)	81.0 (19.0)	0.02	7.0	0.0;19.0
Change baseline-6 months					
Symptoms	60.0 (25.0)	45.0 (30.0)	0.06	10.0	0.0;20.0
Pain	65.0 (18.0)	53.0 (30.0)	0.21	7.0	-5.0;17.0
Act. Daily Living	63.0 (22.0)	56.0 (25.0)	0.1	7.0	-1.0;15.0
Sports	69.0 (31.0)	38.0 (38.0)	0.004	25.0	7.0;37.0
Quality of Life	75.0 (32.0)	56.0 (31.0)	0.01	19.0	6.0;25.0

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 6. Hip range of motion assessment: intent-to-treat

Hip range of motion assessment*					
Variable	Digital PT Group	Control gGoup	P value	Estimate difference between groups	95% confidence interval
Baseline					
Lying Flexion	28.2 (19.1)	37.1 (20.0)	0.07	-8.9	-18.53;0.67
Lying Abduction	12.2 (5.4)	15.9 (9.1)	0.05	-3.7	-7.48;0.02
Standing Flexion	45.1 (15.9)	49.6 (16.7)	0.27	-4.5	-12.52;3.53
Standing Hyperext	-11.9 (7.0)	-15.4 (8.8)	0.31	3.4	-0.44;7.33
Standing Abduction	23.5 (6.8)	25.8 (10.7)	0.08	-2.2	-6.78;2.26
4 weeks					
Lying Flexion	75.3 (26.7)	54.7 (21.3)	0.001	20.6	8.67;32.6
Lying Abduction	45.8 (16.6)	32.2 (10.2)	<0.001	13.6	6.75;20.53
Standing Flexion	80.2 (19.9)	71.2 (17.0)	0.05	9.0	-0.14;18.15
Standing Hyperext	-32.9 (13.5)	-26.5 (7.5)	0.02	-6.4	-11.73;-1.13
Standing Abduction	47.3 (12.8)	35.9 (10.8)	<0.001	11.4	5.55:17.28
Change baseline-4 weeks					
Lying Flexion	47.1 (29.5)	17.5 (27.7)	<0.001	29.6	15.45;43.74
Lying Abduction	33.6 (15.8)	16.3 (12.3)	<0.001	17.4	10.36;24.38
Standing Flexion	35.1 (18.7)	21.6 (20.0)	0.01	13.5	3.95;22.99
Standing Hyperext	-20.9 (11.6)	-11.1 (9.1)	<0.001	-9.8	-15.03;-4.66
Standing Abduction	23.8 (12.2)	10.1 (12.8)	<0.001	13.7	7.51;19.90
8 weeks					
Lying Flexion	84.0 (23.5)	66.6 (19.6)	0.002	17.5	6.78;28.18
Lying Abduction	50.5 (17.5)	39.2 (15.2)	0.01	11.4	3.27:19.50
Standing Flexion	87.6 (21.2)	80.0 (19.8)	0.14	7.5	-2.58;17.66
Standing Hyperext	-36.7 (14.3)	-30.1 (8.2)	0.03	-6.6	-12.28;-0.96
Standing Abduction	52.2 (13.8)	40.3 (11.3)	<0.001	11.9	5.62;18.13
Change baseline- 8 weeks					
Lying Flexion	55.8 (27.4)	29.4 (25.6)	<0.001	26.4	13.32;39.50
Lying Abduction	38.4 (17.3)	23.3 (15.7)	<0.001	15.1	6.91;23.25
Standing Flexion	42.5 (21.3)	30.4 (20.3)	0.02	12.0	1.81;22.33
Standing Hyperext	-24.7 (12.7)	-14.7 (10.1)	0.001	-10.1	-15.75;-4.38
Standing Abduction	28.7 (13.4)	14.6 (13.5)	<0.001	14.1	7.51;20.76
3 months					
Lying Flexion	84.8 (22.0)	68.6 (19.3)	0.002	16.2	5.93;26.44
Lying Abduction	53.1 (16.9)	38.5 (13.8)	<0.001	14.7	7.03;22.36
Standing Flexion	86.7 (22.1)	82.5 (17.7)	0.41	4.1	-5.79;14.07
Standing Hyperext	-39.0 (15.1)	-28.9 (10.0)	0.002	-10.1	-16.45;3.68
Standing Abduction	53.3 (14.3)	41.4 (12.1)	0.001	11.8	5.27;18.40
Change baseline-3 months					
Lying Flexion	56.6 (27.0)	31.5 (25.2)	<0.001	25.1	12.24;38.00
Lying Abduction	41.0 (16.8)	22.6 (15.0)	<0.001	18.4	10.52;26.26
Standing Flexion	41.5 (23.1)	32.9 (18.9)	0.11	8.6	-1.87;19.08
Standing Hyperext	-27.0 (13.8)	- 13.5 (10.2)	<0.001	-13.5	-19.52;-7.43
Standing Abduction	29.7 (14.1)	15.6 (13.4)	<0.001	14.1	7.32;20.88
6 months					
Lying Flexion	80.7 (24.4)	70.0 (19.3)	0.06	10.7	-0.27;21.6
Lying Abduction	49.8 (18.2)	41.6 (14.3)	0.05	8.2	0.06;16.31
Standing Flexion	90.2 (23. 1)	84.8 (19.8)	0.32	5.4	-5.25; 16.03
Standing Hyperext	-34.1 (15.1)	-28.8 (9.2)	0.10	-5.3	-11.36; 0.81
Standing Abduction	51.7 (15.1)	43.8 (11.8)	0.02	8.0	1.24;14.69
Change baseline-6 months					
Lying Flexion	52.5 (26.6)	32.8 (25.6)	0.003	19.6	6.73;32.50
Lying Abduction	37.6 (18.2)	25.7 (15.2)	0.01	11.9	3.57;20.20
Standing Flexion	45.1 (22.6)	35.2 (20.6)	0.07	9.9	-0.79;20.57
Standing Hyperext	-22.2 (13.3)	-13.5 (11.1)	0.01	-8.7	-14.72;-2.59
Standing Abduction	28.2 (14.3)	18.0 (12.1)	0.003	10.2	3.64;16.74

Legend: *means and standard deviations are presented; #independent samples T-test

3.18.1. Short term outcomes

Four-week assessment

Differences between groups were found for TUG [p<0.001, 9.92 (5.75) seconds *vs* 15.01 (8.19) seconds] (**Table 4**) and for all hip ROM exercises, except standing flexion (p=0.054) (see **Table 6**). There were no differences between groups in terms of PROMs (**Table 5**). Importantly, while there is no MCID for TUG in this population, the difference between groups regarding TUG is higher than the MCD reported for the scale - 2.49 seconds and therefore might be clinically significant.[174]

Change between baseline and the four-week assessment

Both groups showed clinically meaningful improvements from baseline in all outcome measures, with a greater change in the digital PT group for TUG (p<0.001) (**Table 4**) and ROM (**Table 6**), but not for HOOS (**Table 5**).

Eight-week assessment

TUG scores were again lower in the digital PT group (p<0.001) (see **table 4**). The median difference between the TUG scores in the two groups was of -3.34 seconds (95% CI: -5.14;-1.70), again probably clinically significant.

Regarding HOOS, the median scores in the digital PT group were superior to the conventional rehabilitation group for all subscales, except for the HOOS-pain and the HOOS-QoL (see **Table 5**). Importantly, in the Symptoms and Pain subscales, the median scores at the eight-week assessment were either the maximum score that can be attained (100) or close to that value in both groups, revealing a ceiling effect, which persisted over time (**Table 5**).

Hip ROM was also higher in the digital PT group for all exercises, except for standing flexion (see **Table 6**).

Change between baseline and the eight-week assessment

The median difference between the changes in the two groups regarding the primary outcome was of -6.33 seconds (95% CI: -8.79;-3.42), which is more than twice the MDC for this scale and therefore very likely clinically significant (**Table 4**).

No significant differences were detected in the median changes from baseline and week eight in terms of HOOS scores (**Table 5**).

In respect to hip ROM, significant improvements from baseline were noted in both groups, with the digital PT group showing greater improvements in all movements (**Table 6**).

3.18.2. Medium term outcomes

Three-months assessment

The TUG score remained significantly different between groups ($p<0.001$), with patients from the digital PT group experiencing better results (**Table 4**)

As for the HOOS, the median scores in the digital PT group were superior for all subscales except for HOOS-pain ($p=0.10$) and HOOS- Symptoms ($p=0.08$) (**Table 5**).

Hip ROM was also higher in the digital PT group for all measured exercises ($p<0.001$), except for standing flexion ($p=0.41$) (**Table 6**).

Change between baseline and the three-months assessment

The change was superior in the digital PT group in all outcome measures, except for standing hip flexion ROM ($p=0.11$) (**Tables 4, 5** and **6**).

Six-months assessment

The median difference between the TUG scores in the two groups was of -1.87 seconds (95% CI: -3.02;-0.62) in favor of the digital PT group (p<0.01) (**Table 4**). This value is below the MCD and therefore may not be clinically significant.

Regarding HOOS, the median scores in the digital PT group were significantly superior to the conventional rehabilitation group for HOOS-ADL (p=0.02), Sports (p=0.01) and QoL (p=0.02) (see **Table 5**). Again, for HOOS-Symptoms and HOOS-Pain, median scores were either the highest possible score or close to that value, with much greater homogeneity in the digital PT group (IQR 5.0 for HOOS symptoms and 5.0 for HOOS-Pain in the digital PT group vs 10.0 and 7.0) (**Table 5**).

At this time point, the hip ROM was higher in the digital PT group for lying abduction (p=0.048) and standing abduction (p=0.02) (**Table 6**).

Change between baseline and the six-months assessment

The ITT analysis revealed the superiority of the digital PT group in the TUG test, HOOS-Sports and QoL, and all hip ROM exercises, except for standing flexion.

The median difference between the changes in the two groups regarding TUG was of -4.79 seconds (95% CI: -7.24;-1.71) in favor of the digital PT group (**Table 4**).

In terms of HOOS, the difference between median score changes was both statistically and clinically significant for HOOS-sports and HOOS-QoL (**Table 5**).

Regarding hip ROM, significant differences between the mean changes in the two groups were detected in all ROM exercises, except the standing flexion hip ROM (p=0.07). (**Table 6**).

3.18.3 Repeated measures analysis

A repeated measures ANOVA was performed only for variables with normal distribution - TUG (after log-transformation) and hip ROM, and results are summarised in **Table 7**. While both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time, a main effect of group (here with the exception of standing hip flexion) and an interaction between time and group for all outcome measures, in favour of the digital PT group (**Table 7** and **Figure 3**).

Table 7. Repeated measures analysis in the THA trial: intent-to-treat

Outcome variable	Time		Group		Time*Group	
	F(df1,df2)	*p*	F(df1,df2)	*p*	F(df1,df2)	*p*
Patient performance						
TUG[#&]	F(2.5, 159.6)=128.6	<0.001	F(1,64)=12.3	0.01	F(3.2, 159.6)=14.9	<0.001
Hip range of motion						
Lying Flexion[&]	F(1.9,121.6)=119.4	<0.001	F(1,64)=6.5	0.01	F(1.9,121.6)=12.0	<0.001
Lying Abduction[&]	F(2.9,188.1)=139.0	<0.001	F(1,64)=9.4	0.03	F(2.9,121.6)=10.4	<0.001
Standing Flexion[&]	F(1.9,123.1)=154.9	<0.001	F(1,64)=1.06	0.31	F(1.9,123.1)=4.0	0.02
Standing Hyperextension[&]	F(3.3,211.2)=91.1	<0.001	F(1,64)=4.6	0.04	F(3.3,211.2)=8.2	<0.001
Standing Abduction[&]	F(2.1,137.3)=125.5	<0.001	F(1,64)=10.0	0.002	F(2.1,137.3)=12.1	<0.001

Legend: [#]ln transformation; [&]Greenhouse-Geisser correction.

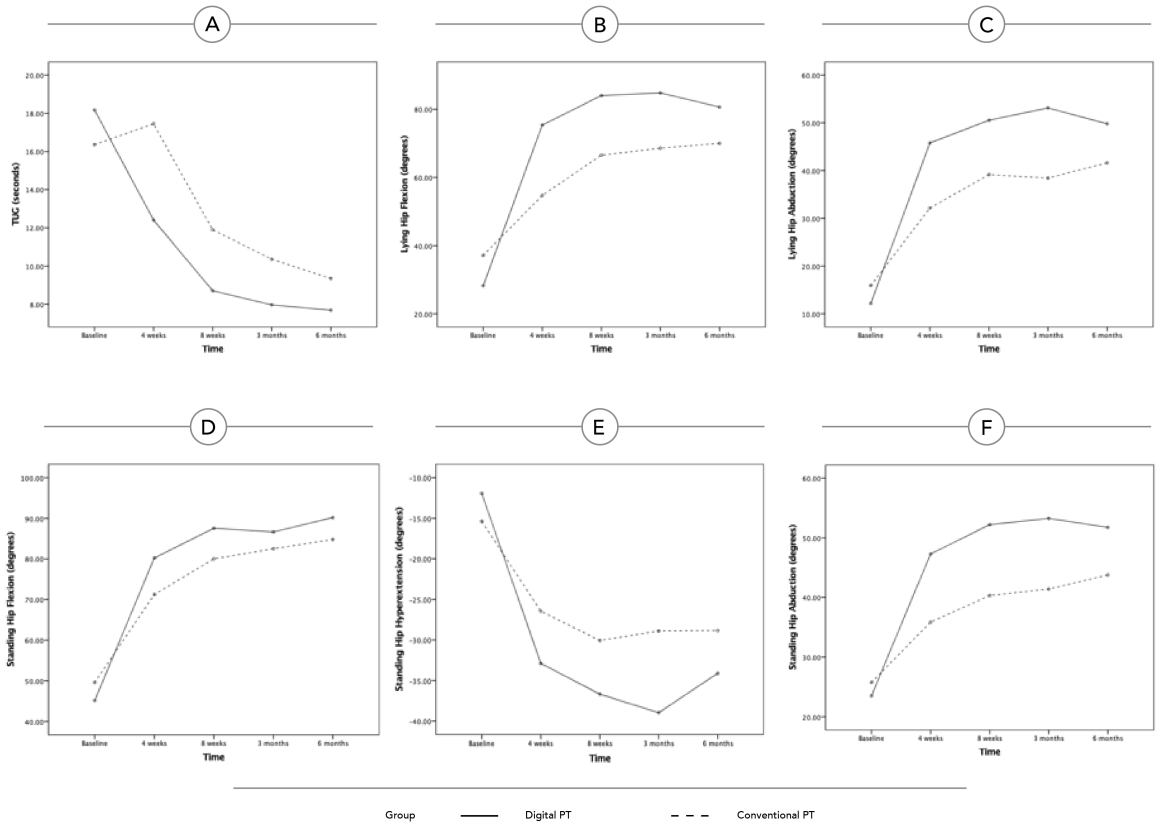


Figure 4. Evolution of outcomes over time in the THA trial: intent-to-treat analysis (estimated marginal means are presented). A- TUG score; B- Lying hip flexion; C- Lying hip abduction; D- Standing hip flexion; E- Standing hip hyperextension; F-Standing hip abduction.

3.19. Per-protocol analysis

For the per-protocol analysis, only patients who completed the rehabilitation program were included. The results of all the timepoints, as well as the difference between each of those timepoints and baseline, can be found in the **Tables 8, 9 and 10** below and then discussed jointly. Globally, they not only confirm the findings of the ITT analysis, but also highlight an even greater superiority of the digital PT group.

Table 8. Primary outcome assessment in the THA trial: per-protocol

Primary outcome - Timed up and Go*					
Time-point	Digital PT Group (n=30)	Control Group (n=27)	P value#	Estimate difference between groups	95% confidence interval
Baseline	17.55 (7.03)	14.89 (9.11)	0.11	2.55	-0.64; 5.73
4 Weeks	9.73 (5.13)	15.01 (7.37)	<0.001	-4.89	-7.10;-2.84
Change baseline- 4 weeks	-6.87(7.64)	0.70 (9.67)	<0.001	-8.50	-11.57; -4.89
8 weeks	6.85 (1.97)	11.03 (6.29)	<0.001	-3.53	-5.38;-1.93
Change baseline-8 weeks	- 10.79 (4.97)	- 3.63 (7.01)	<0.001	-6.87	-9.23;-4.05
3 months	5.87 (1.73)	8.90 (5.37)	<0.001	-2.74	-4.52;-1.49
Change baseline-3 months	-11.7 2(5.91)	-4.72 (7.83)	<0.001	-6.16	-8.85;-3.04
6 months	5.96 (1.83)	7.83 (3.81)	<0.001	-2.04	-3.20;-1.09
Change baseline-6 months	-11.15 (5.69)	-5.67 (7.05)	0.001	-5.22	-7.71;-2.38

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 9. Patient reported outcomes assessment in the THA trial: per-protocol

Patient Reported Outcomes Assessment- HOOS*					
Variable	Digital PT Group	Control Group	P value#	Estimate difference between groups	95% confidence interval
Baseline					
Symptoms	35.0 (30.0)	45.0 (33.0)	0.13	-10.0	0.0;20.0
Pain	33.0 (14.0)	33.0 (37.0)	0.35	5.0	-5.0;15.0
Act. Daily Living	28.5 (15.0)	38.0 (28.0)	0.95	0.0	-7.0;6.0
Sports	0.0 (6.0)	5.0 (16.0)	0.38	0.0	0.0;0.0
Quality of Life	13.0 (19.0)	19.0 (22.0)	0.07	-6.0	013.0;0.0
4 weeks					
Symptoms	90.0 (16.0)	90.0 (18.0)	0.39	0.0	-5.0;10.0
Pain	85.0 (28.0)	90.0 (15.0)	0.70	0.0	0.0; 5.0
Act. Daily Living	78.0 (18.0)	75.0 (14.0)	0.45	3.0	-3.0;9.0
Sports	19.0 (25.0)	31.0 (19.0)	0.09	6.0	0.0;13.0
Quality of Life	56.0 (25.0)	51.0 (25.0)	0.99	0.0	-7.0;12.0
Change baseline- 4 weeks					
Symptoms	55.0 (26.3)	35.0 (32.5)	0.02	15.0	5.0;25.0
Pain	52.0 (25.5)	43.0 (26.0)	0.48	3.0	-8.0; 13.0
Act. Daily Living	44.0 (22.3)	35.0 (25.0)	0.26	4.0	-5.0;13.0
Sports	19.00 (26.8)	25.0 (15.0)	0.48	-6.0	-12.0;7.0
Quality of Life	38.0 (26.5)	31.0 (28.5)	0.26	6.0	6.0;13.0
8 weeks					
Symptoms	100.0 (5.0)	95.0 (17.5)	<0.001	5.00	5.0;15.0
Pain	100.0 (7.0)	98.0 (11.0)	0.08	0.0	0.0; 5.0
Act. Daily Living	93.5 (8.3)	82.0 (13.5)	<0.001	9.0	6.0;14.0
Sports	56.0 (13.8)	38.0 (19.0)	<0.001	13.0	6.0;19.0
Quality of Life	81.0 (19.0)	69.0 (31.0)	0.01	12.0	0.0;19.0
Change baseline- 8 weeks					
Symptoms	65.0 (25.0)	45.0 (28.0)	<0.001	20.0	1.0;30.0
Pain	65.0 (16.0)	48.0 (27.0)	0.03	12.0	0.0;20.0
Act. Daily Living	64.5 (17.0)	50.0 (28.0)	0.002	12.0	4.0;19.0
Sports	50.0 (18.0)	31.0 (19.0)	<0.001	18.0	7.0;25.0
Quality of Life	63.0 (19.0)	44.0 (18.0)	<0.001	19.0	12.0;25.0
3 months					
Symptoms	100.0 (0.0)	95.0 (15.0)	<0.001	5.00	0.0;10.0
Pain	100.00 (1.0)	98.00 (12.0)	0.018	0	0.0; 2.0
Act. Daily Living	96.00 (8.0)	87.00 (11.0)	<0.001	8.0	4.0;12.0
Sports	56.00 (22.0)	50.00 (18.0)	0.006	12.0	6.0;19.0
Quality of Life	78.00 (13.0)	56.00 (38.0)	<0.001	13.0	6.0;25.0
Change baseline-3 months					
Symptoms	65.0 (25.0)	50.0 (35.0)	0.003	15.0	5.0;30.0
Pain	68.0 (17.0)	53.0 (27.0)	0.02	13.0	3.0;23.0
Act. Daily Living	65.5 (13.2)	51.0 (25.0)	0.002	12.0	5.0;19.0
Sports	53.0 (20.5)	38.0 (19.0)	0.003	13.0	6.0;25.0
Quality of Life	69.0 (13.5)	44.0 (32.0)	<0.001	25.0	18.0;37.0
6 months					
Symptoms	100.0 (1.0)	95.0 (10.0)	0.02	0.0	0.0;10.0
Pain	100.00 (2.0)	100.00 (7.0)	0.16	0.0	0.0;2.0
Act. Daily Living	97.00 (5.0)	91.00 (15.0)	0.003	5.0	2.0;11.0
Sports	84.50 (22.0)	75.00 (44.0)	0.002	25.0	12.0;38.0
Quality of Life	100.00 (8.0)	88.00 (25.0)	<0.001	12.0	0.0;19.0
Change baseline-6 months					
Symptoms	62.5 (21.3)	45.0 (30.0)	0.004	15.0	5.0;25.0
Pain	66.5 (17.0)	53.0 (27.0)	0.03	12.0	0.0;20.0
Act. Daily Living	66.0 (16.5)	56.0 (17.0)	0.03	8.0	0.0;16.0
Sports	75.0 (25.0)	44.0 (38.0)	0.001	25.0	12.0;38.0
Quality of Life	81.0 (20.5)	56.0 (31.0)	0.001	19.0	7.0;31.0

Legend: *Medians and IQR are presented; # Mann-Whitney U test.

Table 10. Hip range of motion outcomes assessment: per-protocol

Hip range of motion assessment*					
Variable	Digital PT Group	Control group	P value#	Estimate difference between groups	95% confidence interval
Baseline					
Lying Flexion	28.9 (20.3)	37.7 (19.0)	0.09	-8.8	-19.1;1.4
Lying Abduction	12.4 (5.4)	15.9 (8.8)	0.08	-3.4	-7.2;0.4
Standing Flexion	44.9 (17.0)	50.8 (16.7)	0.18	-5.9	-14.7;2.9
Standing Hyperext	-12.4 (7.2)	-15.6 (9.1)	0.14	2.1	-2.6;6.9
Standing Abduction	24.1 (7.1)	26.2 (10.8)	0.37	-3.2	-1.1;7.4
4 weeks					
Lying Flexion	79.0 (24.1)	57.1 (19.1)	<0.001	5.67	10.5;33.2
Lying Abduction	48.8 (13.4)	33.0 (9.0)	<0.001	15.8	9.8;21.7
Standing Flexion	82.8 (17.9)	72.9 (15.6)	0.03	9.9	1.1;18.7
Standing Hyperext	-35.6 (11.4)	-26.5 (7.1)	<0.001	-9.0	-13.9;-4.1
Standing Abduction	49.8 (10.4)	36.8 (10.3)	<0.001	13.0	7.6;18.4
Change baseline-4 weeks					
Lying Flexion	50.1 (27.0)	19.4 (27.7)	<0.001	30.7	16.4;45.0
Lying Abduction	36.4 (12.3)	17.2 (12.2)	<0.001	19.2	12.8;25.6
Standing Flexion	38.0 (16.4)	22.1 (20.2)	0.002	15.8	6.2;25.4
Standing Hyperext	-23.2 (10.3)	-11.0 (8.9)	<0.001	-12.2	-17.2;-7.2
Standing Abduction	25.7 (10.3)	10.5 (13.1)	<0.001	15.2	9.0;21.3
8 weeks					
Lying Flexion	89.2 (17.4)	69.8 (14.6)	<0.001	19.4	11.0;27.7
Lying Abduction	54.3 (13.2)	40.5 (14.2)	<0.001	13.8	6.7;21.0
Standing Flexion	91.4 (18.1)	82.3 (17.8)	0.06	9.1	-0.3;18.4
Standing Hyperext	-40.0 (11.0)	-30.4 (7.8)	<0.001	-14.0	-14.6;-4.6
Standing Abduction	55.6 (10.2)	41.6 (10.3)	<0.001	14.0	8.7;19.3
Change baseline- 8 weeks					
Lying Flexion	60.3 (22.6)	32.7 (24.2)	<0.001	28.2	16.0;40.4
Lying Abduction	41.9 (13.2)	24.7 (15.3)	<0.001	17.2	9.8;24.6
Standing Flexion	46.5 (18.0)	31.5 (20.2)	0.004	15.0	5.0;25.0
Standing Hyperext	- 27.7 (10.6)	-14.9 (9.9)	<0.001	-13.2	-18.2;-7.4
Standing Abduction	31.5 (10.7)	15.3 (13.6)	<0.001	16.2	9.8;22.5
3 months					
Lying Flexion	90.0 (14.70)	72.0 (13.74)	<0.001	18.0	10.6;25.5
Lying Abduction	57.4 (11.30)	39.8 (12.68)	<0.001	17.6	11.3;23.9
Standing Flexion	90.3 (19.49)	85.0 (14.86)	0.24	5.3	-3.7;14.4
Standing Hyperext	-42.7 (11.48)	-29.2 (9.81)	<0.001	-13.5	-19.1;-7.9
Standing Abduction	56.8 (10.66)	42.7 (11.05)	<0.001	14.1	8.4;19.7
Change baseline-3 months					
Lying Flexion	61.1 (21.8)	36.6 (22.4)	0.001	24.6	12.8;36.3
Lying Abduction	44.9 (11.4)	23.4 (14.1)	<0.001	21.5	14.7;28.3
Standing Flexion	45.4 (20.7)	35.0 (19.0)	0.05	10.5	-0.1;21.1
Standing Hyperext	-30.3 (11.4)	- 13.6 (10.1)	<0.001	-16.8	-22.5;-11.0
Standing Abduction	32.7 (11.4)	16.4 (13.8)	<0.001	16.3	9.6;23.0
6 months					
Lying Flexion	85.2 (19.88)	74.1 (13.53)	0.02	11.1	1.9;20.2
Lying Abduction	53.5 (14.61)	43.2 (12.06)	0.06	10.3	3.09-17.40
Standing Flexion	94.5 (20.01)	88.3 (16.89)	0.21	6.2	-3.7; 16.1
Standing Hyperext	-37.0 (12.98)	-29.3 (9.21)	0.01	-7.7	-13.8; -1.7
Standing Abduction	55.0 (12.29)	45.5 (10.43)	0.03	9.5	3.5;15.6
Change baseline-6 months					
Lying Flexion	56.3 (22.3)	38.2 (22.5)	0.003	18.2	6.3;30.1
Lying Abduction	41.0 (14.8)	27.1 (14.0)	0.001	14.0	6.3;21.6
Standing Flexion	49.6 (19.2)	37.6 (20.6)	0.03	12.0	1.5;22.6
Standing Hyperext	-24.7 (12.1)	-13.5 (11.2)	0.001	-11.1	-17.4;-4.9
Standing Abduction	30.9 (12.1)	19.1 (12.1)	0.001	3.2	5.4;18.2

Legend: *means and standard deviations are presented; # independent samples T-test

3.19.1. Short term outcomes

Four-week assessment

Differences between groups were found for TUG [p<0.001, 9.73 (5.13) seconds *vs* 15.01 (7.37) seconds] (**Table 8**) and for all hip ROM exercises (**Table 10**). There were no differences between groups in terms of patient reported outcomes (**Table 9**). The difference between groups regarding TUG of 4.89 seconds is clinically significant.

Change between baseline and the four-week assessment

Both groups showed clinically meaningful improvements from baseline in all outcome measures, with a greater change in the digital PT group for TUG (p<0.001) (**Table 8**), ROM (**Table 10**) and for the Symptoms subscale of HOOS (**Table 9**).

Eight-week assessment

TUG scores were again lower in the digital PT group (p<0.001) (see **table 8**). The median difference between the TUG scores in the two groups was of -3.53 seconds (95% CI:-5.38;-1.93), again very likely clinically significant.

Regarding HOOS, the median scores in the digital PT group were superior to the conventional rehabilitation group for all subscales, except for HOOS-Pain (see **Table 9**). Again, as observed in the ITT analysis, for HOOS-Symptoms and HOOS-Pain, the median scores at the eight-week assessment were either the maximum score that can be attained (100) or close to that value in both groups, which persisted over time (**Table 9**).

Hip ROM was also higher in the digital PT group for all exercises, except standing flexion (**Table 10**).

Change between baseline and the eight-week assessment

The median difference between the changes in the two groups regarding TUG was of -6.87 seconds (95% CI: -9.23;-4.05).

In respect to HOOS and hip ROM, significant improvements from baseline were noted in both groups,

again with the digital PT group showing greater improvements (**Tables 9** and **10**).

3.19.2 Medium term outcomes

Three-months assessment

The TUG and HOOS scores remained significantly different between groups, with patients from the digital PT group experiencing better results (**Tables 8** and **9**). Hip ROM was also higher in the digital PT group for all measured exercises ($p<0.001$), except for standing flexion ($p=0.41$) (**Table 10**).

Change between baseline and the three-months assessment

The change was superior in the digital PT group in all outcome measures, except for standing hip flexion ($p=0.052$) (**Tables 8, 9** and **10**).

Six-months assessment

The median difference between the TUG scores in the two groups was of -2.04 seconds (95% CI: -3.27;-1.09) in favor of the digital PT group ($p=0.002$) (**Table 8**). This value is below the 2.49 second MCD and therefore may not be clinically significant.

Regarding HOOS, the median scores in the digital PT group were significantly superior to the conventional rehabilitation group for all subscales except for HOOS-Pain (**Table 9**). Again, for HOOS-Symptoms and HOOS-Pain, median scores were either the highest possible score or close to that value (**Table 9**), with much greater homogeneity in the digital PT group (IQR 1.0 for HOOS symptoms and 2.0 for HOOS-Pain in the digital PT group vs 10.0 and 7.0, respectively).

At this time point, the hip ROM was higher in the digital PT group for lying flexion ($p=0.02$), standing hyperextension ($p=0.01$) and standing abduction ($p=0.03$) (**Table 10**).

Change between baseline and the six-months assessment

The ITT analysis revealed the superiority of the digital PT group in the TUG test, all HOOS subscales and all ROM exercises (**Tables 8, 9 and 10**).

The median difference between the changes in the two groups regarding TUG was of- 5.22 seconds (95% CI: -7.71;-2.38) in favor of the digital PT group (**Table 8**), which is more than twice the MCD reported for this scale

In terms of HOOS, the difference between median score changes was both statistically and clinically significant in the HOOS-Symptoms, Sports and QoL. (**Table 9**).

3.19.3. Repeated measures analysis

A repeated measures ANOVA was performed only for variables with normal distribution - TUG (after log-transformation) and hip ROM, and results are summarised in **Table 11**. While both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time, a main effect of group (here with the exception of the standing hip flexion ROM) and an interaction between time and group for all outcome measures, in favour of the digital PT group (see **Table 11** and **Figure 4**).

Table 11. Repeated measures analysis in the THA trial: per-protocol analysis

Outcome variable	Time		Group		Time*Group	
	F(df1,df2)	*p*	F(df1,df2)	*p*	F(df1,df2)	*p*
Patient performance						
TUG#&	F(2.6,144.1)=150.4	<.001	F(1,55)=17.8	<0.001	F(2.6,144.1)=18.0	<0.001
Hip range of motion						
Lying Flexion&	F(2.2,119.2)=147.8	<0.001	F(1,55)=11.2	0.001	F(2.2,119.2)=11.6	<0.001
Lying Abduction&	F(3.56,195.9)=158.2	<0.001	F(1,55)=21.3	<0.001	F(3.5,195.9)=13.4	<0.001
Standing Flexion&	F(2.2,120.2)=169.5	<0.001	F(1,55)=1.4	0.25	F(2.2,120.2)=5.1	0.01
Standing Hyperextension&	F(3.6,200.3)=94.1	<0.001	F(1,55)=12.2	0.001	F(3.6,200.3)=11.3	<0.001
Standing Abduction&	F(2.5,136.1)=138.5	<0.001	F(1,55)=18.6	<0.001	F(2.5,136.1)=15.0	<0.001

Legend: #ln transformation; &Greenhouse-Geisser correction.

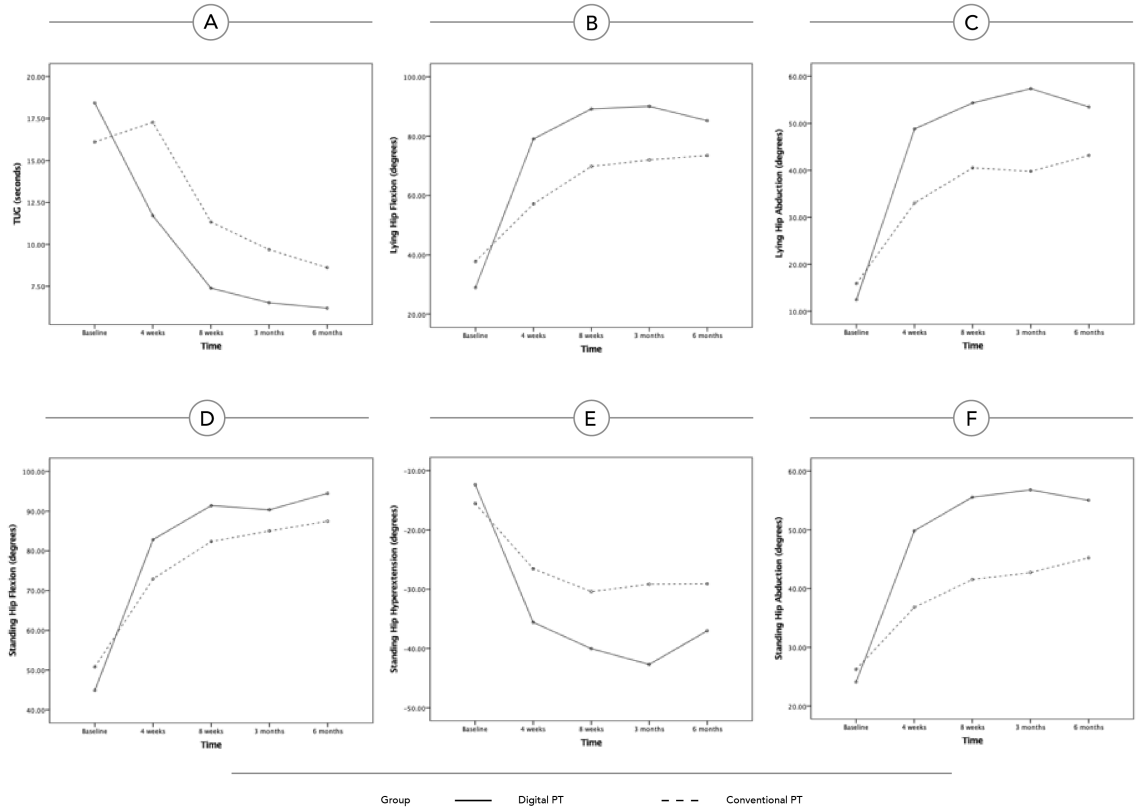


Figure 5. Evolution of outcomes over time in the THA trial: per-protocol analysis (estimated marginal means are presented). A- TUG score; B- Lying hip flexion; C- Lying hip abduction; D- Standing hip flexion; E- Standing hip hyperextension; F-Standing hip abduction.

3.20. Safety and adverse events

These were analyzed considering all patients enrolled in the trial (66 patients). As per the protocol, patients with serious medical/surgical complications not allowing discharge home within 10 days were excluded from the trial, which therefore resulted in an absence of serious adverse events in the period between surgery and discharge.

In the digital PT group, the total adverse event rate was 14.3% (5/35), and the treatment-related adverse event rate was 11.4% (4/35). In the conventional PT group, the total adverse event rate was 22.6% (7/31) and the treatment-related adverse event rate was 19.4% (6/31). There was no statistical difference between adverse events in both groups (p=0.525). Adverse events in both groups are summarized below in **table 12**.

Table 12. Adverse events in the THA trial

Adverse events	Digital PT group	Control group
Before discharge		
Treatment-related	0 (0.0%)	0 (0.0%)
Non-treatment related	0 (0.0%)	0 (0.0%)
During rehabilitation program		
Treatment-related	4 (11.4%)	6 (19.4%)
Groin pain	3	1
Inflammatory signs surgical wound	1	2
Thromboflebitis	-	1
Lower limb oedema	-	1
Non-treatment related	1 (2.9%)	1 (3.2%)
Falls	1 (2.9%)	1 (3.2%)
After rehabilitation program		
Treatment-related	0 (0.0%)	0 (0.0%)
Non-treatment related	0 (0.0%)	0 (0.0%)
Total	5 (14.3%)	7 (22.6%)

3.21. Usability and Engagement

3.21.1. Independence of Use

In the digital PT group, 37.1% (13/35) of the patients required assistance of a caregiver for tracker/strap placement or navigation. Patients requiring assistance were older (p=0.001) than those that did not require assistance- mean age 68.0 years; (sd=7.6) versus 57.7 years (sd=6.6).

3.21.2. Adherence to the digital intervention

In the digital PT group, 7/30 (23%) of the patients who completed the program did not comply with the recommended session frequency of five times per week, with only 4/30 (13%) patients having performed, on average, less than four days per week.

3.21.3. Patient-Therapist interaction

Patients in the conventional rehabilitation group had 24 in-person sessions, whereas patients in the digital PT group had three face-to-face contacts with the therapist and, on average, 0.6 (range 0-2) extra contacts for technical assistance. Regarding telephone calls, in addition to the two scheduled calls per protocol, each patient received a median of 4 extra calls (range 0-7), the vast majority due to difficulties in interacting with the system.

3.21.4 Treatment intensity

Total active treatment time was similar in both groups in both intent-to-treat (ITT) and per-protocol (PP) analysis (ITT: p=0.113; PP: p=0.240). In the ITT analysis, treatment intensity in the digital PT group was 20 hours (IQR 11.0; range 1.0-59.0) and in the PP analysis was 21 hours (IQR 10.3; range 8.0-59) versus 24 hours in the conventional PT group.

3.21.5. Patient Satisfaction

At the end of the program, patients in the digital PT group were asked to report their satisfaction level by answering the question: “On a scale from zero to ten, how much would you recommend the system to one of your friends or neighbours?”. Thirty-two (91.4%) rated the system with ten, two patients rated the system with nine and one did not answer.

DISCUSSION

3.22. Clinical outcomes

3.22.1. Introduction to clinical outcomes discussion

For the purpose of this thesis, we presented the results of the both ITT and PP analysis of this clinical trial. Given that, in this trial, the results of the PP and ITT analysis broadly lead to the same conclusions, we decided to keep the discussion centered in the ITT analysis. While this is a conservative approach not defended by all researchers[175] as it underestimates the true effects of the intervention, the ITT approach is defended by others as a way to reduce the source of bias.[176]

Taking into account the reference values for the TUG,[174] HOOS[173] and hip ROM,[177] both groups attained great clinically relevant improvements in all outcome measures in the short and medium-term assessments. This is in line with the findings of other authors that reported the effectiveness of early exercise interventions post-THA.[106,114,178–180]

3.22.2. Overall discussion

Globally, greater benefits were observed in the digital PT group, both at the end of the eight- week program and at the six-months assessment, and this was particularly evident in the PP analysis for all outcome measures, and when analyzing the change from baseline to six months. Still, we can observe a convergence trend between the two groups after the eight-week program. In the ITT analysis, this leads to a non-clinically significant difference at the six-month assessment for TUG (but not in the change from baseline, where the difference remains clinically significant) and to a convergence of all ROM measurements except for lying and standing abduction. Notwithstanding this, the repeated measures analysis confirms an interaction between time and group in favor of the digital PT group for TUG and hip ROM. For HOOS, the scores in the digital PT group were greater for ADL, Sports and QoL at the six-month assessment. The results reported for HOOS and ROM, when analyzed together, also confirm reports that ROM is not a good marker of implant success and patient satisfaction. [16,109,165,166]

These results are a major achievement for remotely-assisted physiotherapy programs, considering no evidence exists yet on the superiority of a specific exercise intervention post-THA[11,17,181,182] and no studies comparing digital with conventional PT in this context.

In the absence of studies using similar technologies to the one presented herein, it was nearly impossible to establish inter-studies comparisons. Furthermore, reports on physiotherapy interventions for THA recipients revealed high methodological variability regarding timing, duration and intensity, outcome measures and timelines for assessment.[9,18,103,182] Thus, only broad comparisons can be made between the present work and previous ones.

3.22.3. Timed up and Go test

Despite being among the most often used and recommended performance-based outcome measures,[17,183,184] the TUG test was only found in four studies.[185–188] From these, one compared the change between baseline and nine to twelve months post-surgery,[186] and the others presented data on the four-,[188] eight-,[185] twelve- and twenty-six-week[187] assessment or on the change between baseline and nine to twelve months.[186] All studies but one[188] reported similar significant improvement on TUG test with time in both intervention groups. Overall, reported changes in TUG scores varied between 0.36 seconds[188] and -5.8 seconds[187]. The results in the conventional PT group from the present trial fall broadly within these values, whereas the results of the digital PT group were higher, even surpassing the scores previously reported for healthy community living older adults (mean 8 seconds).[189,190]

Additionally, although the pattern of recovery from the conventional group followed a similar trend to the ones found in other studies using conventional PT,[191,192] patients from the digital PT group improved faster (38% at four weeks after surgery) and to a greater extent in the medium term (60% at 24 weeks). Indeed, in the study from Naylor et al,[191] an Australian cohort of 44 THA recipients (mean age 65 years) with TUG baseline values similar to ours (18 seconds), patient recovery at four weeks was approximately 6% and plateaued at 36% 24 weeks after surgery. Additionally, Kennedy *et al.*[192] reported a very slow recovery in a Canadian cohort of 68 patients (mean age 68 years), with a 78% TUG aggravation within the first four weeks following surgery (18 seconds) and a 21% improvement from baseline after 24 weeks. However, in this latter case, baseline values were oddly low (10.14 seconds), masking an actual 73% recovery after 24 weeks when the postoperative TUG (30 seconds) was set as the reference value.

3.22.4. Hip Osteoarthritis Outcome Score

Regarding HOOS, all subscales from both groups presented higher scores than those reported on a French (n=30, 37.5 to 55.3 points),[173] or on a Swedish HOOS validation study (n=90, 56.3 to 82.3

points),[172] three and six months after THA, respectively. In another RCT (n=68) on the effect of a walking skill training program in THA patients, significant improvements were detected between three- and five-months. However, changes were much smaller than those we observed. Also, in terms of changes from baseline, both the digital PT and the control group improved significantly from baseline to four weeks postoperatively, which was sooner than what was reported by Mikkelsen *et al.* (RCT, n=73).[114] Importantly, a ceiling effect was observed on HOOS-Symptoms and HOOS-Pain, with patients from both intervention groups reporting the best possible score from eight weeks onwards. Ceiling effects have also been reported on all subscales in the Swedish HOOS validation study, six months after THR,[172] and in the Dutch RCT by Mikkelsen *et al.*[114] Considering some sensitivity is lost using this scale, a revision and adaptation to the context of digital interventions, such as the one we presented, would be very useful in the future.

3.22.5.. Hip Range of Motion

Regarding hip ROM, it must be noted that all reports use goniometry as a means to measure hip range of motion, whereas we applied a high-precision sensor-based technology to assess active hip ROM, greatly reducing operator errors.[193] In a retrospective study by Davis *et al.* (n=1383), a logistic regression model yielded three levels of post-surgery hip ROM: high (115° of flexion, 25° of abduction), average (90°–114° of flexion, 16°–24° of abduction), or low (less than 90° of flexion, 15° or less of abduction) motion. Considering these ranges, scores from our trial revealed very high abduction amplitudes in both groups at month 6 post-op, particularly in the digital PT group. Indeed, we found no other reports showing superior results than those reported in this work.[188,194–197]

On the other hand, flexion ROM values fell in the lower range reported, revealing some room for improvement. Notwithstanding, our results at six months were comparable to the one reported on another prospective study (n=15)[197] on THA outcomes twelve months post-surgery (mean flexion± sd: 93.3°±18.7°).

Another study, by Umpierres *et al.* (RCT, n=106)[196], also reported on the improvement of hip flexion and extension ROM following THR, with an early two-week inpatient supervised versus unsupervised intervention. Although closer to the values reported at the four-week assessment of this trial, results from the digital PT group in our trial were superior to the ones reported in this RCT. Other studies were found where flexion and extension ROMs were higher than those we reported.[188,194,195] However, even considering possible differences related to measurement methods, high baseline angles revealed that the population in these studies was not as disabled as the one in the present trial.

Finally, although the improvements achieved in hip ROM are substantial, the values are still far from those reported for healthy individuals.[198]

3.23. Patient Acceptance and Usability

Given that this trial and the TKA trial had a similar methodology, with both involving a home-based post-surgery rehabilitation program with the same medical device, a decision was made to combine the discussion of these aspects in **Chapter 6**, as this provides a much more robust and clear picture of acceptance and usability.

3.24. Safety

As shown above, there were no differences in adverse event rates between both groups. However, there was a tendency for greater reporting of local vascular/inflammatory phenomena (oedema, thrombophlebitis and inflammatory signs) in the conventional PT group, and for more groin pain reported by members in the digital group. In regards to the first aspect, we believe there may have been an underreporting of such adverse events in the digital group, also when looking at what was reported in the TKA trial. As to the groin pain, we cannot find any potential relationship between the group/program and this report – something to be further clarified in larger studies. Additionally, it is noteworthy that there have been no adverse events reported in both groups between the end of the program and the 6 month assessment, which we also attribute to underreporting. This aspect is further discussed below, in the limitations section.

3.25. Limitations

Given that this trial and the TKA trial had a similar methodology and were performed in the same investigation centre, the limitations that need to be acknowledged and discussed are very similar in both trials, and therefore will be discussed jointly below, **in Chapter 6**.

CHAPTER 4 | TKA Clinical Trial

METHODS

4.1. Design

Single-center, non-randomized, parallel-group, clinical trial, designed to compare the clinical outcomes of TKA plus digital home-based rehabilitation versus TKA plus conventional rehabilitation, as well as to assess patient acceptance, usability and engagement with the system.

4.2. Investigation hypothesis

It was hypothesized that there would be no differences in the clinical outcomes of surgery plus digital rehabilitation versus surgery plus conventional rehabilitation after TKA.

In terms of safety, it was hypothesized that the adverse event rate of the surgery plus digital intervention group would be similar to that of surgery plus conventional rehabilitation.

In terms of usability, it was hypothesized that the digital program would be well accepted by patients.

4.3. Outcomes

Several studies suggest that clinical outcomes should be measured not only in terms of range of motion, which is considered a poor marker of implant success and patient satisfaction, [16,109,165,166] but also using PROMs and performance tests.[16,82–86] As such, clinical outcomes were evaluated according to three outcome measures: **a)** a performance test; **b)** PROMs; and **c)** range of motion of the knee.

In regards to the performance test, the TUG was chosen. TUG measures the time the patient takes to rise up from a chair, walk three meters, turn around, walk again towards the chair and sit down again. This test was chosen as it is simple and practical, quick and easy to administer, has excellent inter-rater reliability and very good test-retest reliability [167] and has been demonstrated to predict both short- [168] and long-term [80,169] function following hip and knee arthroplasty. Moreover, Podsiadlo and Richardson confirmed it's content validity in elder persons in that it evaluated a well-recognized series of maneuvers in daily life.[170]

In regards to PROMs, KOOS[199] was used. This scale was validated for patients submitted to TKA by Alviar and colleagues [200]. The KOOS scale (**Annex VIII**) consist of 5 subscales: 1) Pain; 2) other Symptoms; 3) Activities of Daily Living (ADL); 4) Function in sport and recreation (Sport/Rec) and 5) hip/knee related

QoL. The previous week is the time period considered when answering the questions. Standardized options are given and each question is assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. The MCID reported in subjects undergoing rehabilitation after TKA [201] was: 10.7 points for Symptoms; 16.7 points for Pain; 18.4 points for ADL; 12.5 points for Sports; 15.6 points for QoL.

Knee ROM was assessed in the following movements- lying, sitting and standing flexion and sitting extension. Given that SWORD Phoenix® is a certified medical device with a joint angle measuring function, ROM was measured in all patients using this system. According to the technical specifications of the device, the measurement error in comparison to standard goniometry is of 5.5 degrees.

All clinical outcomes were assessed at baseline (pre-operatively), on discharge (in-hospital), four weeks after initiating the rehabilitation program, at the end of the program (eight weeks), three months after surgery and finally six months after surgery.

4.3.1. Primary outcome

The primary outcome was the change in TUG score from baseline to the week 8 reassessment.

4.3.2. Secondary outcomes

The remaining clinical clinical outcomes (including other timepoints for TUG) were assessed as secondary outcomes. Hierarchically, changes from baseline to week 8 were given particular emphasis, followed by changes from baseline to 6 months and by changes from baseline to 3 months. Assessments at each of the timepoints were also considered, with the 4 week and 3 month assessment being given less relevance than the other timepoints.

Safety was measured through adverse event rates in both groups, divided in 3 periods: in-hospital; during rehabilitation program and after rehabilitation program.

Usability was measured through global enrollment rate, retention rate (drop-outs) in each of the groups and also, need for therapist contact in both groups. In the digital group, compliance to the program, independence of use, need for therapist contact and patient satisfaction were also measured.

4.4. Locations and timelines

This was a single-center clinical trial which was held at the Hospital da Prelada- Dr. Domingos Braga da Cruz, Porto, Portugal, in collaboration with the Orthopedics Department. All consecutive patients admitted for TKA between December 19th 2016 and November 27th 2017 were screened for eligibility by the two orthopedic surgeons that oversaw the trial- José Tulha and Rosmaninho Seabra. Completion date for the assessment at the end of the 8-week active rehabilitation period was January 29th 2018 and for the six month follow-up was May 27th 2018.

4.5. Sample size estimation

Sample size estimation was performed considering the primary outcome measure – Change in TUG scores from baseline to week 8. Calculations were based on a MCID of 2.27 seconds as reported by Yuksel *et al.*[202] The behavior of the variable of interest (TUG) at baseline was calculated based on that reported by Mizner *et al.*[203] (mean 9.6 seconds ; standard deviation 2.4 seconds) in a study where patients performed a rehabilitation protocol broadly comparable to the one used in the present trial. The resulting computed effect size was of 0.95. Considering this effect size, a power of 90%, a two-sided 0.05 significance level and a 15% dropout rate, 55 patients would be necessary to detect a 2.27 second difference between the two groups. Given the wide variation in the standard deviation of the TUG reported by different authors - from 0.5 seconds[86] to 6.3 seconds[28]- it was decided to increase sample size to 70 patients, to account for a greater variation than the one reported by Mizner and collaborators.

4.6. Inclusion & Exclusion Criteria

3.6.1. Inclusion Criteria

a) Patients over 18 years old;
b) Clinical and imaging evidence of knee osteoarthritis;
c) Indication for total hip/knee replacement according to patient´s orthopedic surgeon;
d) Ability to walk unaided or requiring assistive device (unilateral or bilateral);
e) Availability of a carer to assist the patient after surgery.

3.6.2. Exclusion Criteria

f) Patients admitted for revision of total knee replacement;

g) Contralateral hip or knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program;
h) Aphasia, dementia or psychiatric comorbidity interfering with the communication or compliance to the rehabilitation process;
i) Respiratory, cardiac, metabolic or other condition incompatible with at least 30 minutes of light to moderate physical activity;
j) Major medical complications occurring after surgery that prevent the discharge of the patient within 10 days after the surgery;
k) Other medical and/or surgical complications that prevent the patient from complying with a rehabilitation program;
l) Blind and/or illiterate patients.

4.7. Patient enrollment

3.7.1. Patient identification and recruitment

Whenever a potential candidate was identified, the local investigator approached the candidate and explained the clinical trial in detail. The prospective candidate was given the patient information document and informed consent (see **Annex IX**) and sufficient time to consider whether he wished to participate in the trial. Subsequently, the prospective candidate was given opportunity to clarify any doubts, after which the informed consent form was signed and dated in duplicate by the patient and the investigator. Only then was the baseline assessment performed.

3.7.2. Patient allocation

Patient allocation was performed upon hospital discharge using patient address as criterion. Subjects residing in areas outside the administrative limits of the city of Oporto were allocated to the digital PT group. Conversely, patients residing within the administrative limits of the city were allocated to the conventional rehabilitation group. Patient allocation was performed centrally by one investigator – Fernando Dias Correia.

3.7.3. Blinding

The nature of the trial did not allow blinding of the patients. Patient assessment was performed by two investigatosr- José Tulha and Rosmaninho Seabra - blinded for allocation groups. Primary statistical analysis was performed by a blinded statistician – Laetitia Teixeira.

4.8. Intervention

Patients were admitted for elective surgery and proceeded to surgery as per the existing hospital protocols. Between day 1 post-op and hospital discharge, all patients were taught, as per the hospital protocol, how to safely get in and out of bed and were asked to perform alternate ankle flexion and extension exercises regularly. All patients performed initial gait training with canes. After that, both groups received early-onset home-based rehabilitation immediately after discharge, for eight weeks.

4.8.1. Digital PT Group

In the digital PT group, patients received an initial visit from the physical therapist, to assess specific rehabilitation needs and to teach patients and/or caregivers how to set up and use the biofeedback system. After this initial visit, the digital PT group performed a rehabilitation program solely through the use of the biofeedback system, under remote monitoring from a physical therapist. Patients were instructed to perform sessions between five and seven days a week, but compliance to this frequency was not mandatory per protocol and patients were not excluded in case of lower adherence. The number of sessions, daily adherence and total training time was registered automatically by the system and was made available through the web Portal.

4.8.1.1. Face-to-face visits

Each patient in this group received three visits from the assigned physical therapist:

Visit 1: Initial deployment

In this visit, the physical therapist taught the patient how to operate the system, and adapted the exercise program based on the presented guidelines (see below) and adapted to the patient´s specific needs. The therapist performed an initial session with the patient, ensuring that the patient was able to perform each exercise and that he could operate the system, alone or with the help of a caregiver.

Visit 2: Interim visit (4 weeks ± 5 days)

In this visit, the physical therapist assessed patient progress and adjusted the rehabilitation program accordingly. This visit did not consist of a conventional face-to-face rehabilitation session.

Visit 3: Termination visit (8 weeks ± 5 days)

The purpose of this visit was to collect the equipment. This visit did not consist of a conventional face-to-face rehabilitation session.

4.8.1.2. Telephone calls

Each patient received two interim telephone calls per protocol, at weeks 2 and 6 (± 3 days) after initiation of the rehabilitation program. In these calls, the therapist ascertained more details on patient progress to help guide the treatment, and explicitly questioned the patients about adverse events.

4.8.1.3. Additional visits or telephone calls

When required, additional visits or telephone calls for technical assistance were performed by the physical therapist, and registered as such in the patient file (date, motive, duration).

4.8.2. Conventional Rehabilitation Group

The conventional rehabilitation group received a home-based supervised program provided by a physiotherapist, three times a week, for one hour. Patients were instructed by their physical therapist to perform additional unsupervised sessions in at least two other days of the week.

Specific instructions regarding exercises, sets and repetitions were laid out in paper for each patient.

Compliance to these unsupervised sessions was not mandatory and formal registry of these sessions were not kept.

4.8.3. Rehabilitation Protocols

In the absence of a gold standard, the rehabilitation protocols were designed taking into account a recent systematic review on the subject,[16] the results of a Delphi panel on best practices for rehabilitation after THA/TKA[17] and the protocols published by SOFMER.[108]

Detailed rehabilitation programs are presented in **Tables 13** and **14.** In any case, as can be seen in the tables, these protocols were tailored to the patient´s specific needs, according to the joint assessment between the orthopedic surgeon and the physical therapist.

Table 13. Rehabilitation protocol for the TKA trial (stage 1)

Stage 1 (weeks 0-4)	
Objectives	**Precautions**
Decrease pain and swelling Restore range of motion Strengthen knee extensors and flexors Restore fully load capacity on both legs	Ice pack application after each session and throughout the day as needed
Intervention	
Digital PTI Group	**Conventional rehabilitation**
Open kinetic chain exercises without added resistance Lying: - Hip flexion with knee flexion (2x10 reps) - Hip abduction (2x10 reps) - Knee flexion (2x10 reps) - Knee Extension against resistance (2x10 reps) Sitting: - Knee flexion (2x10 reps) - Knee extension (2x10 reps) - Sit to stand (2x10 reps) Standing (initially with support): - Hip abduction (2x10 reps) - Hip hyperextension (2x10 reps) - Knee flexion (2x10 reps) - Hip flexion with knee flexion (2x10 reps) **Closed kinetic chain** Lying: - Bridge (2x10 reps) Standing: - Mini-squats (2x10 reps) **Note 1:** adjust sets, reps and total session duration according to patient tolerance (based on patient performance and on the pain and fatigue scores) **Note 2:** aim for at least 30 minutes in total **Note 3:** recommend two daily sessions as soon as tolerated	Soft tissue massage Active assisted mobilization of the knee to increase range of motion Gait training with bilateral support Isometric exercises - quadriceps contraction (3x10 sec) Active plantar flexion (2x20 reps) Progress to **open kinetic chain exercises and closed kinetic chain exercises** without added resistance according to patient's tolerance - Same exercises as the digital PT group **Note 1:** adjust sets, reps and total session duration according to patient tolerance **Note 2:** recommend additional sessions twice per week (write down exercises, sets and reps)

Table 14. Rehabilitation protocol for the TKA trial (stage 2)

Stage 2 (weeks 5-8)	
Objectives	**Precautions**
Strengthening of knee flexors and extensors Increase active range of motion Improve balance Independence on all activities of daily living	Identical to stage 1
Intervention	
Digital PTI Group	**Conventional rehabilitation**
Open kinetic chain exercises in the lying, sitting and standing positions: - Same exercises as above but with higher number of repetitions and added resistance Progression to closed kinetic chain exercises: - Squat (2x10 reps) - Wall Sit (2x10 reps) - Sit to stand (2x10 reps) - Forward lunges (2x10 reps) - Lateral lunges (2x10 reps) **Note 1:** adjust sets, reps and total session duration according to patient tolerance (as in stage 1) **Note 2:** maintain recommendation of 2 sessions/day	Soft tissue massage Balance exercises with progression to one-leg support Gait training Open kinetic chain exercises with added resistance according to patient's tolerance Progressing to closed kinetic chain exercises with added resistance according to patient's tolerance - same exercises as the digital PT group **Note 1:** adjust sets, reps and total session duration according to patient tolerance

4.9. Patient Assessment

Patients were assessed at baseline (pre-operatively), on discharge (in-hospital), four weeks after initiating the rehabilitation program, at the end of the program (eight weeks), three months after surgery and finally six months after surgery. These assessments were performed in the ward or in the outpatient clinic by the patient orthopaedic surgeon. For each of the post-discharge visits, a timeframe of five working days before or after the date was allowed.

3.9.1. Baseline assessment (V1): pre-operative

Participant characterization consisted of:

a) Demographics (gender, age at enrollment);

b) Affected side

c) Comorbidities and risk factors for adverse events

- Body Mass Index
- Smoking
- Diabetes

- Cardiac disease
- Respiratory disease
- Hypertension
- Stroke
- Renal Disease
- Bleeding disorders
- American Society of Anesthesiologists physical status classification score
- Intake of steroids for chronic condition
- Previous hip replacement
- Previous knee replacement

d) Timed Up and Go test score

e) Knee Osteoarthritis Outcome Score

3.9.2. Assessment on discharge (V2)

An additional assessment on discharge was performed, with collection of the following information:

a) Data on hospitalization and surgical procedure

- Time between admission and surgery
- Surgical technique
- Type of prosthesis
- Type of anesthesia
- Operative time
- Length of stay

b) Complications before discharge

- Falls
- Infectious complications (urinary, respiratory, prosthesis)
- Thromboembolism (deep vein thrombosis, pulmonary embolism)

3.9.1. Subsequent assessments (V3, V4, V5)

These assessments consisted of:

d) Timed Up and Go test score

e) Knee Osteoarthritis Outcomes Scale score

f) Complications after discharge
    a. Falls
    b. Infectious complications
    c. Thromboembolism
    d. Readmissions

4.10. Safety and Adverse Events

As per the protocol, patients with serious medical/surgical complications not allowing discharge home within 10 days were excluded from the trial. Other adverse events during hospitalization were retrieved from medical records at the time of discharge.

During the rehabilitation period, patients in the conventional rehabilitation group were under regular monitoring by a physical therapist, enabling early detection and reporting of adverse events. In the digital PT group, safety was evaluated through pain and fatigue scores (graduated from 0 to 10) at the end of each session, which were available for remote monitoring through the web-based portal. Patients were also asked to report any adverse events to their physical therapist or to the investigator through a direct telephone contact.

In the follow-up period, adverse events were not proactively questioned to participants.

4.11. Statistical Analysis

To assess differences in clinical and demographic variables of the patients allocated to the two groups, independent samples T test or Mann–Whitney U test were used for quantitative variables. For categorical variables, Chi-squared test and Fisher's exact test were used.

Outcome analysis was performed using both an intent-to-treat (ITT) and a per-protocol (PP) analysis. Differences between the two groups were performed using independent samples T test or Mann-Whitney U test. For non-normally distributed variables, the magnitude of median difference was assessed using Hodges-Lehman estimator.

Since outcomes were measured in different moments, a repeated measures analysis was also performed, using a repeated Analysis of Variance (ANOVA) with group as an independent factor and time as a within-subjects factor.

4.12. Data Protection & Ethics Approval of Research

This clinical trial was jointly approved, together (but not independently) with the TKA trial, by the National Data Protection Commission (authorization number 1476/2017) – see **Annex X**- and by the local ethics committee at Hospital da Prelada (Chair: Dr. Juiz Conselheiro Almeida Lopes)- see **Annex XI**. The methods were conducted in accordance with the approved guidelines. All patient data was anonymized and linked to the patient by a unique number that did not contain any personal identifiers.

4.13. Registration

This clinical trial was prospectively registered at www.clinicaltrials.gov with the following Unique identifiers: NCT03047252; date of registration: 8 February 2017.

4.14. Availability of data and materials

The protocols of the trial is available from www.clinicaltrials.gov. Individual patient data (in Excel format) that underlie the results reported in each of the published papers was submitted as supplementary information, accessible through the online version of each paper.

4.15. Funding

This work was supported in part by the European Commission through the Project H2020 SME Instrument Phase 2 - Grant Agreement number 672814.

The manufacturer of the SWORD Phoenix medical device - SWORD Health, SA - was the sponsor of the trials and, in that capacity, provided financial and logistics support to the work herein presented.

RESULTS

4.16. Patient flow

Two hundred and thirty six patients were assessed for eligibility between 19th December 2016 and November 27th 2017. **Figure 5** shows the CONSORT diagram for the trial. Trial inclusion rate was of 29%. Between the eligibility screening and allocation to one of two arms, a total of 93 patients refused to participate or withdrew consent, corresponding to 56% (93/167) of all screening failures.

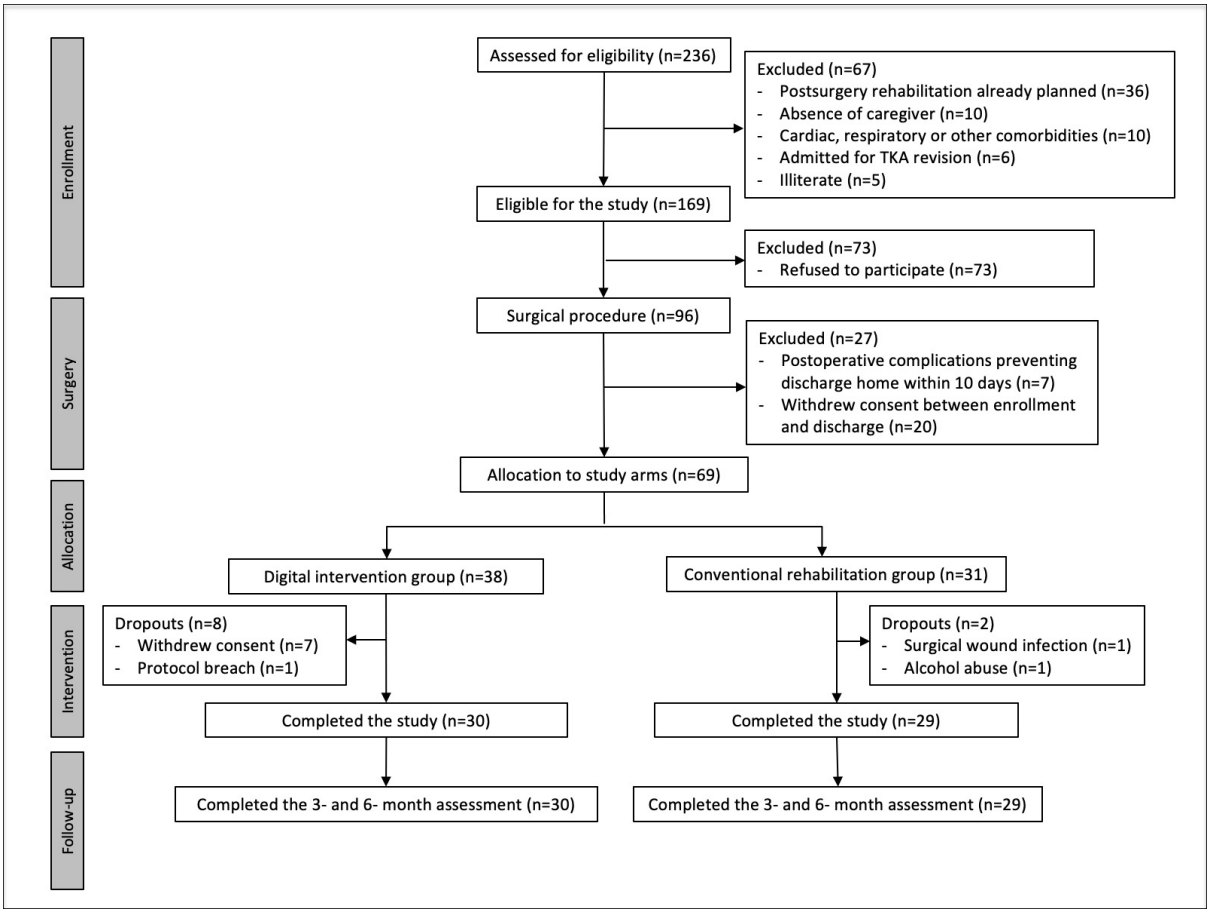


Figure 6. TKA trial CONSORT diagram

Sixty-nine patients were included and allocated to one of two groups (37 on the digital PT group and 32 on the conventional rehabilitation group). On the digital PT group, 7 patients withdrew consent on the first week, and one additional patient was excluded due to a protocol breach (additional physical therapy program started) corresponding to a 21% dropout rate in this group. On the conventional rehabilitation group, 2 patients were excluded, corresponding to a 7% dropout rate in this group. In total, 59 patients

completed the 8-week rehabilitation program (30 patients in the digital PT group and 29 in the conventional rehabilitation group) and the follow-up assessments. There were no differences between the dropout rates in the two studies (p=0.167)

4.17. Baseline population characterization

Baseline characteristics of trial participants regarding demographics, comorbidities and risk factors for adverse events, as well as data on hospitalization and surgery are summarized in **Table 15**.

Table 15. Baseline characteristics of participants in the TKA trial

	Digital PT Group (n=38)	Control Group (n=31)	*p* value
Demographics			
Age (years) mean (sd)	67.3 (6.8)	70.0 (7.2)	0.12$
Gender female (%)	84.2	71.0	0.30#
Side right (%)	63.2	45.2	0.21#
Comorbidities & Known risk factors for adverse events			
Body Mass Index mean (sd)	31.0 (4.5)	30.8 (5.4)	0.84$
Smoking (%)	10.5	12.9	1.00·
Hypertension (%)	65.8	74.2	0.62#
Diabetes (%)	18.4	12.9	0.74·
Pulmonary disease (%)	7.9	19.4	0.28·
Cardiac disease (%)	5.3	6.5	1.00·
Stroke (%)	0.0	0.0	NA
Renal disease (%)	0.0	3.2	0.45·
Bleeding disorders (%)	0.0	0.0	NA
ASA€ class 3 or 4 (%)	13.2	16.1	0.74·
Steroids for chronic condition (%)	0.0	0.0	NA
Previous contralateral knee replacement (%)	18.4	32.3	0.30#
Previous hip replacement (%)	7.9	0.0	0.25·
Hospital admission and surgical procedure			
Time between admission and surgery (hours)	<24 h	<24 h	NA
Operative time (min) mean (sd)	62.4 (9.87)	62.8 (13.0)	0.89$
Length of stay (days) median (IQR)	6 .0(1.0)	6.0 (2.0)	0.83#

Legend: €American Society of Anesthesiology physical status classification system; #Chi-Square test; ·Fisher´s exact test; $independent samples T test; §Mann-Whitney U

There were no differences between the two groups regarding these characteristics. Additionally, in all cases, cemented, fixed-bearing and non-ligament sparing prosthetics were used. There were also no differences between the two groups regarding TUG **(Table 15)** nor regarding knee range of motion **(Table**

17). Of note, both groups had severe impairments regarding knee extension, where the goal is to reach full extension (0 degrees). Regarding the KOOS, the population in the digital PT group had lower scores in every subscale (Table 17).

4.18. Intent-to-treat analysis

For the intent-to-treat analysis all patients who enrolled in the trial were considered. For those who dropped out or were lost to follow-up, the last known assessment was carried forward.

The results of all the timepoints, as well as the difference between each of those timepoints and baseline, can be found in the Tables 16, 17 and 18 below and then discussed jointly.

Table 16. Primary outcome assessment in the TKA trial: intent-to-treat

Primary outcome - Timed up and Go*					
Time-point	Digital PT Group (n=38)	Control Group (n=31)	P value#	Estimate difference between groups	95% confidence interval
Baseline	18.19 (7.55)	15.98 (8.58)	0.12	1.94	-0.65;4.41
4 Weeks	11.75 (7.79)	16.76 (8.50)	0.06	-3.62	-6.67;-0.90
Change baseline- 4 weeks	-6.93(10.50)	-0.88 (6.51)	0.003	-5.14	-8.83;-1.60
8 weeks	8.17 (6.34)	10.58 (4.18)	0.02	-1.95	-3.30;-0.47
Change baseline-8 weeks	- 8.48 (8.97)	-4.62 (6.72)	0.12	-2.79	-5.83;0.77
3 months	8.35 (5.93)	10.67 (4.31)	0.03	-1.86	-3.19;-0.26
Change baseline-3 months	-8.55 (8.24)	-5.23 (7.83)	0.08	-3.10	-5.82;0.31
6 months	7.49 (4.85)	8.88 (4.66)	0.01	-1.60	-2.48;-0.49
Change baseline-6 months	-8.51 (8.61)	-5.08 (9.20)	0.13	-2.70	-5.91;0.73

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 17. Patient reported outcomes assessment in the TKA trial: intent-to-treat

Patient Reported Outcomes Assessment- KOOS*					
Variable	Digital PT Group	Control Group	P value#	Estimate difference between groups	95% confidence interval
Baseline					
Symptoms	32.0 (16.0)	50.0 (25.0)	<0.001	-18.0	-28.0;-11.0
Pain	34.5 (14.0)	47.0 (20.0)	<0.001	-11.0	-17.0;-6.0
Act. Daily Living	34.0 (16.0)	43.0 (16.0)	0.001	-9.0	-15.0;-3.0
Sports	0.0 (0.0)	5.0 (5.0)	0.004	0.0	-5.0;0.0
Quality of Life	13.0 (19.0)	19.0 (19.0)	0.01	-6.0	-13.0;0.0
4 weeks					
Symptoms	68.0 (25.0)	68.0 (25.0)	0.89	0.0	-8.0;7.0
Pain	73.5 (25.0)	69.0 (14.0)	0.65	2.0	-6.0; 8.0
Act. Daily Living	72.0 (43.0)	69.0 (21.0)	0.74	1.0	-9.0;10.0
Sports	10.0 (10.0)	15.0 (10.0)	0.03	-5.0	-5.0;0.0
Quality of Life	50.0 (25.0)	38.0 (31.0)	0.95	0.0	-7.0;12.0
Change baseline- 4 weeks					
Symptoms	32.0 (32.0)	14.0 (17.0)	0.002	18.0	7.0;25.0
Pain	36.0 (25.0)	22.0 (19.0)	0.01	11.0	3.0; 22.0
Act. Daily Living	36.0 (22.7)	24.0 (17.0)	0.01	11.0	3.0;19.0
Sports	10.0 (15.0)	10.0 (10.0)	0.67	0.0	-5.0;5.0
Quality of Life	31.0 (31.2)	19.0 (18.0)	0.06	12.0	0.0;19.0
8 weeks					
Symptoms	82.0 (31.0)	71.0 (22.0)	0.08	8.0	0.0;18.0
Pain	89.0 (24.0)	78.0 (14.0)	0.07	6.0	0.0; 11.0
Act. Daily Living	87.5 (38.0)	76.0 (16.0)	0.12	6.0	-1.0;13.0
Sports	20.0 (20.0)	15.0 (10.0)	0.98	0.0	-5.0;5.0
Quality of Life	69.0 (33.0)	56.0 (25.0)	0.04	12.0	0.0;19.0
Change baseline- 8 weeks					
Symptoms	46.0 (43.7)	14.0 (22.0)	0.001	25.0	11.0;35.0
Pain	54.5 (26.2)	33.0 (25.0)	0.003	16.0	8.0;25.0
Act. Daily Living	49.5 (33.0)	34.0 (15.0)	0.004	25.0	6.0;22.0
Sports	20.0 (16.2)	15.0 (15.0)	0.29	5.0	0.0;10.0
Quality of Life	56.0 (39.5)	31.0 (31.0)	0.01	19.0	6.0;31.0
3 months					
Symptoms	86.0 (33.0)	75.0 (22.0)	0.31	4.0	-4.0;11.0
Pain	92.0 (29.2)	83.0 (25.0)	0.09	6.0	0.0;11.0
Act. Daily Living	91.0 (24.7)	81.0 (22.0)	0.10	4.0	-2.0;10.0
Sports	20.0 (16.2)	20.0 (10.0)	0.16	5.0	0.0;10.0
Quality of Life	75.0 (37.0)	56.0 (25.0)	0.06	12.0	0.0;19.0
Change baseline-3 months					
Symptoms	46.0 (33.0)	25.0 (28.0)	0.001	21.0	10.0;32.0
Pain	54.5 (19.7)	31.0 (25.0)	0.002	17.0	8.0;25.0
Act. Daily Living	50.0 (30.2)	34.0 (18.0)	0.01	15.0	6.0;22.0
Sports	20.0 (20.0)	15.0 (10.0)	0.02	10.0	0.0;15.0
Quality of Life	59.5 (38.7)	44.0 (37.0)	0.01	18.0	6.0;31.0
6 months					
Symptoms	91.0 (31.5)	82.0 (22.0)	0.24	4.0	-3.0;11.0
Pain	97.0 (21.2)	86.0 (25.0)	0.20	3.0	0.0;11.0
Act. Daily Living	95.0 (24.7)	87.0 (15.0)	0.06	6.0	0.0;11.0
Sports	27.5 (42.5)	20.0 (20.0)	0.21	10.0	-5.0;20.0
Quality of Life	88.0 (42.5)	63.0 (44.0)	0.03	13.0	0.0;25.0
Change baseline-6 months					
Symptoms	50.0 (36.0)	29.0 (35.0)	0.004	18.0	7.0;32.0
Pain	58.0 (24.2)	39.0 (25.0)	0.003	14.0	5.0;22.0
Act. Daily Living	51.0 (23.7)	43.0 (22.0)	0.01	13.0	4.0;22.0
Sports	25.0 (43.5)	15.0 (25.0)	0.05	10.0	0.0;25.0
Quality of Life	75.0 (50.2)	44.0 (44.0)	0.004	25.0	7.0;38.0

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 18. Knee range of motion outcomes assessment: intent-to-treat

Knee range of motion assessment*					
Variable	Digital PT Group	Control group	P value#	Estimate difference between groups	95% confidence interval
Baseline					
Lying flexion	81.3 (13.7)	84.8(18.4)	0.37	-3.52	-11.24;4.20
Sitting flexion	85.8 (15.2)	90.7 (12.8)	0.16	-4.91	-11.78;1.95
Sitting extension	27.4 (9.6)	24.8 (7.6)	0.24	2.53	-1.70;6.76
Standing flexion	72.0 (20.5)	78.2 (16.2)	0.17	-6.26	-15.31;2.79
4 weeks					
Lying flexion	87.9 (12.59)	90.0 (10.6)	0.47	-2.07	-7.75;3.61
Sitting flexion	93.1 (9.88)	95.1 (11.1)	0.42	-2.04	-7.10;3.01
Sitting extension	18.8(11.68)	24.4 (8.9)	0.03	-5.66	-10.73;-0.58
Standing flexion	84.7 (11.88)	84.0 (12.0)	0.81	0.71	-5.05;6.47
Change baseline-4 weeks					
Lying flexion	6.6 (12.7)	5.11 (17.4)	0.69	1.45	-5.81;8.71
Sitting flexion	7.3(14.6)	4.4 (12.7)	0.39	2.90	-3.77;9.58
Sitting extension	-8.6 (13.2)	-0.4 (12.0)	0.01	-8.19	-14.33;-2.05
Standing flexion	12.7 (20.8)	5.7 (15.0)	0.12	6.97	-1.95;15.89
8 weeks					
Lying flexion	96.2 (15.4)	92.4 (13.1)	0.28	3.77	-3.18;10.71
Sitting flexion	98.4 (12.0)	97.0 (11.6)	0.63	1.40	-4.32;7.11
Sitting extension	17.1 (11.0)	23.5(10.8)	0.02	-6.37	-11.64;-1.11
Standing flexion	91.9 (13.2)	86.4 (11.3)	0.07	5.51	-0.48;11.50
Lying flexion	96.2 (15.4)	92.4 (13.1)	0.28	3.77	-3.18;10.71
Change baseline- 8 weeks					
Lying flexion	14.9 (17.5)	7.6 (16.2)	0.08	7.29	-0.90;15.48
Sitting flexion	12.6 (17.3)	6.3 (12.9)	0.09	6.34	-1.13;13.81
Sitting extension	-10.3 (11.3)	-1.34(13.5)	0.004	-8.90	-14.87;-2.93
Standing flexion	19.9 (20.9)	8.1 (13.7)	0.01	11.80	3.10;20.49
3 months					
Lying flexion	96.3 (16.1)	93.1 (13.5)	0.38	3.19	-4.07;10.45
Sitting flexion	99.2 (14.6)	96.1 (11.6)	0.35	3.06	-3.38;9.49
Sitting extension	14.9 (11.6)	19.9 (10.4)	0.07	-4.92	-10.29;0.44
Standing flexion	91.7 (14.0)	85.3 (11.0)	0.04	6.43	0.29;12.57
Change baseline-3 months					
Lying flexion	15.0 (16.4)	8.3 (14.7)	0.08	6.72	-0.86;14.29
Sitting flexion	13.4 (19.4)	5.5 (14.4)	0.06	7.94	-0.44;16.32
Sitting extension	-12.4 (10.2)	-5.0 (12.6)	0.01	-7.48	-12.96;-2.00
Standing flexion	19.7 (18.3)	7.0 (14.3)	0.002	12.68	4.66;20.70
6 months					
Lying flexion	98.8 (15.7)	100.7 (13.6)	0.60	-1.87	-9.00;5.27
Sitting flexion	99.2 (13.1)	101.9 (12.5)	0.37	-2.78	-8.97;3.41
Sitting extension	11.3 (11.9)	11.2 (9.5)	0.98	0.06	-5.20;5.33
Standing flexion	93.1 (14.2)	90.0 (12.1)	0.34	3.11	-3.32;9.53
Change baseline-6 months					
Lying flexion	17.5 (15.4)	15.87 (17.2)	0.67	1.66	-6.19;9.50
Sitting flexion	13.4 (18.5)	11.26 (13.8)	0.60	2.14	-5.88;10.15
Sitting extension	-16.1 (10.9)	-13.61 (11.2)	0.36	-2.47	-7.78;2.85
Standing flexion	21.1 (20.5)	11.71 (14.0)	0.03	9.40	0.75;18.04

Legend: *means and standard deviations are presented; #independent samples T-test

4.18.1. Short term outcomes

Four-week assessment

Differences between groups were found only for KOOS Sports and for sitting knee extension (**Tables 17** and **18**), favouring the digital PT group, but not for TUG (p=0.06).

Change between baseline and the four-week assessment

Only the digital PT group showed clinically meaningful improvement in the TUG, with a much greater change in the digital PT group (p=0.003) (**Table 16**). Regarding KOOS, based on the MCID reported for this scale[202], significant changes were noted in both groups except for KOOS Sports, with greater changes in the digital PT group in KOOS-Symptoms, Pain and ADL (**Table 17**). For ROM, changes were higher in the digital PT group only for sitting knee extension (p=0.01) (**Table 18**).

Eight-week assessment

TUG scores were again lower in the digital PT group (p=0.02) (see **Table 16**). The median difference between the TUG scores in the two groups was of -1.94 seconds (95% CI: -3.67;-0.59), which is lower than the MCID reported for the scale – 2.27 seconds (**Table 16**).

Regarding KOOS, the median scores in the digital PT group were superior to the conventional rehabilitation group only for HOOS-QoL (p=0.04) (**Table 17**). Knee ROM was higher in the digital PT group only for sitting knee extension (p=0.02) (**Table 18**).

Change between baseline and the eight-week assessment

Even though the median differences between the changes in the two groups are higher than the MCID reported for the scale, this did not reach statistical significance (p=0.12) (**Table 16**). For KOOS, clinically significant changes were noted in both groups in all subscales except for Sports, with greater changes in the digital PT group in KOOS-Symptoms, Pain and ADL (**Table 17**). For ROM, changes were higher in the digital PT group only for sitting knee extension (p=0.004) and standing knee flexion (p=0.01) (**Table 18**).

4.18.2. Medium term outcomes

Three-months assessment

The TUG score remained significantly different between groups (p=0.03), with patients from the digital PT group experiencing better results, but with a difference between groups lower than the MCID for the scale (**Table 16**). As for KOOS, no differences were found between groups (**Table 17**). ROM was higher in the digital PT group only for standing knee flexion (p=0.04) (**Table 18**).

Change between baseline and the three-months assessment

The change was superior in the digital PT group for sitting knee extension (p=0.011) and standing knee flexion (p=0.002) but not for TUG(p=0.08) or KOOS. (**Tables 16, 17** and **18**).

Six-months assessment

The median difference between the TUG scores in the two groups was of -1.60 seconds (95% CI: -2.48;-0.49) in favor of the digital PT group (p=0.01) (**Table 16**). This value is below the MCID and therefore not clinically significant.

Regarding KOOS, the median scores in the digital PT group were significantly superior only for QoL (p=0.03) (**Table 17**). At this time point, knee ROM was similar in the two groups (**Table 18**).

Change between baseline and the six-months assessment

The median difference between the changes in the two groups regarding TUG was of -2.70 seconds (95% CI: -5.91;0.73) in favor of the digital PT group, which is higher than the MCID for the scale, but it did not reach statistical significance (p=0.13) (**Table 16**)

In terms of KOOS, the difference between median score changes was statistically significant for all subscales except for Sports and clinically significant for Symptoms and QoL (**Table 17**).

Regarding ROM, significant differences between the mean changes in the two groups were detected only for standing knee flexion (p=0.03) (**Table 18**).

4.18.3. Repeated measures analysis

A repeated measures ANOVA was performed only for variables with normal distribution - TUG (after log-transformation) and knee ROM, and results are summarised in **Table 19**. While both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time for all outcome measures, no effect of group, and an interaction between time and group for TUG, sitting knee extension and standing knee flexion in favour of the digital PT group (**Table 19** and **Figure 6**).

Table 19. Repeated measures analysis in the TKA trial: intent-to-treat analysis

Outcome variable	Time		Group		Time*Group	
	F(df1,df2)	p	F(df1,df2)	p	F(df1,df2)	p
Patient performance						
TUG#&	F(2.9,193.4)= 60.248	<0.001	F(1,67)=3.177	0.08	F(2.9,193.4)= 5.460	0.001
Knee range of motion						
Lying flexion&	F(2.5,170.4)=35.0	<0.001	F(1,67)=0.001	0.97	F(2.5, 170.4)=2.404	0.08
Sitting flexion&	F(2.1,140.0)=21.5	<.0001	F(1,67)=0.188	0.67	F(2.1, 140.0)=2.495	0.08
Sitting extension&	F(3.0,200.2)=41.8	<0.0001	F(1,67)=.2.007	0.49	F(3.0, 200.2)=5.371	0.001
Standing flexion&	F(2.0,131.4)=33.8	<0.001	F(1,67)=0.475	0.16	F(2.0, 131.4)=5.209	0.01

Legend: #In transformation; &Greenhouse-Geisser correction.

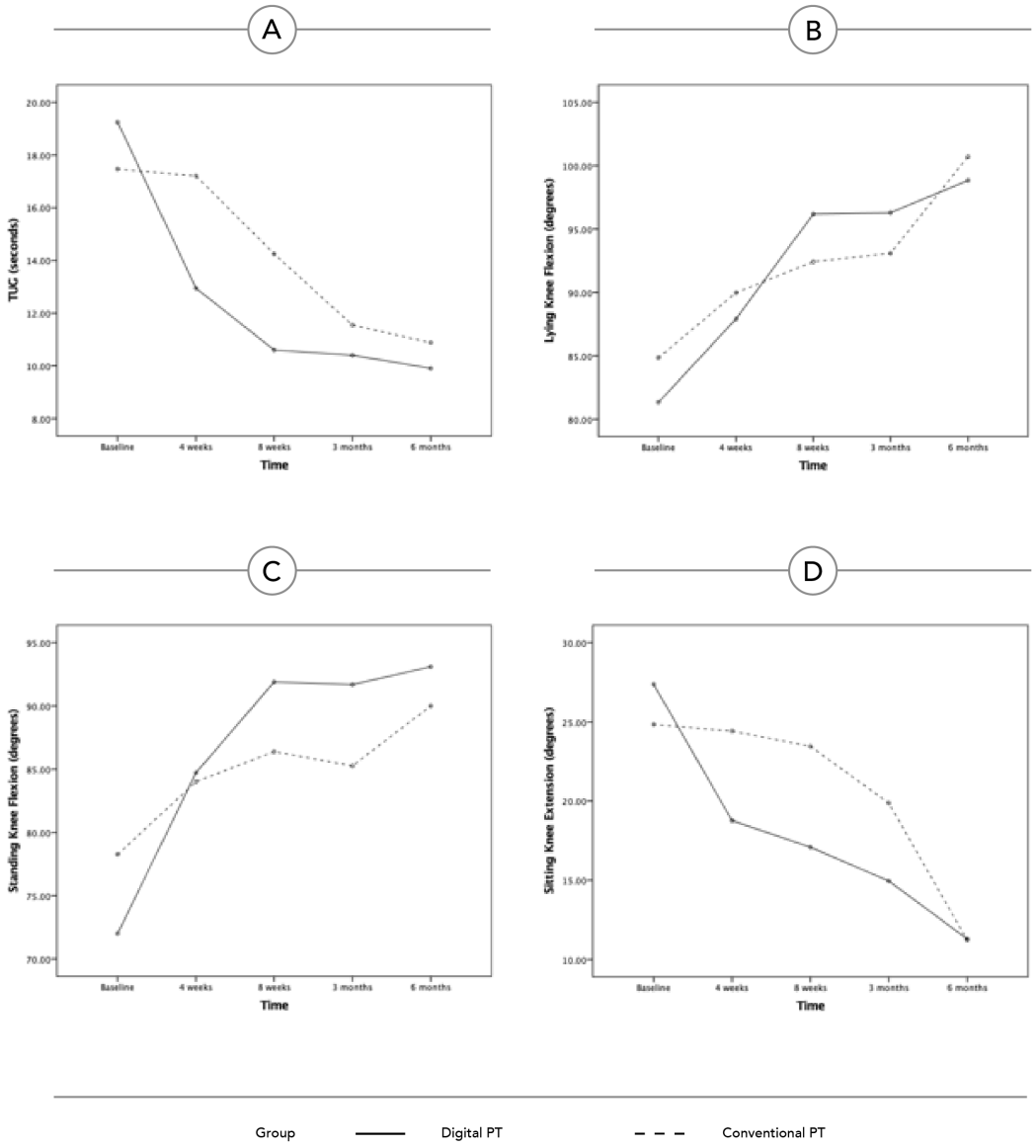


Figure 7. Evolution of outcomes over time in the TKA trial: intent-to-treat analysis (estimated marginal means are presented). A- TUG score; B- Lying knee flexion; C- Standing knee flexion; D- Sitting knee extension

4.19. Per-protocol analysis

For the per-protocol analysis, only patients who completed the rehabilitation program were included. The results of all the timepoints, as well as the difference between each of those timepoints and baseline, can be found in the **Tables 20, 21 and 22** below and then discussed jointly. Globally, they not only confirm the findings of the ITT analysis, but also highlight an even greater superiority of the digital PT group.

Table 20. Primary outcome assessment in the TKA trial: per-protocol

Primary outcome - Timed up and Go*					
Time-point	Digital PT Group (n=30)	Control Group (n=29)	P value#	Estimate difference between groups	95% confidence interval
Baseline	18.19 (6.21)	15.27 (8.49)	0.13	2.02	-0.78;4.40
4 Weeks	10.01 (3.64)	16.76 (8.25)	<0.001	-4.78	-7.57; -2.04
Change baseline- 4 weeks	-7.54(10.59)	-0.88 (5.94)	0.001	-6.72	-9.93;-3.06
8 weeks	7.79 (2.77)	10.07 (4.13)	<0.001	-2.84	-4.16;-1.60
Change baseline-8 weeks	- 9.49 (7.97)	-4.62 (7.67)	0.004	-4.48	-7.30;-1.81
3 months	7.83 (2.43)	10.32 (3.47)	<0.001	-2.50	-3.80;-1.43
Change baseline-3 months	-10.28 (5.87)	-5.23 (8.49)	0.003	-4.47	-7.47;-1.85
6 months	6.86 (1.60)	8.74 (3.98)	<0.001	-1.95	-2.90;-1.24
Change baseline-6 months	-10.47 (7.32)	-5.08 (9.3)	0.004	-4.87	-7.47; -1.85

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 21. Patient reported outcomes assessment in the TKA trial: per-protocol

Patient Reported Outcomes Assessment- KOOS*					
Variable	Digital PT Group	Control Group	P value#	Estimate difference between groups	95% confidence interval
Baseline					
Symptoms	34.0 (20.0)	50.0 (29.0)	<0.001	-18.0	-25.0;-17.0
Pain	33.0 (12.0)	47.0 (24.0)	<0.001	-11.0	-19.0;-6.0
Act. Daily Living	34.0 (18.0)	41.0 (18.0)	0.005	-9.0	-15.0;-3.0
Sports	0.0 (0.0)	5.0 (8.0)	0.006	0.0	-5.0;0.0
Quality of Life	13.0 (19.0)	25.0 (19.0)	0.007	-12.0	-18.0;0.0
4 weeks					
Symptoms	71.0 (8.0)	68.0 (25.0)	0.21	3.0	-4.0;11.0
Pain	81.0 (15.0)	69.0 (14.0)	0.04	6.0	0.0; 12.0
Act. Daily Living	77.0 (25.0)	68.0 (24.0)	0.05	7.0	0.0;16.0
Sports	15.0 (6.0)	15.0 (10.0)	0.45	0.0	-5.0;0.0
Quality of Life	50.0 (18.0)	38.0 (31.0)	0.17	6.0	-6.0;13.0
Change baseline- 4 weeks					
Symptoms	37.5 (19.0)	14.0 (21.0)	<0.001	22.0	11.0;29.0
Pain	44.0 (18.5)	22.0 (17.5)	<0.001	17.0	9.0; 25.0
Act. Daily Living	41.0 (16.8)	24.0 (18.0)	<0.001	17.0	9.0;23.0
Sports	12.5 (5.0)	10.0 (10.0)	0.40	0.0	0.0;5.0
Quality of Life	38.0 (25.0)	19.0 (15.0)	<0.001	18.0	7.0;25.0
8 weeks					
Symptoms	84.0 (11.0)	71.0 (24.0)	0.001	14.0	7.0;21.0
Pain	90.5 (10.0)	78.0 (14.0)	<0.001	11.0	5.0; 14.0
Act. Daily Living	90.5 (10.0)	76.0 (16.0)	0.001	10.0	5.0;16.0
Sports	20.0 (10.0)	15.0 (10.0)	0.09	5.0	0.0;10.0
Quality of Life	69.0 (18.0)	56.0 (25.0)	<0.001	19.0	12.0;25.0
Change baseline- 8 weeks					
Symptoms	50.0 (26.0)	18.0 (21.5)	<0.001	29.0	21.0;40.0
Pain	57.0 (17.0)	33.0 (25.0)	<0.001	22.0	14.0;28.0
Act. Daily Living	54.5 (16.5)	35.0 (16.0)	<0.001	19.0	13.0;26.0
Sports	20.0 (7.5)	15.0 (15.0)	0.007	5.0	0.0;10.0
Quality of Life	56.0 (20.5)	31.0 (31.0)	<0.001	31.0	19.0;38.0
3 months					
Symptoms	87.5 (11.8)	82.0 (19.5)	0.01	9.0	0.0;15.0
Pain	95.5 (11.8)	86.0 (22.5)	<0.001	11.0	5.0;17.0
Act. Daily Living	93.0 (8.0)	87.0 (22.5)	0.001	7.0	3.0;15.0
Sports	30.0 (11.3)	20.0 (7.5)	0.001	10.0	5.0;15.0
Quality of Life	81.0.0 (14.5)	56.0 (25.0)	<0.001	19.0	12.0;25.0
Change baseline-3 months					
Symptoms	51.5 (24.25)	25.0 (27.0)	<0.001	25.0	15.0;35.0
Pain	58.0 (12.0)	31.0 (23.5)	<0.001	23.0	15.0;31.0
Act. Daily Living	57.5 (17.8)	35.0 (16.5)	<0.001	20.0	13.0;27.0
Sports	30.0 (11.3)	15.0 (10.0)	<0.001	10.0	10.9;15.0
Quality of Life	65.0 (22.0)	44.0 (21.0)	<0.001	25.0	18.0;37.0
6 months					
Symptoms	96.0 (15.0)	86.0 (22.0)	0.006	7.0	3.0;14.0
Pain	100.0 (8.0)	86.0 (23.5)	0.002	11.0	3.0;16.0
Act. Daily Living	97.0 (6.0)	87.0 (14.5)	0.001	7.0	4.0;13.0
Sports	42.5 (36.3)	20.0 (22.5)	0.003	15.0	5.0;30.0
Quality of Life	94.0 (12.0)	63.0 (37.5)	0.001	25.0	12.0;32.0
Change baseline-6 months					
Symptoms	60.5 (25.8)	29.0 (33.5)	<0.001	25.0	15.0;36.0
Pain	61.0 (11.8)	39.0 (24.0)	<0.001	20.0	14.0;28.0
Act. Daily Living	58.0 (17.5)	43.0 (23.0)	<0.001	19.0	11.0;26.0
Sports	40.0 (35.0)	15.0 (27.5)	<0.001	20.0	10.0;30.0
Quality of Life	81.0 (20.0)	43.0 (40.5)	<0.001	36.5	24.0;49.0

Legend: *Medians and IQR are presented; #Mann-Whitney U test.

Table 22. Knee range of motion outcomes assessment: per-protocol

Knee range of motion assessment*					
Variable	Digital PT Group	Control group	P value	Estimate difference between groups	95% confidence interval
Baseline					
Lying flexion	80.7 (12.4)	84.7 (18.7)	0.34	4.0	-12.2:4.3
Sitting flexion	85.3 (16.0)	90.4 (13.1)	0.19	5.1	-12.8;2.5
Sitting extension	26.5 (8.4)	24.8 (7.8)	0.42	1.7	-2.5;6.0
Standing flexion	71.6 (20.3)	78.8 (16.6)	0.15	7.2	-16.8;2.6
4 weeks					
Lying flexion	89.5 (9.4)	90.1 (10.6)	0.85	-0.5	-5.7;4.7
Sitting flexion	94.7 (8.1)	94.9 (10.8)	0.95	-0.2	-5.1;4.8
Sitting extension	16.6 (9.9)	23.8 (7.3)	0.01	-7.2	-11.7;-2.7
Standing flexion	86.7 (9.5)	83.5 (11.5)	0.25	3.2	-2.3;8.7
Change baseline-4 weeks					
Lying flexion	8.8 (13.3)	5.3 (18.0)	0.41	3.5	-4.8;11.7
Sitting flexion	9.5 (15.7)	4.5 (13.0)	0.19	5.0	-2.5;12.5
Sitting extension	-9.9 (13.8)	-1.0 (11.2)	0.009	-8.9	-15.5;-2.4
Standing flexion	15.1 (22.2)	4.8 (14.8)	0.04	10.3	0.4;20.3
8 weeks					
Lying flexion	100.0 (11.3)	92.6 (13.1)	0.02	7.4	1.0;13.8
Sitting flexion	101.5 (9.6)	97.0 (11.3)	0.10	4.6	-0.9;10.0
Sitting extension	95.8 (8.8)	86.1 (10.8)	0.001	-8.3	-13.0;-3.7
Standing flexion	14.5 (8.2)	22.8 (9.6)	<0.001	9.8	4.6;14.9
Change baseline- 8 weeks					
Lying flexion	19.3 (17.0)	8.0 (16.7)	0.01	11.3	2.5;20.1
Sitting flexion	16.3 (17.7)	6.6 (13.1)	0.02	9.7	91.6;17.9
Sitting extension	-12.1 (11.1)	-2.0 (12.9)	0.002	-10.0	-16.2;-3.8
Standing flexion	24.2 (20.9)	7.3 (13.5)	0.001	16.9	7.7;26.1
3 months					
Lying flexion	100.1 (12.6)	93.3 (13.6)	0.05	6.8	-0.04;13.62
Sitting flexion	102.5 (13.1)	96 (11.3)	0.05	6.5	0.10;12.89
Sitting extension	11.8 (8.3)	19 (8.8)	0.002	-7.2	2.73;11.65
Standing flexion	95.6 (10.2)	84.9 (10.4)	<0.001	10.7	5.22;16.08
Change baseline-3 months					
Lying flexion	19.4 (15.5)	8.7 (15.1)	0.01	10.7	2.8;18.7
Sitting flexion	17.3 (20.1)	5.7 (14.7)	0.01	11.6	2.4;20.8
Sitting extension	-14.8 (9.0)	-5.9 (11.6)	0.002	-8.9	-3.5;-14.3
Standing flexion	23.9 (17.6)	6.1 (14.1)	<0.001	17.8	9.5;26.2
6 months					
Lying flexion	103.4 (10.6)	101.5 (13.3)	0.55	1.9	-4.38;8.15
Sitting flexion	102.5 (10.8)	102.2 (12.3)	0.93	0.3	-5.77;6.29
Sitting extension	7.1 (6.6)	9.7 (5.8)	0.12	-2.6	-5.83;0.64
Standing flexion	97.4 (9.9)	89.9 (11.7)	0.01	7.5	1.78;13.08
Change baseline-6 months					
Lying flexion	22.7 (12.9)	16.8 (17.4)	0.15	5.8	-2.1;13.8
Sitting flexion	17.2 (19.1)	11.9 (13.9)	0.22	5.4	-3.4;14.1
Sitting extension	-19.4 (8.4)	-15.1 (8.7)	0.06	-4.3	-8.8;0.2
Standing flexion	25.7 (20.1)	11.2 (14.0)	0.002	14.6	5.5;23.6

Legend: *means and standard deviations are presented; #independent samples T-test

4.19.1. Short term outcomes

Four-week assessment

Differences between groups were found for TUG [p<0.001, 10.01 (3.64) seconds *vs* 16.76 (8.25) seconds] (**Table 20**), for KOOS-Pain (p=0.04) (**Table 21**) and sitting knee extension (p=0.002) (**Table 22**). The median difference between groups for TUG is more than double the MCID for the scale, and therefore clinically significant.

Change between baseline and the four-week assessment

Only the digital PT group showed clinically meaningful improvement in the TUG, with a much greater change in the digital PT group (p=0.001) (**Table 20**). Regarding KOOS, clinically significant improvements were noted in both groups, with a greater change in the digital PT group for all subscales except for Sports (**table 21**). Regarding ROM, the difference between groups was significant for sitting knee extension (p=0.01) and standing knee flexion (p=0.04) (**Table 22**).

Eight-week assessment

Differences between groups were found for TUG [p<0.001, 7.79 (2.77) seconds *vs* 10.07 (4.13) seconds] (**Table 20**) and the difference was higher than the MCID reported for this scale, and therefore clinically significant. Regarding KOOS, the scores in the digital PT group were superior to those of the conventional group for all scales except for KOOS-Sports (p=0.09) (**Table 21**) and the difference between groups was clinically significant for KOOS-Symptoms. For ROM, scores were higher in the digital PT group for all movements except for sitting knee flexion (p=0.10) (**Table 22**).

Change between baseline and the eight-week assessment

The change was superior in the digital PT group in all outcome measures (**Tables 20,21** and **22**). The median difference between both groups was of -4.48 seconds (95% CI -7.30;-1.81), more than double the MCID for TUG, and therefore clinically significant. Regarding KOOS, clinically significant improvements were noted in both groups; plus, the difference between median changes in both groups was also superior to the MCID for each subscale, and therefore clinically significant (**Table 21**).

Regarding knee ROM, even though there are no MCID validated for knee range of motion in patients submitted to TKA, a study by Stratford and collaborators[204] reported a MDC90 (MDC at a 90% confidence interval) of 9.6 degrees for knee flexion and 6.3 degrees for knee extension in patients after TKA. Therefore, significant improvements in knee range of motion were noted only in the digital PT group (**Table 22**).

4.19.2. Medium term outcomes

Three-months assessment

The TUG score remained significantly different between groups ($p<0.001$), with patients from the digital PT group experiencing better results, with a difference between groups higher than the MCID for the scale (**Table 20**).

As for KOOS, differences were found between groups in all subscales, favoring the digital PT group (**Table 21**). ROM was higher in the digital PT group for sitting extension and standing flexion (**Table 22**).

Change between baseline and the three-months assessment

The change was superior in the digital PT group for all outcome measures (**Tables 20, 21** and **22**).

Six-months assessment

TUG scores in the digital PT group were lower than in the conventional group, with median difference between the TUG scores in the two groups of -1.95 seconds (95% CI: -2.90;-1.24), which is lower than the MCID for the scale (**Table 20**).

Regarding KOOS, the median scores in the digital PT group were significantly superior for all subscales (**Table 21**). ROM was higher in the digital PT group only for standing knee flexion $p=0.01$) (**Table 22**).

Change between baseline and the six-months assessment

The median difference between the changes in the two groups regarding TUG was of -4.87 seconds (95% CI: -7.87;-1.85) in favor of the digital PT group, which is higher than the MCID for the scale and therefore clinically significant (**Table 20**).

In terms of KOOS, the difference between median score changes was statistically and clinically significant for all subscales (**Table 21**).

Regarding ROM, significant differences between the mean changes in the two groups were detected only for standing knee flexion (p=0.002) (**Table 22**).

4.19.3. Repeated measures analysis

A repeated measures ANOVA was performed only for variables with normal distribution - TUG (after log-transformation) and knee ROM, and results are summarised in **Table 23**. While both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time, a main effect of group (with the exception of lying and sitting knee flexion) and an interaction between time and group for all outcome measures, in favour of the digital PT group (**Table 23** and **Figure 7**).

Table 23. Repeated measures analysis in the TKA trial: per-protocol analysis

Outcome variable	Time		Group		Time*Group	
	F(df1,df2)	p	F(df1,df2)	p	F(df1,df2)	p
Patient performance						
TUG[#&]	F(2.2,124.5)= 76.406	<0.001	F(1,57)=9.346	0.003	F(2.2,124.5)= 7.801	<0.001
Knee range of motion						
Lying flexion[&]	F(2.6,150.9)=42.3	<0.001	F(1,57)=0.8	0.38	F(2.6,150.9)=4.29	0.008
Sitting flexion[&]	F(2.2,126.2)=24.8	<0.001	F(1,57)=0.27	0.60	F(2.2,126.2)=3.98	0.02
Sitting extension[&]	F(3.0,169.4)=50.9	<0.001	F(1,57)=11.4	0.001	F(3.2,169.4)=5.6	0.001
Standing flexion[&]	F(2.0,116.2)=37	<0.001	F(1,57)=3.88	0.05	F(2.2,116.2)=9.17	<0.001

Legend: [#]ln transformation; [&]Greenhouse-Geisser correction.

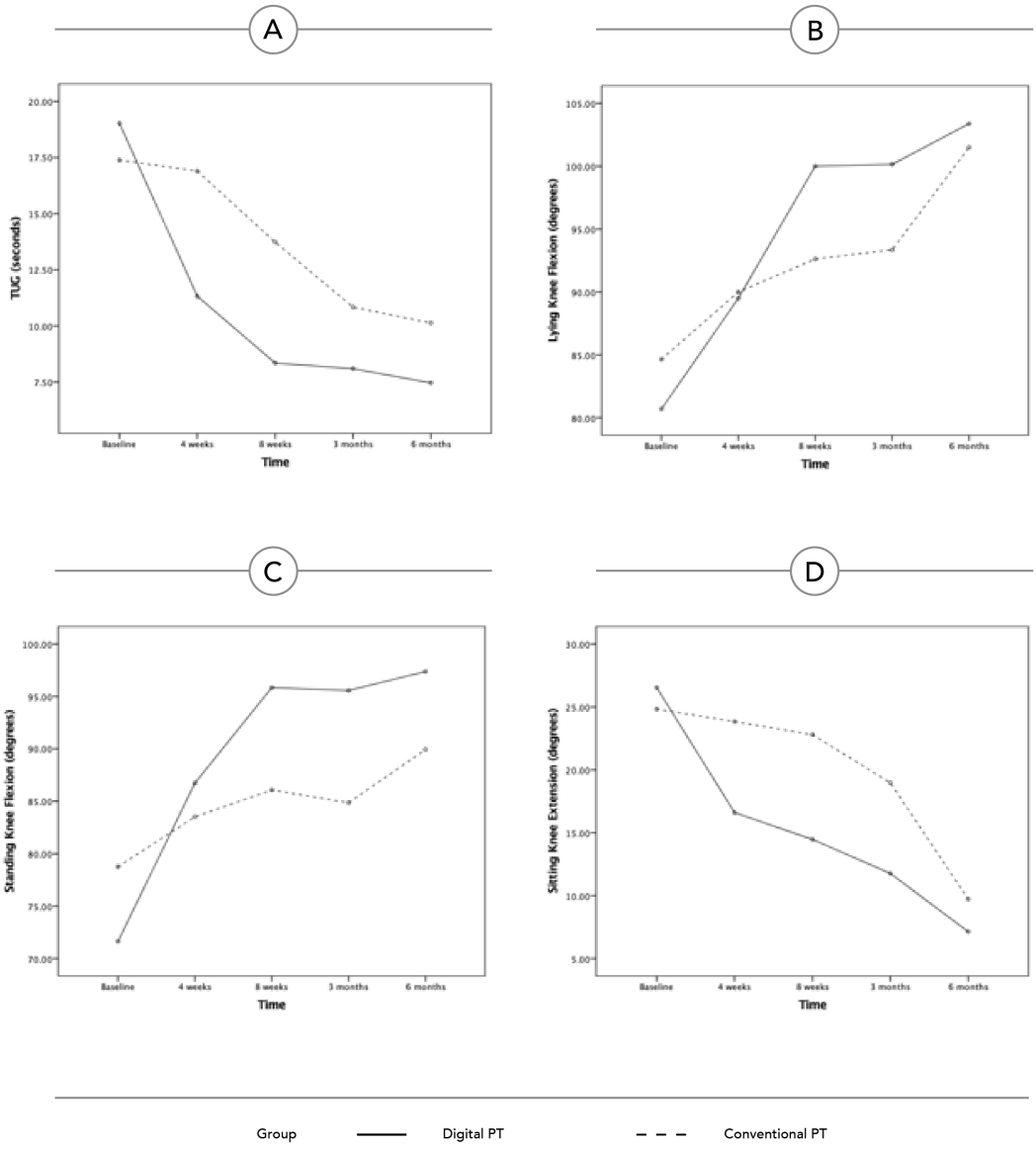


Figure 8. Evolution of outcomes over time in the TKA trial: per-protocol analysis (estimated marginal means are presented). A- TUG score; B- Lying knee flexion; C- Standing knee flexion; D- Sitting knee extension.

4.20. Usability and engagement

4.20.1. Independence of Use

From the 38 patients allocated to the digital PT group, 58.0% required the assistance of a caregiver either in motion tracker placement or in interacting with the app. There was a trend for a higher age in the non-autonomous patients (median 69.4 years; IQR 10 vs median 65.5; IQR 10) which did not reach statistical significance (p=0.06).

4.20.2. Adherence to the digital intervention

In the digital PT group, only 4/30 (13%) of the patients who completed the program did not comply with the recommended session frequency of five times per week, with none performing below four days per week on average.

4.20.3. Patient-Therapist interaction

Patients had three face-to-face contacts with the therapist (one deploy session, one at 4 weeks and one at the end of the eight-week program) and, on average, 0.4 (±0.7; range 0-2) additional face-to-face contacts, as well as a median of 2.5 extra calls (IQR 3.0; range 1-12) for technical assistance.

4.20.4. Treatment intensity

Total active treatment time was superior in the digital PT group in the per-protocol analysis (p=0.001) but not in the intent-to-treat analysis (p=0.36). In the ITT analysis, treatment intensity in the digital PT group was 26.1 hours (IQR 21.2; range 0.1-69.1) and in the PP analysis was 31.5 hours (IQR 18.0; range 10.8-69.1) versus 24 hours in the conventional PT group.

4.20.5. Patient Satisfaction

Patients in the digital PT group were asked to report their satisfaction level by answering the question: “On a scale from zero to ten, how much would you recommend the system to one of your friends or neighbours?”. From the 37 patients who answered, twenty-eight (73.7%) rated the system with 10/10, one rated 9/10, two rated 8/10, one rated 7/10, 4 rated 5/10 and 1 rated the system with 4/10. The lowest scores were attributed by patients who dropped out in week 1 of the rehabilitation program.

4.21. Safety and adverse events

These were analyzed considering all patients enrolled in the trial (69 patients). As per the protocol, patients with serious medical/surgical complications not allowing discharge home within 10 days were excluded from the trial, which therefore resulted in an absence of serious adverse events in the period between surgery and discharge.

In the digital PT group, both the total and treatment-related adverse event rate was 5.2% (2/38). In the conventional PT group, the total adverse event rate was 19.4% (6/31) and the treatment-related adverse event rate was 16.2% (5/31). This difference is statistically significant for both the total adverse event rate (p=0.02) and for the treatment-related adverse event rate (p=0.04). Adverse events in both groups are summarized below in **table 24**.

Table 24.Adverse events in the TKA trial

Adverse events	Digital PT group	Control group
Before discharge		
Treatment-related	0 (0.0%)	0 (3.2%)
Thrombophlebitis	0	1
Non-treatment related	0 (0.0%)	0 (0.0%)
During rehabilitation program		
Treatment-related	1 (2.6%)	5 (16.2%)
Inflammatory signs surgical wound	-	3
Thromboflebitis	1	1
Surgical wound infection+readmission	-	1
Non-treatment related	0 (0.0%)	1 (3.2%)
Alcohol abuse	0 (0.0%)	1 (3.2%)
After rehabilitation program		
Treatment-related	0 (0.0%)	0 (0.0%)
Non-treatment related	0 (0.0%)	0 (0.0%)
Total	1 (2.6%)	7 (22.6%)

DISCUSSION

4.22. Clinical outcomes

4.22.1. Introduction to clinical outcomes discussion

For the purpose of this thesis, we presented the results of both the ITT and PP analysis for the TKA trial. Of note, the papers where the results of the TKA trial were published were based on the PP analysis, whereas the papers published on the results of the THA trial were based on the ITT analysis. Even if this represents a methodological contradiction, the first paper to be published was of the main results of the TKA trial, in 2018, based on a PP analysis, and therefore it made sense to maintain the same methodology for the follow-up paper. We subsequently decided to base the discussion of the THA trial results in the ITT analysis, as discussed above, essentially due to the fact that, while this is a conservative approach not defended by all researchers[175] as it underestimates the true effects of the intervention, the ITT approach is defended by others as a way to reduce the source of bias.[176]

In the TKA trial, the results of the two approaches differ in some degree, a fact that was not observed to the same extent in the THA tral. In all likelihood, this difference is due to the higher dropout rate in the TKA trial, where seven patients withdrew consent in the first week, in comparison to two patients in the THA trial - the other three dropouts in the THA were at a later stage. In an ITT design, these early dropouts have a tremendous impact, as the assessment that was carried forward was the baseline (pre-surgery) assessment. Throughout the discussion, differences between the ITT and the PP analysis will be highlighted.

4.22.2. Overall discussion

Taking into account the reference values for the TUG and [174] KOOS,[202] and the extent of the improvement in knee ROM in comparison to published studies,[205] both groups attained great clinically relevant improvements in all outcome measures in the short and medium-term assessments.

Regarding TUG, at the end of the rehabilitation program, the results in the digital PT group are higher in both cases, but the estimated difference between groups is likely to only be clinically significant in the PP analysis. In any case, there is a convergence after eight weeks in both cases, with the results at the six-month assessment being statistically but likely not clinically significant. Crucially, the repeated measures analysis confirms an interaction between time and group in favor of the digital PT group for TUG, in both cases (ITT and PP).

Regarding KOOS, at the end of the rehabilitation program, and also at the six-month assessment, the results in the digital PT group are higher only for the QoL subscale in the ITT analysis, whereas in the PP they are higher in all subscales. When assessing the change from baseline to 6 months, the results are higher in the digital PT group for all subscales in the PP analysis, and for all but the Sports subscale in the ITT.

Regarding knee ROM, at the end of the rehabilitation program, in the ITT analysis, the digital PT group demonstrated higher ROM for sitting knee extension only, whereas in the PP analysis ROM was higher in all movements except for sitting knee flexion. At the six-month assessment, the ITT analysis revealed a similar knee ROM between both groups, whereas in the PP analysis standing flexion was higher in the digital PT group. When analyzing the change from baseline to 6 months, it was superior only for standing knee flexion in the digital group. In any case, in both analysis, the same tendency for convergence after the 8 week assessment is noted.

Overall, the ITT analysis shows superior outcomes in the digital PT group for the primary outcome in both short- and medium-term outcomes, albeit with a tendency for convergence in the medium term, as well as superior outcomes regarding KOOS-QoL, and all but the sports scale when considering the change from baseline to 6 months. In summary, in this analysis, there is little difference between groups at the end of the rehabilitation program, and a convergence at six months. The results in the PP analysis are much more expressively in favor of the digital PT group.

In all, while we do agree that the ITT approach is a valuable way to reduce bias, and despite the fact that we will also be considering the results of the ITT analysis in the discussion, it is our opinion that, in this case, this analysis represents a true underestimation of the impact of this intervention.

Given the paucity of studies in this area, comparison of the results of the present trial with similar studies is not possible, except with a study published by Piqueras *et al.*[28], where a solution broadly similar to the SWORD device was tested. We have therefore considered, in addition, other studies published on rehabilitation after TKA[100,101,203], on home versus clinic-based interventions[206] or tele-rehabilitation versus conventional rehabilitation.[23,24,28]

In the study by Piqueras *et al.*[28], the outcomes were similar in both groups.[28] However, in this trial, the intervention time (ten sessions over two weeks) was too short to allow the detection of differences between groups, and treatment intensity was inferior to current recommendations.[16,17] In fact, treatment intensity is highly variable in published studies on rehabilitation after TKA and we have found only one study where treatment intensity was comparable to the one provided to the patients in the present

study.[101] This study, by Bade *et al.*[101], compared two different treatment intensities in the rehabilitation after TKA, in an outpatient setting, with the high intensity group performing 25 sessions in 12 weeks, which was similar to the treatment intensity in the conventional rehabilitation group in our trial.

4.24.1. Timed up and Go test

Given the wide variation in terms of pre- and post- intervention TUG scores in published studies on rehabilitation after TKA[23,28,100,101,203], comparison with published data is difficult. Still, the study by Mizner *et al.*[203] on the time course of functional recovery after TKA reported a mean improvement of 1.7 seconds between the pre-operative and 3 months assessment, and the study by Bade *et al.* [101] reported a mean change of 1.6 seconds in the high intensity rehabilitation group after 3 months. These results are lower than what was observed in our trial for both groups. Another study, by Petterson *et al.* [100] on progressive strengthening interventions after TKA reported a mean improvement of 4.08 seconds at three months, again less than what was observed in our trial in that timeline, for both groups, but especially for the digital PT group.

Regarding absolute scores, Stevens-Lapsley *et al.* [86] published a retrospective cohort evaluation on the self-reported and performance-based assessments of knee recovery following TKA. Despite a much lower baseline TUG in their cohort (9.23 seconds±0.55), the results obtained in our trial in the digital PT group are in line with those reported in this study, both at the three-month assessment (8.35 seconds vs 8.46 seconds) and at the six-month assessment (7.49 versus 7.92 seconds), while the results in the conventional rehabilitation group are higher in both time points, but with a small difference at the six-month assessment.

Considering papers published on tele-rehabilitation solutions, the results observed in the digital PT group are clearly superior to those reporter by Piqueras *et al.* for the tele-rehabilitation group (-5.22 seconds change)[28]- still, with the caveat of the short timeline of the intervention in this study - but lower than those reported by Russel *et al.* [23] However, in the latter study, and contrary to the study by Piqueras *et al.*, the baseline and TUG scores were much higher than those observed in our trial (baseline mean scores of 28.8±16.6 seconds in the tele-rehabilitation group and 26.8±12.1 seconds in the control group) resulting in also higher final scores. [23]

Regarding the percental change from baseline to the six-month assessment in our trial - >50% change in the digital PT group and 33% in the conventional PT group – it was higher that in other published studies. However, it must be noted that baseline TUG values in the present trial were much higher than those

reported by other authors, with pre-operative values between 8 and 12 seconds, which in turn yields poor changes from baseline with intervention (~8%-30% improvement).[100,101,129,203]

It is also important to note that the values reported for TUG at the six-month assessment in the digital PT group (in both PP and ITT analysis) are much lower than the value reported by Bade et al the same authors for patients treated with conventional physiotherapy 6 months after TKA (9.1±2.4 seconds)[207] and that the value in this group in the PP analysis (6.9±1.6 seconds) is near the one reported for healthy older individuals (50-85 years old) in the same study (5.6±1.0 seconds).[207] In the conventional group, the results at the 6 months assessment are in line with those reported Bade *et al.* [207]

Overall, the TUG analysis shows that important benefits were attained in both groups, with those of the conventional group being in line with the results reported by other authors, and those of the digital PT group being superior to the results reported in the literature.

4.22.3. Knee Osteoarthritis Outcome Score

Regarding short-term outcomes, in the conventional rehabilitation group, the results of the present trial were broadly comparable to those reported by Moffet *et al.* in a study comparing face-to-face rehabilitation with in-home telerehabilitation after TKA, both in the two-month assessment after hospital discharge and when considering the change from baseline. Despite the broadly comparable results, the absolute score for the Sports subscale at the two-month assessment (corresponding closely to our eight-week assessment) was higher in the study by *Moffet et al.* (26.0-26.1 in that study, versus 15 points in our study), whereas the change from baseline was lower than in our trial for the Pain (23.5-26.7 points versus 33.0 in our study) and ADL subscores (26.0-27.2 versus 34.0 in our trial).[24]

In the digital PT group, the changes from baseline were significantly higher than those reported by Moffet *et al.*, with differences of over 20 points in all subscales except for the Sports subscale.[24] Plus, the absolute scores are also higher than those of that study at the two-month assessment, except for the Sports subscale.[24]

Regarding medium-term outcomes, the scores obtained in this trial for both groups surpassed those reported by Stevens-Lapsley *et al.* [86] for KOOS Symptoms, Pain and ADL, in all time points, but not for KOOS Sports. This could be explained by the fact that, in this study, baseline score in the Sports subscale were much lower. Regarding the QoL subscale, the outcomes for the conventional rehabilitation group

were slightly lower than those reported by Stevens-Lapsley *et al,* whereas the digital PT group achieved much higher scores.[86]

Overall, the results of the KOOS demonstrate, for the comparison group, clinical improvements in line with those published by other authors, with results in the digital PT group much higher than those reported by other authors.

4.22.4. Knee Range of Motion

Regarding knee range of motion, even if these measures represent poor markers of implant success and patient satisfaction[16,109,165], significant improvements were noted in both groups.

When comparing our results with other published literature, it must be noted that, similarly to what was stated regarding hip ROM, all reports use goniometry as a means to measure hip range of motion, whereas we applied a high-precision sensor-based technology to assess active hip ROM.[193]

Still, the mean change in lying knee flexion observed in the digital PT group (14.9 degrees in the ITT analysis and 17.9 in the PP analysis) during the rehabilitation program was comparable to that reported in other studies on home- versus clinic-based rehabilitation (15.0-17.0 degrees),[206] slightly lower than those reported by Russel et al, in a study on tele-rehabilitation (17.8-19.8)[23] in the ITT analysis (but higher in the PP analysis) and higher than those reported by Piqueras *et al.* for the tele-rehabilitation group (7.7).[28] The results in the conventional rehabilitation group were inferior to those reported by these authors, but still with a mean lying flexion angle above 90 degrees at the eith-week assessment. Regarding the medium-term outcomes, the results in knee flexion at six months, in both groups, are in line with previously published studies, which ranged from 97 degrees to 116 degrees.[204]

Regarding knee extension, this parameter was much worse in all assessments (including baseline) than what was reported by other studies.[23,28,204–208] The difference could be a result of a combination of the different method for measuring ROM, together with a more demanding position used to measure knee extension - sitting versus supine (less demanding) - with some authors opting for the latter[100,101,203] or simply not specifying patient position.[21,24,25,28]

4.23. Patient Acceptance and Usability

Given that this trial and the THA trial had a similar methodology, with both involving a home-based post-surgery rehabilitation program with the same medical device, a decision was made to combine the discussion of these aspects in **Chapter 6**, as this provides a much more robust and clear picture of acceptance and usability.

4.24. Safety

As shown above, the adverse event rate was higher in the conventional PT group. However, looking into the adverse event breakdown, it is apparent that this difference was largely due to the reporting of inflammatory signs over the surgical wound in the conventional PT group. We therefore believe that the difference between groups may have been due to an underreporting of adverse events in the digital group. Additionally, it is noteworthy that there have been no adverse events reported in both groups between the end of the program and the 6 month assessment, which we also attribute to underreporting. This aspect is further discussed below, in the limitations section.

4.25. Limitations

Given that this trial and the THA trial had a similar methodology and were performed in the same investigation centre, the limitations that need to be acknowledged and discussed are very similar in both trials, and therefore will be discussed jointly below, **in Chapter 6**.

CHAPTER 5 | DISCUSSION OF COMMON AND CONTRASTIC ASPECTS

5.1. Patient Acceptance and Usability

In terms of patient acceptance, the enrollment rate of both trials – especially in the TKA trial - was low (42% in the THA trial and 29% in the TKA trial), with patient refusal and consent withdrawal being the main reasons for screening failures in both trials (51% in the THA study and 56% in the TKA study).

The explanation for this high refusal rate resides in patient skepticism on the patient side, a factor that can be explained by the inclusion of older individuals (the mean age in the THA study THA was 64.0±9.4 years and in the TKA study was 68.5±7.0 years), with little technological literacy.

This same difficulty was reported by other authors in studies with similar devices[28] and is one of the challenges that these technologies need to overcome. Other patients, namely the oldest, were afraid of hidden costs, even though it was clear and thoroughly explained that participation in the study did not imply any cost. This aspect can be improved by ensuring better training and broader involvement of clinical teams (both doctors and nurses) who approach the patient upon admission.

In the THA trial, there were two dropouts in the digital PT group (6%), both of which in the first week. Likewise, in the TKA study, there were seven dropouts in the first week of the rehabilitation program (18%). Plus, from the patients who completed the program, a high percentage of patients needed assistance from a caregiver to interact with the system (37.1% in the THA trial and 58.0% in the TKA trial).

Even if the number of additional face-to-face contacts for technical assistance was low, the number of extra calls for this reason was relatively high. This likely represents the combined effect of: a) challenges felt by an older population when dealing with technology and; b) issues with user interface that need to be overcome. In particular, each physical interaction i.e., the need to calibrate sensors and the multiple touches needed to start a session, represent huge hurdles for elders. This is challenge transversal to all such new technologies and is an aspect where there is still much room for improvement.

In fact, in the TKA trial there was a trend for higher mean patient age between independent users and non-independent users, which did not, however, reach statistical significance, whereas in the THA trial patients needing assistance were older than independent users. This leads authors to speculate that age is indeed related to increased dependence when interacting with technology. Of note, the higher percentage of patients in the TKA trial who needed assistance, versus the THA trial, is accompanied by a greater percentage of patients with 65 years of age or above in the TKA study (63% vs 36%). This reinforces the idea that age is indeed a very important determinant of independent use and that the

specific needs and challenges of this population need to be taken into account when designing these systems.

In spite of the challenges mentioned above, in the patients who completed the eight-week program, user compliance with the program was very high. In fact, in both trials, only 11 patients in the digital PT group - seven in the THA study and four in the TKA trial - used the system, on average, less than five days per week, and only four patients (all in the THA trial) used the system, on average, less than five days a week. Plus, patient satisfaction score was also very high, with 88% of patients (64/73) rating the system with a 9 or 10/10. This is particularly interesting considering the high percentage of patients who needed assistance in using the system. When they were asked to elaborate on the reasons, almost all referred the possibility of performing sessions at home, at their convenience. Still, it must be considered that patients who agreed to enter the study were more prone to use new technologies, and thus more likely to give high scores.

In all, these results show that a home-based rehabilitation with this novel digital biofeedback system is feasible, but there is still a long way to go in terms of acceptance of these novel technologies – namely in overcoming skepticism in an older population. Still, when this initial resistance is overcome, it is associated with high adherence and patient satisfaction, essentially due to the advantages of performing their rehabilitation program entirely at home, when and where it is more convenient.
These trials also allowed the identification of the main issues that need to be improved in terms of usability by this population: a) facilitating sensor placement by the patient; b) reducing the number of physical interactions with the tablet. Still, it is expected that newer generations will have higher technological literacy, thereby making age a less important factor and facilitating the adoption of these digital approaches.

One other factor that is important to discuss is that the operation of the system requires local internet access on the patient home. While the percentage of patients with wireless internet access is increasing, the great majority of the elderly population still lacks any form of internet access, wired or wireless. To circumvent this, the system is provided with a 4G internet card. However, the availability of wireless internet access is still an issue in remote areas. This is a major limitation of these systems, which needs to be overcome in a near future, especially since patients in remote areas are those who present more challenges to payers and providers and that these patients are the ideal candidates for these systems.

5.2. Factors influencing outcomes in the digital vs conventional group

Available evidence on rehabilitation after THA and TKA highlights the benefits of an increased treatment intensity.[16] Therefore, it would be expected that differences in treatment intensity would translate into better clinical outcomes in the higher intensity group, at least for short-term outcomes.

In this regard, while both trials report, overall, better outcomes in the digital PT group, at least for TUG, treatment intensity was only higher in the per-protocol analysis of the TKA trial, but not in THA trial, and therefore this factor alone does not appear sufficient to explain the trial results.

Furthermore, the analysis which was performed did not factor in additional time spent in unsupervised sessions by patients in the conventional rehabilitation group. Still, even if the effect of treatment intensity on clinical outcomes is truly significant, it means that, in the TKA trial, the digital biofeedback system enabled patients to increase treatment intensity without a corresponding linear increase in therapist contact time or supervision needs, which is the exact purpose of such a system.

Besides treatment intensity, we hypothesize that following factors may have played a role in the superiority of the digital PT group: a) the positive impact of a kinematic biofeedback tool on patient performance, especially regarding error correction and stimulation of a greater range of motion; b) patient empowerment regarding their rehabilitation process; c) high patient engagement through the use of gamification strategies; c) the effect of remote monitoring on patient effort (that is, patients knew that their adherence and performance was being registered and monitored) and d) the availability of objective data for clinical review, enabling data-driven decisions on program changes. The relative importance of each of these factors, as well as how exactly they interplay with each other warrants further investigation.

One other aspect which is noteworthy is the fact that, on both trials, while there was a tendency for convergence between the digital PT group and the conventional group, the outcomes at the three- and six-month assessments were still superior in the digital PT group, at least for TUG. While there is no clear explanation for this finding, we speculate that the following aspects may have contributed to this:

a) The positive impact of a biofeedback device on normalizing motor patterns early on the rehabilitation process, thus maximizing outcomes
b) Maximizing short-term outcomes may interfere positively with the natural history of the recovery process, thus maximizing medium-term (and possibly long-term) results.

c) Performing an independent rehabilitation program at home may lead to a lasting behavioral change, with maintenance of some of the exercises even after the end of the program and/or to a more active lifestyle.

In any case, these aspects warrant further investigation.

5.3. Differential rate of recovery

One very interesting aspect that warrants further discussion is the different rate of recovery between patients submitted to THA and TKA, with an apparently slower rate in the latter.

When analyzing the results from the HOOS and KOOS scales, and although careful consideration must be made here regarding the similarities but not equivalence of the scales, one aspect that is apparent is that, from the eight-week assessment onwards, a ceiling effect is noted for the Symptoms and Pain subscales of HOOS, for both groups, and that for KOOS near-maximum levels are noted only at the six-month assessment. Also, for the QoL subscale, the results of the TKA trial at the six-month assessment are comparable to those of the three-month assessment of the THA trial. The analysis of the TUG scores does not provide such a clear picture though, despite a greater change from baseline to six months in the digital PT group on the THA trial.

This is particularly relevant when combined with the fact that, on the digital PT group, adherence was higher in the TKA trial, with only four patients in that study performing on average less than five days a week, and none below four days a week, whereas in the THA strial seven patients performed, on average, less than five days a week and four of them less than four days a week. Comparing treatment intensities in the digital PT group, we can conclude these were also higher in the TKA trial – ITT 26.1 hours (IQR 21.2; range 1.0-69.1) versus 20 hours (IQR 11; range 1.0-59.0); PP 31.5 hours (IQR 18.0; range 10.8-69.1) versus 21 hours (IQR 10.3; range 8.0-59).

All of the above, when combined, seem to indicate that the natural history of the recovery after THA is more favorable than that after TKA, and this has also been reported recently by Judd et al.[209] Furthermore, we speculate that this may be the reason behind the different behavior of the two groups of patients regarding adherence (and, hence, total treatment time).

On this same topic, it is interesting to note that, regarding rehabilitation after THA, an expert consensus on best practices for post-acute rehabilitation after THA and TKA, recommends four to eight weeks of supervised rehabilitation for THA and four to 12 weeks after TKA.[17] Plus, it is also noteworthy that the

studies comparing supervised versus unsupervised rehabilitation that are starting to appear are all related to THA.[113–115]

Overall, these two trials corroborate recent findings indicating a different rate of recovery between THA and TKA, and warrant further investigation regarding the impact this may have on patient behavior and on the total duration of rehabilitation programs after THA, which can be lower than TKA.

5.4. Limitations

The two clinical trials presented in this thesis have several limitations that need to be discussed. First, the chosen design implied that the intervention in analysis was surgery plus post-surgery rehabilitation, and not purely the post-surgical rehabilitation. This aspect needs to be reviewed in ulterior studies. Another notorious aspect is that, in both trials, patient allocation was performed using a geographical criterion, and not through randomization, with patients living outside the city´s administrative boundaries being allocated to the digital intervention. This decision was made taking into consideration the need to rationalize human resources and simplify logistics, thus maximizing both the value created and fulfilling the initial purpose of such an approach. Still, the authors are aware that this may have introduced an important source of bias in the trials. In this regard, however, it must be stated that, by and large, no difference were found in demographics, comorbidities, risk factors for adverse and clinical characteristics at baseline between groups - except for the QoL subscale of the HOOS in the digital PT group of the THA trial and for lower baseline KOOS scores in the digital PT group of the TKA trial. Irrespective of this, a number of factors (e.g. socio-economic) may have influenced the results. Nonetheless, and given the nature of the socio-economical tissue in the region, and the geographical dispersion of the patients included in the trials- with almost all the patients resided in urban areas - the authors speculate that the impact of these aspects is small, but nonetheless needs to be controlled in ensuing trials. The reasons for the differences found at baseline regarding the QoL subscale of HOOS and the KOOS subscales, respectively, are unclear. Nonetheless, authors expect that, in future trials, randomization will allow for a better control of these aspects.

Treatment intensity was also not adequately controlled in both trials. In the THA trial, total active time was similar between groups, but that was not the case in the TKA trial, where treatment intensity was higher in the digital PT group. This may have potentiated results in this group. Irrespective of treatment intensity, total treatment time was highly variable in the digital PT group in both trials. In the conventional group, time spent in unsupervised sessions was not taken into consideration. In fact, several aspects

related to these were not standardized, namely content and duration, and patient compliance to these was not formally registered. These aspects need to be homogenized and better controlled in ensuing trials, namely through a better standardization of treatment times in the digital PT group, more rigorous definition of criteria for exclusion from the study due to low compliance, and through patient logs regarding unsupervised sessions in the conventional rehabilitation group.

Apart from treatment intensity, the rehabilitation protocols allowed a certain degree of liberty regarding the choice of specific exercises, targets, sets and repetitions. Therefore, inter-therapist variation could have influenced the results. To minimize this, all patients in the digital PT group of each study were treated by the same therapist and patients in the conventional rehabilitation group were treated by two different therapists, all equally trained and with similar levels of experience.

It is also noteworthy that these were two single-center trials performed in a relatively low-volume orthopedic hospital (in comparison to larger international centers, but not to the large public hospitals in Porto), and all patients were admitted for elective surgery, which may not reflect the reality of other hospitals. Also, the average length of stay – of 6 days – is higher than in other reported studies.[210] Generalization of the results hereby reported needs, therefore, to be confirmed in multicentric trials including larger hospitals.

In terms of safety and adverse events, the fact that participant allocation was performed upon discharge, and that patients with major adverse events after surgery not allowing discharge home within 10 days were excluded from the trials (prior to allocation), resulted in the absence of proper recording and reporting of these adverse events. Only minor adverse events during hospitalization were recorded. This is a clear limitation that needs to be solved in future trials. Also, when analysing the adverse events reported in both groups, there appears to have been an underreporting of adverse events in the digital group, namely in regards to inflammatory signs over the surgical wound. We believe this may explain the difference found in the adverse event rate between the two groups in the TKA trial. Additionally, even though no serious adverse events were reported until the six-months assessment, the absence of minor adverse events, in particular after the eight-week period, is more difficult to explain, and was most likely due to an underreporting of these events. In future trials, besides direct telephone contacts and specific questioning of adverse events in assessment appointments, event logs should be delivered to the patients to avoid underreporting.

Additionally, and still within the safety aspects, one important topic that was not approached in these trials was that of patient safety after discharge and in the home environment. The delivery of leaflets and/or, in the case of the digital group, digital educational materials addressing safety aspects (for example,use of appropriate shoes, removing rugs, how to safely lift weights) should have been contemplated.

In terms of acceptance and usability, the low inclusion rate may have represented a selection bias towards more technology-prone patients/caregivers, something that needs to be properly addressed in future trials. To overcome this, a greater involvement of the clinical teams (physicians and nursing staff) in the wards is required, to overcome natural patient skepticism. Additionally, usability was not systematically assessed. Even though parameters were collected that allowed us to assess usability, and that additional data was assessed in the digital group by the assigned physical therapist in person, this aspect should have been addressed both through structured surveys - to ensure standardization of information collection and formal analysis- as well as through the use of a specific software usability scale, like the System Usability Scale.[211] Therefore, while the authors believe that all relevant information was captured, it was not done in such a way as to allow it to be presented clear and elegantly.

CHAPTER 6 | COST COMPARISON ANALYSIS

COST COMPARISON ANALYSIS

Cost-comparison analysis was performed combining both clinical trials, using a per-protocol approach (i.e. only patients who completed the eight-week program were included).

The business model of the company who produces the system is not that of a rental fee or direct sale of the device, and therefore this precludes inclusion of system costs in this analysis. Instead, the company provides an integrated service, employing physical therapists who deploy the system and remotely supervise patients. This analysis, therefore, focused on comparing the cost of delivering rehabilitation services in both contexts, conventional and digital PT, to ascertain the magnitude of the potential cost reduction of this new type of intervention.

6.1 Hypothesis

For this analysis, the hypothesis was that the cost of providing rehabilitation, factoring in both direct and indirect costs, would be lower in the digital intervention group.

6.2 Methods

Costs were measured during the intervention period for both groups only for the patients who completed the trial (per-protocol analysis). Data was collected by the therapists after each session or interaction with the patient (face-to-face visit or telephone call), through the use of dedicated spreadsheets. Both direct and indirect costs were considered. These are explained below and summarized in **Table 25**. Only costs relevant to the healthcare provider (not for the patient) were considered.

For the conventional rehabilitation groups, the cost calculations included the cost of each face-to-face session (cost of therapist time plus travel costs) for a total of 24 sessions, plus the costs associated with telecommunications.

For the digital PT group, in addition to the cost of the visits (cost of therapist time plus travel costs)- scheduled and unscheduled- and the costs associated with telecommunications (for both scheduled and unscheduled calls), the cost associated with the time spent by the therapist on the web-based Portal was also considered, as were the cost of the computer equipment (laptop), amortized over three years and the cost related to Internet service for the period of the rehabilitation program. For the latter, we

calculated the cost per hour, assuming the cheapest market price of a basic large bandwidth program (20Mbps download/2 Mbps upload) as of 5/03/2019 – 21,99€/month[1] - and a total of 176 working hours per month.

The cost of therapist time for all purposes (travel, telecommunications and web-based portal) was calculated multiplying the estimated time (in hours) by the standard hourly salary in effect in the Public Health Sector for physical therapists at the time of the trial (i.e. considering the year of 2017) – 1049,14€ per month.[212] To find the hourly rate, the following formula was used: hourly rate= (monthly salary*14/12)/176 working hours= 6,95€/hour.

Travel costs included both travel-related expenses and the cost of therapist time. Travel-related expenses were calculated as the roundtrip distance to the investigation center in Km multiplied by 0,36€, which was the reference amount for the public sector in the Portuguese law at the time of the study.[213] For each patient, the mean travel time (roundtrip) was considered.

Cost of telecommunications was calculated taking into consideration the cost of the time spent by the therapists in telephone calls as well as the cost of the telecommunications plan. To determine the latter, we calculated the hourly price of the pre-paid plan (which included 2000 minutes of telephone calls), dividing the monthly price for the total number of working hours in a month (176 hours).

Time spent in the web Portal was calculated automatically for each therapist by the system. Given that a precise calculation of the time spent with each patient was impossible to obtain, the mean time spent by patient throughout the intervention was considered.

The breakdown of cost calculations for each group is presented in **Table 23**.

[1] www.vodafone.pt/

Table 25. Breakdown of cost calculations for each group

Cost category	Digital PT Group	Conventional rehabilitation
Direct costs		
Direct clinical contact	Deployment Visit	Face-to-face sessions
	Re-evaluation Visit	
	Termination Visit	
	Unscheduled visits	
Indirect clinical contact	Cost of therapist time using the Web Portal	
Indirect costs		
Travel-related costs	Travel distance	
	Travel time	
Telecomunications	Cost of therapist time	
	Cost of therapist time: Scheduled calls Unscheduled calls	Cost of therapist time: Initial Call Rescheduling calls
	Cost of service	
Other costs	Cost of computer equipment	-
	Cost of internet plan	-

6.3 Statistical analysis

Differences between the two groups were evaluated using the Mann-Whitney U test and the magnitude of the median difference was assessed using Hodges-Lehman estimator.

6.4 Results

A breakdown of the cost estimation analysis for each group is presented in **Table 26**.

Table 26.Cost analysis for each group

		Conventional rehabilitation (n=60)	Digital PT (n=58)	P value#
Direct Costs				
Direct clinical contact median (IQR)				
Sessions/visits duration	Face-to-face session	1	-	-
	Deployment visit	-	1.75 (0.25)	-
	Re-evaluation visit	-	0.50 (0.16)	-
	Termination visit	-	0.50 (0.08)	-
	Unscheduled visits	-	0.25 (0.16)	-
Total visit time		24	2.71 (0.48)	<0.001
Cost per patient		**166.80**	**18.82 (3.33)**	**<0.001**
Rehabilitation system				
Cost of Portal usage time	Usage time per patient	-	1.2	-
	Cost per patient	-	8.34	-
Direct costs per patient		**166.80**	**27.16 (3.33)**	**<0.001**
Indirect costs				
Travel related expenses median (IQR)				
Travel distance	Distance per travel	11.50 (14.30)	25.30 (16.50)	<0.001
	Distance per patient	276.00 (343.20)	89.00 (60.10)	<0.001
	Cost per patient	99.36(123.55)	32.04 (21.63)	<0.001
Travel time	Time per travel	0.30 (0.24)	0.50 (0.20)	<0.001
	Time per patient	7.20 (5.80)	1.70 (1.07)	<0.001
	Cost per patient	50.04 (40.31)	11.82 (7.41)	<0.001
Cost of travels		**154.96 (168.86)**	**43.86 (30.35)**	<0.001
Telecommunications related expenses median (IQR)				
Call duration	Initial call	0.07 (0.01)	-	-
	Re-scheduling calls	0.05 (0.04)	-	-
	Scheduled calls	-	0.08 (0.01)	-
	Unscheduled calls	-	0.11(0.01)	-
Total call time		0.08 (0.04)	0.55 (0.40)	<0.001
Cost of time spent in calls		0.56 (0.30)	3.84 (2.76)	<0.001
Cost of service		0.02 (0.01)	0.10 (0.08)	<0.001
Cost per patient		**0.58 (0.32)**	**3.95 (2.83)**	<0.001
Other costs				
Internet service costs	Monthly fee	-	22.99	-
	Mean time per patient	-	1.2	-
	Cost per patient	-	0.16	-
Computer equipment costs	Laptop price	-	594.99	-
	Cost for the study	-	264.40	-
	Cost per patient	-	4.41	-
Other costs per patient		-	**4.57**	-
Indirect costs per patient median (IQR)		**155.86 (168.94)**	**52.79 (31.70)**	**<0.001**
Total cost per patient median (IQR)		**322.66(168.94)**	**80.48(33.35)**	**<0.001**

Legend: #Mann-Whitney U

Notes: The time unit used is hours; travel distance and travel time were calculated considering roundtrip travels to and from the patient home; all costs are in euros.

a) Direct costs

In the conventional rehabilitation group, each patient had 24 face-to-face sessions, with a total of 24 hours of direct clinical contact. In the digital PT group, the median direct clinical contact was of 2.75 hours (range 2.17 to 4.25). As a result, the total cost per patient regarding visit time was much lower in the digital PT group ($p<0.001$) (see **Table 21**).

b) Indirect costs

Distance per travel and time per travel were higher in digital PT group, resulting from the fact that patient allocation to the two groups was performed based on patient address, with patients living outside the city administrative limits being allocated to the digital PT group.

However, total distance per patient and total time per patient were higher in the conventional rehabilitation group, given the much higher number of travels in this group (24 roundtrip travels) versus the digital PT group. As such, the cost of travels in the conventional rehabilitation group was higher ($p<0.001$) (see **Table 21**).

Telecommunications related expenses were higher in the digital PT group ($p<0.001$), where in addition to the three scheduled calls, patients had, on average, 3.8 extra calls (range 0-12), for technical assistance/difficulties interacting with the system. In the conventional group, the costs associated with these expenses are negligible (see **Table 21**).

As a result of the much higher number of travels, indirect costs were higher in the conventional rehabilitation group ($p<0.001$) (see **Table 21**).

c) Total costs

Total costs per patient were much lower in the digital PT group ($p<0.001$) (**Table 21**). In the conventional rehabilitation group, the median percental weight of the direct costs was 51.7% (range 28.4-85.4%); the median weight of the cost of therapist time (direct clinical contact plus time spent in travels plus time spent in calls) was 69.1% (range 46.5-91.5%) and the median weight of the cost of travels was 30.89% (range 6.2-53.5%). In the digital PT group, the median weight of the cost of therapist time was 54.3%(range 29.4-79.5%), and the median weight of the cost of travels was 55.2% (range 20.9-86.9%).

c) Ratio between total treatment time and therapist time

The total clinical time spent per patient was lower in the digital PT roup (p=<0.001), with a median of 6.29 hours (range 4.42-12.47) versus 31.34 (range 25.69-39.34) in the conventional rehabilitation group.

Regarding treatment intensity, patients in the conventional rehabilitation group had a total of 24 hours of treatment (excluding unsupervised sessions), whereas patients in the digital PT group had as median of 25.63 hours of treatment (range 8.10-69.10 hours). The difference is not clinically significant (p=0.18).

This translates into a median ratio between treatment intensity and time spent by the therapist of 1.31 hours (IQR 0.24) for the conventional group and of 0.26 (IQR 0.17) for the digital PT group (p<0.001). This means that, for every therapy hour provided to the patient, therapists in the conventional group needed to spend five times more time.

6.5 Discussion

Analyzing the weight of the different items related to the cost of providing treatment, it is clear that the main factors driving the costs are: a) the cost of therapist time and b) the cost of travel distance. The other costs are largely negligible. The results of this analysis largely favor the digital PT group, resulting from the added weight of indirect costs in the conventional group, due to the higher number of travels and consequently, higher travel costs (cost of distance plus cost of time) in this group, particularly for patients living further away from the investigation center.

To our knowledge, this the first cost analysis of a rehabilitation solution based on inertial motion trackers, in comparison with conventional rehabilitation. Thus, direct comparison with published literature is not possible. Still, even if the digital rehabilitation program featured in these trials cannot be strictly classified as telerehabilitation, some parallel can be found between the two interventions, in the sense that they both seek to deliver home-based care while reducing the need for travels and saving costs. In regards to telerehabilitation, a systematic review performed by Torre-Diez *et al.* [162] found evidence demonstrating that telemedicine can reduce costs [162] and a study by Tousignant et al[163] reported that the cost for a single session of in-home telerehabilitation was lower or about the same as conventional rehabilitation, depending on the distance between the patient's home and health care center, with a favorable cost differential when the patient was more than 30km from the provider.[163]

As such, the results of this analysis corroborate these findings, given the unfavorable ratio between

treatment intensity and therapist time in the conventional rehabilitation group, due to the time spent in travels. Still, the efficiency of tele-rehabilitation is hindered by the fact that there is still need for real-time clinical contact between the patient and the therapist. Thus, the theoretical limit of the ratio between treatment intensity and therapist time is 1 (unless we also consider unsupervised sessions). The system presented here allows further reduction of this ratio, to a median of 0.26 (IQR 0.17), which is five times less than conventional rehabilitation, where the ratio was of 1.31 (IQR 0.24), by enabling independent sessions to be performed by the patient, under the guidance of the biofeedback system, while ensuring remote asynchronous monitoring of patient performance by the therapist.

Of course that, in respect to the digital PT group, we need to add the cost of the system per patient. Given that the business model of the company marketing the device is not that of a buying or rental fee per system, the market price is not available and therefore was not included in the analysis. However, regarding this topic, IMUs are inexpensive, making the tablet computer the most expensive component of the system. Plus, these values will undoubtedly reduce with time, as technological components become cheaper and with volume, bringing the system cost to below 200 euros. This, coupled with the possibility of re-using each system multiple times over a projected lifetime of three years, means that a solution with very low cost per patient will be widely available at scale, reinforcing the financial sustainability of this novel PT delivery model.

Apart from this, one other factor to consider is that, in the context of these clinical trials, the protocol in the digital PT group included three visits from the physical therapist. However, in a clinical context, the last visit would not be necessary, as this visit was only for evaluation purposes and to retrieve the system. Furthermore, improvements on the usability of the system, with the intent of reducing the need for unscheduled visits, would likewise help drive down the costs of the digital PT group. In this context, this system could potentially be used to further increase treatment intensity without requiring significant added therapist time, thus potentially improving the outcomes even further without increasing costs.

6.6 Limitations

This post-hoc analysis has several limitations that need to be discussed. The first is that, due to the geographical criterion used for patient allocation in regards to the post-surgery rehabilitation program, balancing of the two groups regarding travel distance was not achieved. The net effect of this imbalance, however, benefitted the conventional group and not the digital PT and, as such, did not influence results towards this group.

Second, in this analysis, the distances were calculated centered on the clinical facility where the trials took place, which is an artificial scenario that does not take into account route optimization. This represents an important confounding factor that needs to be considered when interpreting the results and that needs to be better controlled in future trials.

Third, as discussed above, it does not consider the cost of the system per patient, for reasons related to the business model of the company marketing the device. Even if, given what was discussed above, the system can be re-used multiple times over a lifetime of three years, massively diluting the cost of the hardware, this is an aspect that needs to be reviewed, namely also considering refurbishment costs.

CHAPTER 7 | CONCLUSIONS AND FUTURE DIRECTIONS

7.1 Conclusions

As stated in **Chapter 1**, the goal of the work presented herein was to validate this novel system for home-based rehabilitation after THA/TKA, by answering three different research questions. In the previous chapters (**Chapters 3-6**), we presented and discussed the two clinical trials which were undertaken, as well as the post-hoc cost analysis, having addressed all three questions. The main conclusions will be summarized below:

Question 1: Is there any difference between the clinical outcomes of THA/TKA plus digital rehabilitation versus surgery plus conventional rehabilitation?

Before providing a concluding answer to this question, it is important to mention several aspects that arise from these two clinical trials. The first, and perhaps more immediate, is that, given the paucity of research on wearable motion tracking systems for rehabilitation after THA and TKA,[158] the work presented herein contributes substantially to increase the body of knowledge in this area.

In this regard, both trials demonstrate the positive impact of THA/TKA surgery plus a digital program involving a biofeedback device, adding new information to that presented by Pfeufer *et al.* on their systematic review on the use of biofeedback devices in comparison to usual care after TKA,[121] where the authors conclude that training with biofeedback after TKA is a viable way to improve gait symmetry, reduce pain and increase activity level – to this we can now add that they can be used to improve range of motion, reduce pain, symptoms, increase QoL and improve function. Furthermore, these two trials confirm that IMU-based solutions do hold great promise in this realm, as indicated by the results of studies reported by other authors, namely on knee OA.[29,30] Of note, as far as we know, the THA trial was the first on the subject involving an IMU-based device. As to TKA, the only study published so far with a similar solution, by Piqueras et al,[28] randomized patients to receive a two-week after surgery with the system versus conventional rehabilitation. As such, given the short intervention period, this study does not allow drawing definitive conclusions regarding clinical outcomes, but only feasibility. Therefore, the TKA trial presented herein is effectively the first trial that can allow meaningful comparison of THA/TKA surgery plus digital rehabilitation versus conventional rehabilitation.

Another important aspect is that, as discussed in **Chapter 1**, there is no clear consensus on timings, dosage and composition of rehabilitation programs after THA or TKA, and that the evidence regarding this is limited, with variable quality and sometimes inconsistent.[11,15–18] Furthermore, the need for

supervised rehabilitation has been recently challenged, especially after THA.[114,115,187] In this regard, what these two trials show is that, at least in the short and medium-term, different programs (or different forms of delivery of a given program) can indeed lead to different outcomes, even if both are supervised. One corollary is that the wide variation in rehabilitation programs between studies significantly hampers not only the comparison of results with other published papers, but also the validity of the conclusions of a given study (ie, the superiority – or not – of a given intervention of interest may be largely influenced by the treatment provided to the control group). Another corollary of this is that further research is mandatory to ascertain what the most crucial components of the rehabilitation program are, in terms of timings, dosage, progression and mode of delivery (including digital versus conventional), so that it is possible to provide more detailed guidelines on the composition of these programs. In this regard, these two trials, namely the level of detail in which the intervention protocols were described, add significant value to the body of evidence currently available, and may be used to advance towards such guidelines.

Regarding the research question, to our knowledge, the two clinical trials presented herein are the first to demonstrate that THA/TKA surgery plus digital rehabilitation solution can potentially achieve not only similar but better clinical outcomes than surgery plus conventional rehabilitation, both in the short and in the medium-term. Of note, the results obtained in the control group are broadly comparable to those previously published by other researchers, thus confirming that the intervention performed in the control group was comparable to that of the best available data.

The promising results obtained in these two trials justify further investigation, namely through larger, randomized controlled trials, that address the limitations of these trials - mainly regarding randomization, control of treatment intensity between groups, systematic collection of adverse events, structured assessments of the usability of the technology, and activity levels/exercise continuation after the end of the program – to confirm these findings.

Question 2: Is the digital intervention well accepted, easily usable and engaging for patients undergoing rehabilitation after THA/TKA independently at home?

In terms of patient acceptance, the low enrolment rate demonstrates that these novel interventions still face significant skepticism, especially from older patients, as noted also by other authors in studies with similar devices.[28] This indicates that, in programs involving novel technologies, significant attention has to be given to the aspects that entice this skepticism, namely hidden costs.

Regarding usability, the percentage of dropouts occurring in the first week (6% in the THA trial and 18% in the TKA trial), together with the high percentage of patients requiring the help of a caregiver (37.1% in the THA trial and 58.0% in the TKA trial) – with data pointing to a correlation with older age - show that usability must still be improved, especially in the older population. The improvements here are mainly related to: a) facilitating sensor placement by the patient; b) reducing the number of physical interactions with the tablet. Despite the opportunities for improvement, in the patients who completed the eight-week program, both compliance to the program and satisfaction were very high.

In all, these results show that a home-based rehabilitation with this novel digital biofeedback system is feasible, but there is still a long way to go in terms of acceptance of these novel technologies – namely in overcoming skepticism in an older population. Still, when this initial resistance is overcome, it is associated with high adherence and patient satisfaction, albeit with room for improvement in terms of usability by elderly patients.

Question 3: Is the digital intervention associated with potential cost savings versus conventional rehabilititation?

To our knowledge, the work presented herein represents the first cost analysis estimation of a rehabilitation solution based on inertial motion trackers, in comparison with conventional rehabilitation. The results show that this intervention was able to markedly reduce not only the time spent by each physical therapist to provide one hour of treatment, but the total cost per patient of providing the rehabilitation program. This, coupled with the fact that such a system can, at scale, be produced at very low cost (less than 200 euros), and that the hardware components be re-used in multiple patients over the course of two years, open the door to potentially large cost savings. The potential impact of this intervention is particularly relevant to patients living in remote areas, which are traditionally underserved (thus, often times, without any possibility of performing a rehabilitation program in an inpatient or outpatient setting) and where a face-to-face intervention delivered at home is not possible due to obvious logistics and financial reasons on the provider side.

Moreover, by reducing the dependence from human resources, this intervention can allow a more rational distribution of human resources, which can be directed to more complex cases, which may require rehabilitation in an inpatient or outpatient setting, thus increasing both directly and indirectly the efficiency of the service delivery.

Overall conclusion

In conclusion, the work herein presented demonstrates that THA/TKA plus digital rehabilitation is feasible, safe and capable of maximizing clinical outcomes in comparison to surgery plus conventional rehabilitation, both in the short and medium term, while being far less demanding in terms of human resources. This approach appears to hold great promise in the treatment of hip/knee OA, by offering a scalable and effective solution for post-surgery rehabilitation, and provides a potential way forward in terms of rehabilitation of MSK conditions.

7.2 Improvements to SWORD Phoenix® arising from these trials

As stated above, both in the discussion and in the conclusion, two main issues were identified in the work herein presented that needed to be improved in terms of usability by this population: a) facilitating sensor placement by the patient; b) reducing the number of physical interactions with the tablet.
The results of these trials have led to changes in both hardware and software of the medical device to address these two aspects, which are currently already implemented and an integral part of the medical device. We decided, therefore, to present these improvements separately from the future directions.

Regarding sensor placement and calibration, the following changes were made:

a) The mechanism for securing straps was changed from Velcro to a hook mechanism, to facilitate strap placement;
b) The shin strap was made more round to fit the tibial anatomy, thus securing the strap more firmly in its place and minimizing soft tissue displacement;
c) A new algorithm was developed to allow calibration by movement. This, in turn, enables the patient to place the motion trackers in any given strap, and eliminates the need to match a specific tracker to a specific strap

The above measures, combined, led to a marked improvement in the ability of even elderly people understanding the setup process and placing the straps and trackers correctly.

Regarding the increase in ease of use by reducing the number of physical interactions with the tablet, the version used in the trials required a total of six physical interactions (touches) with the tablet until the initiation of each session. The flow was since completely reviewed, such that currently, under normal conditions, only one physical interaction is required. This, coupled with the changes above, has markedly reduced the need for assistance in operating the device.

One other aspect that was improved was related to the exercise interface and gamification strategy used. In the version used in the trials, the patient was presented with a video and audio description of the exercise before he was asked to perform the actual exercise, but there was no guidance during the execution screen (see **Figure 1**). The current version displays the desired movement during the execution, facilitating a correct execution especially in patients who have more difficulty in understanding what is

required (see **Figure 8**). Also, the gamification strategy was improved – instead of getting the patient to focus on a specified goal in terms of range of motion, while allowing him to surpass that goal, a bar is now presented with the normal range of motion of each exercise, and the patient is asked to go as far as he can, earning more stars if they reach further (see **Figure 8**).

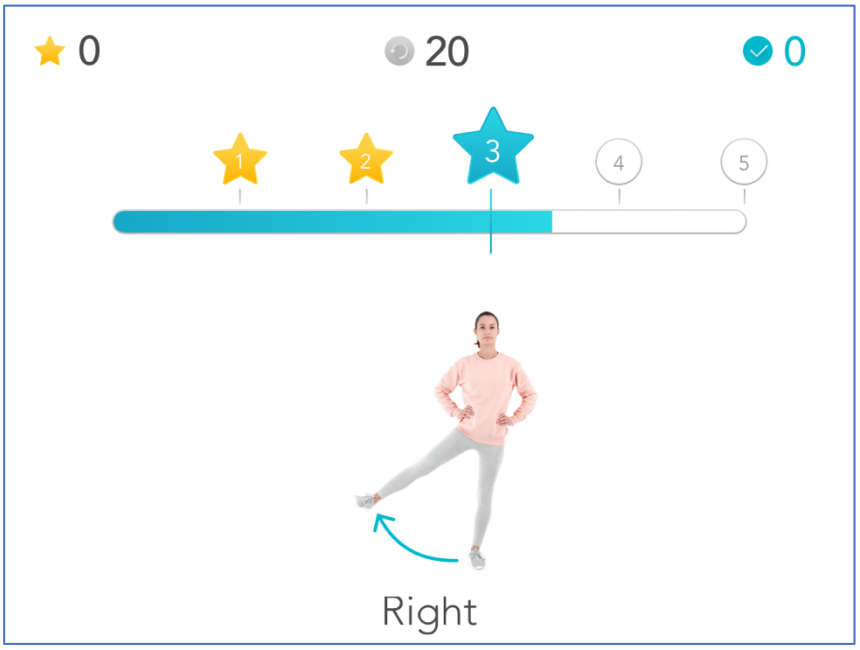


Figure 9. New exercise execution interface

7.3 Future directions

As with all scientific work, each question leads to answers which inspire action, as well as other questions. In this section, we will explore these in more detail.

7.3.1 Usability and engagement

As stated above, significant changes were already introduced to simplify usability, as a direct result of the findings of the two trials. However, there are many other aspects that can be improved, which will be briefly discussed here.

As far as usability is concerned, the logical step further is to simplify usage to the point that the learning curve is practically non-existent (ie, the usage of the system is almost self-explanatory) even for older individuals. In this regard, further improvements on several aspects related mainly to the hardware are required, namely those related to the charging of the tablet and trackers, for example, by developing a charging station instead of requiring patients to connect cables to the tablet/trackers and to chargers.

Also, the development of a tutorial mode where the patient is guided by the system in the first session could, in addition to the improvements mentioned above, eliminate the need for the initial visit by the physical therapist, thereby further reducing the need for therapist time. This, coupled with an increase in the efficiency of off-boarding processes, might eventually lead to a completely remote program for rehabilitation after THA/TKA. The potential scalability and the huge savings associated with such a program are definitely worth exploring.

One important note about these developments is that, while promoting patient autonomy, must be achieved in a way that preserves the healthcare professional-patient interaction or, by other words, human touch, as this is a crucial component of any healthcare intervention that needs to be cherished.[214]

In the specific case of this approach, there are three main avenues for preserving the human touch.

The first, and more analogue one, is to recognize that the time gained by the reduced need for therapist (and clinician) time may be funneled not to an increase in productivity measured by numbers, but to an increase in the attention given to each patient, even if this interaction is made through messaging apps or telephone calls. This is one of the challenges faced by the new era in medicine, and a concern which has been voiced by prominent researchers in the field.[215]

The second is the possibility of transforming each interaction between the therapist or clinician and the web-based Portal into a healthcare professional – patient interaction, by way of automatic messages

every time the exercise session is changed, therefore conveying to the patient that the clinical team is indeed monitoring his progress and making the necessary adjustments. In fact, this feature is already being developed and tested.

The third, and most challenging from a technological standpoint, is to humanize the patient app, by embedding natural language processing. This would have the added advantage of reducing the need for physical interactions with the tablet even further, thus increasing usability. This novel avenue of technological investigation is currently in planning for 2021.

In regards to patient safety, as noted above, in the limitations section, the inclusion of educational materials within the program, providing information to participants on "best practices" and "safety procedures", can add tremendous value from a safety point of view. In fact, such recommendations were since developed and included in the app – they are now presented to the patient before and after each session. One other potential avenue worth exploring is the inclusion of a "call me" or "alarm" button to connect the member to the PT/healthcare professional. Finally, the addition of a heart rate monitor, coupled with automated warnings, could be used to detect both bradycardia or tachycardia which could signal risk and either trigger an alarm to the healthcare professional and/or stop the exercise program. Such sensor would also allow more refined analysis of effort and fatigue.

7.3.1. Directions for future research on rehabilitation after THA/TKA

As stated above, the work hereing presented opens the door to further investigation, namely through trials that address the limitations of the two herein presented.

in particular, the following aspects need to be reviewed/modified:

a) Randomisation of participants (ie RCT vs non-randomized)
b) Revision of endpoints and assessment timelines compatible with trials looking at post-surgery rehabilitation alone (vs surgery plus rehabilitation). One immediate consideration would be to do a baseline assessment post-surgery (instead of pre-surgery).
c) Clearer definition of short and mid-term endpoints
d) Given the tendency for convergence between after the eight-week assessment, consider increasing the follow-up from 6 months to 12 months after surgery.
e) Balancing treatment intensity between groups (as discussed in the limitation section)

f) Systematic collection of adverse events, as there seems to have been underreporting of adverse events in the digital group
g) Systematic assessment of usability, namely through the Inclusion of a technology usability assessment scale (such as the System Usability Scale) and more granular assessment of satisfaction through structured interviews/surveys in both groups

Other aspects also merit further consideration and potential exploration in additional studies. Firstly, if the promising results obtained in the digital group are confirmed in larger trials, it is necessary to clarify which specific components of the digital intervention are the main drivers of success – namely whether it is the effect of the biofeedback, the gamification strategies used, patient empowerment, or the ability to make clinical decisions based on objective data. An initial approach to gaining more insight on this could be through the form of a patient and PT questionnaire.

Equally important is to ascertain the impact of exercise levels on clinical outcomes. To this effect, measuring participant activity levels through a dedicated questionnaire (for example, the International Physical Activity Questionnaire) would be important. It would also be important to measure whether patients in both groups (and to which extent) continued to perform some sort of structured exercise after the end of the program.

It would also be interesting to consider additional parameters that can be derived from the motion trackers, namely velocity, acceleration and movement patterns. These parameters could be used to compare groups at specific timelines and, through that, gain insights into the specific influence of the biofeedback component in the rehabilitation process. In this regard, the inclusion of a comparison group composed of healthy, age-matched individuals would provide important insights and allow the comparison of movement parameters against this group. Additionally, the inclusion of such a group would also allow the comparison of clinical outcomes (PROMs and functional outcomes). These aspects would provide deeper insights into the magnitude of the deficits in individuals undergoing THA/TKA in comparison to healthy individuals, and their evolution over time, enabling a clearer assessment of gaps in care that need to be addressed to address existing gaps and strive to minimize them.

One other aspect, which was also mentioned in the discussion, is the different rate of recovery after THA and TKA, and the impact this can have on the duration of the rehabilitation programs. In the studies

herein presented, program duration was the same (eight weeks), with the patients in the THA trial having higher HOOS scores which, for the Symptoms and Pain subscales, were at near-maximum levels since the eighth week. Therefore, two aspects that would be interesting to explore would be the possibility of: a) shortening total program duration in THA; b) increasing the total program duration for TKA. On a similar line of thought, the need for structured rehabilitation after THA has been recently challenged. One possibility would be, therefore, to design a clinical trial with three groups: digital rehabilitation; conventional rehabilitation and no structured intervention.

A final aspect that also merits further discussion is that in the trials herein presented, the rehabilitation program, especially in the digital PT group, targeted mostly the affected limb. However, from a biomechanical point of view, the lower limbs function in tandem and are part of the same kinetic chain. Therefore, and before considering additional trials, a decision was made to increase the number of motion trackers in the setup to five – which required several technological developments that fall outside the scope of the present work – to enable simultaneous bilateral lower limb training. This setup was tested in a single-arm prospective trial (clinicaltrials.gov registry number NCT03648060) in patients submitted to THA or TKA, also in partnership with Hospital da Prelada. Unfortunately, due to the COVID-19 pandemic, patient enrollment was interrupted at a point where 82 patients had been enrolled (52 TKA and 30 THA), and it was not possible to resume enrollment for the following year. Still, preliminary results were very promising, and a decision was made to keep the new bilateral setup and discontinue the previous one.

7.3.2 Health economics analysis

In this thesis, we have performed an ad-hoc analysis of the cost of providing the two interventions (digital versus conventional), and in previous sections, we have discussed how several improvements can be made, which will result in an increase in the efficiency of the digital program, potentiating it's scalability and enabling further reduction in costs. However, no formal health economic analysis was performed. Within the several approaches used for health economics analysis, cost-effectiveness and cost-utility analysis are the most relevant for physical therapy.[216] The difference between these two analysis lies in the fact that cost-effectiveness relies on a measure of the change in health status whereas a cost-utility analysis uses the notion of Quality Adjusted Life Year (QALY), an economic indicator.[216]

In the present case, we believe that a cost-effectiveness analysis would be most appropriate, with a follow up of at least 1 year after surgery, using the HOOS/KOOS scales as the measure of change in healthcare

status, and calculating not only the costs associated with providing the service but also direct medical expenditure (outpatient visits, readmissions, costs with medication) as well as indirect costs, namely those related with absence leave and temporary or permanent disability.

7.3.4 Artificial intelligence

It would not be possible to conclude this thesis, on the validation of a novel (digital) technological approach to rehabilitation without addressing Artificial Intelligence (AI) regarding its potential application in this particular context and its impact.

As stated quite accurately by Eric Topol, in a recent paper published in Nature Medicine, "Medicine is at the crossroad of two major trends. The first is a failed business model, with increasing expenditures and jobs allocated to healthcare (...) with worse human health outcomes. The second is the generation of data in massive quantities (...). The limits on analysis of such data by humans alone have clearly been exceeded".[215] Once thought a thing of the future, the reality is that AI is already here and is already starting to exert its impact in medicine – as clearly stated in this paper, and others.[215,217]

The excerpt reproduced above is particularly relevant to the work presented in this thesis, which essentially represents the validation of a scalable technological solution to reduce the need for human contact in real time, thus seeking to restore the balance between supply and demand, on the one side, and on the other, between cost and effectiveness. In fact, the improvements on the usability aspects discussed above, either already developed or in the pipeline, are precisely aligned with this view.

However, even with such a technological system, which includes a web-based Portal that allows the clinical teams to monitor all data that is captured during each session, the analysis of the enormous amounts of data generated still requires significant effort from the clinical teams, and has the potential to become the rate-limiting step in the scalability of care. In fact, if there is to be a serious effort in preserving the human touch, such a system cannot evolve to transform healthcare professionals into data clerks, looking into charts in a monitor.

This is exactly where AI comes into play. To provide a better notion of the amount of data generated by this system, each motion tracker produces data on special orientation of the body segment in question at a frequency between 40-50 Hz, which is then combined with the data provide by the other trackers – altogether, this enables highly precise motion tracking both spatially and temporally. With this, an incredible amount of information is registered and stored for each movement performed by the patient, a database of human motion which keeps increasing exponentially with each session and each new patient.

The possibilities that AI can open in this realm are almost unfathomable, but can be distilled down into one main goal: providing the best rehabilitation program to each individual patient. Achieving this would require combining the data on the recovery process of thousands of patients with unique data from the

patient record, as well as continuously updating the program (on a session by session basis, or even within the same session) according to the movement patterns in each repetition or set.

While in reality this goal remains elusive, initial steps in this direction have already been taken. The first goal is to develop an AI engine that is able to process the information gathered by the system automatically and provide suggestions to the clinical team regarding potential changes to the rehabilitation program – akin to having a digital assistant. While this may appear a simplistic goal, it is a daunting task, but one which, if successful, can have a huge impact in the workload of the clinical team, freeing time to focus more on caring for the patient as a person. Even if an in-depth analysis of this subject is out of the scope of the present work, it is interesting to note that, as an anecdotal example (based on internal data) a prototype version of the AI engine, by resorting to 69 different variables and to logistic regression models, was already able to predict with an overall accuracy of 70% when a given exercise should be removed (totally or partially, ie, reducing the number of repetitions). Still, given the amount of data and the way it is structured, the tool that will most likely be used in a near future will be some variation of Deep Neural Networks (DNN)- these are networks built to simulate the activity of the human brain, specifically pattern recognition and the passage of inputs through various layers of processing, where each layer performs specific types of sorting and ordering. These DNN are a subset of machine learning techniques which have been demonstrating groundbreaking results in several areas of medicine – radiology, dermatology, pathology, ophthalmology, cardiology and even gastroenterology- as elegantly reviewed Eric Topol in the above mentioned Nature Medicine Paper.[215] One aspect which is very interesting to note is that these areas rely heavily on imaging but also, and more importantly, on pattern recognition. It can therefore be argued that they can and will achieve similar results when applied to the recognition of normal or abnormal movement patterns, especially if we factor in the advances in signal-processing algorithms developed for automated interpretation of the electrocardiogram.

7.3.5 Application to other clinical conditions

According to the 2017 Global Burden of Disease study,[218] musculoskeletal conditions are the second highest contributor to global disability, accounting for 16% of all years lived with disability), and lower back pain remained the single leading cause of disability since it was first measured in 1990.[218] Also, it is estimated that between 20%–33% of people across the globe live with a painful musculoskeletal condition.[45]

As such, given the promising results of the trials herein presented, the potential application of this digital approach across the spectrum of musculoskeletal disorders is a possibility worth exploring, as it can represent a paradigm shift in musculoskeletal care.

In this regard, there are two contexts where this approach can be used: a) in the recovery process after surgical interventions for musculoskeletal disorders, in line with the work presented in this thesis; b) in the management of chronic musculoskeletal conditions, with the intent of reducing pain and disability;

Rehabilitation after surgical interventions for musculoskeletal conditions

When discussing the application of this approach in the recovery after surgery for musculoskeletal conditions, it is important to mention the opportunities that arise in the rehabilitation after shoulder surgery, namely after rotator cuff repair. Since conservative treatment is not always effective, rotator cuff repairs are commonly used surgical procedures,[219,220] and rehabilitation plays an essential role in the recovery process.[221,222] As a result of this, we have adapted the medical device for upper limb rehabilitation and designed an RCT to compare the clinical outcomes of this digital approach after shoulder rotator cuff repair, against those of conventional rehabilitation. Here, the proposed approach was to use the digital approach reduce the need for face-to-face sessions by two thirds. This trial (clinicaltrials.gov registry number NCT03648047), performed in partnership with Hospital da Prelada, had a target sample of 68 patients, but had to be interrupted due to the COVID-19 pandemic, at 60% inclusion. The results, which have been recently published, showed no differences between groups regarding pirmary or secondary endpoints at the end of the 12-week program. However, follow-up results (at 12 months post-surgery) revealed the superiority of the digital group for QuickDASH, as well as an interaction between time and group in the CM score in favor of the digital group. Again, these results are very promising regarding the potential of this novel approach.

In regards to lower limb orthopedic surgery, surgical repair of meniscal tears is one of the most common surgeries performed worldwide, and while a case can be made regarding the need to better select the patients (see below), there are cases where it is indicated and associated with high healing rates following repair.[223] Therefore, the opportunity arises here to apply the digital approach in the rehabilitation after surgery, as exercise is the mainstay of the recovery process[224] and that early range of motion and immediate post-operative weightbearing (which form the basis of the digital approach) appear to have no detrimental effect on the clinical outcomes.[225]

Management of chronic musculoskeletal conditions

In direct relation with this thesis, the feasibility and clinical impact of a digital program for knee and hip osteoarthritis is one immediately apparent possibility. especially given recent evidence that early rehabilitation after osteoarthritis can reduce the risk of THA/TKA.[226]

In fact, one such program with this technology is already being piloted in the Portuguese NHS, in partnership with Centro Hospitalar de Leiria, with the objective of providing access to rehabilitation programs in patients living in underserved areas, who suffer from chronic hip/knee osteoarthritis. Even though it is out of the scope of this thesis, it is interesting to refer that, this program has already included around 200 patients. Patients participating in this program were assessed at baseline, upon completion of the program (which has a duration of four weeks) and then three and six months after completion. Preliminary results have been very promising, with very high compliance rates and with clinically significant improvements at the four-week assessment, with a maintenance of gains until the three-month assessment and only small decline between the three- and six- month assessments. Public presentation of the pilot results is scheduled for the upcoming congress of the International Society of Physical and Rehabilitation Medicine, 2021.

Regarding potential applications of this approach on chronic musculoskeletal disorders, low back pain, being the single leading cause of disability worldwide is an obvious target, especially given that there is proven efficacy of therapeutic exercise for this condition,[48] which is recommended in all major guidelines on the subject.[227] In fact, given the worldwide impact of this condition, we have recently launched a randomized controlled trial with the objective of assessing the clinical impact of a digital exercise program for chronic low back pain, in comparison with conventional physical therapy. This RCT, which is looking to enroll 144 patients, is being performed in partnership with Emory Spine Center, Atlanta, Georgia.

Another condition where this approach can have a huge potential is shoulder tendonitis, a very common condition,[228] affecting between 2.4% and 14% of the working population, where several studies and systematic reviews support patient should be firstly directed to a physical therapy program and not surgery[220,229–231] and that exercise programs can be as effective as surgery or multimodal physiotherapy.[49] We have, therefore, designed a randomized controlled trial with the objective of assessing the acceptance and clinical impact of a digital exercise program for shoulder tendonitis, in comparison with conventional physical therapy. This RCT, which will involve 82 patients, will be performed in partnership with University College of San Francisco, California, and is expected to launch in June 2021.

Still within the realm of chronic musculoskeletal disorders, other knee disorders are potential targets also, namely those involving the knee ligaments and, especially, meniscal tears. The latter are one of the most commonly encountered knee injuries,[232] with many cases being treated surgically.[233] However, especially after the age of 35, a great proportion of these are degenerative in nature[234] and there is growing evidence, both from a meta-analysis[235] and a more recent well-designed RCT,[236] that surgical treatment is not superior to an exercise program.

7.3.6 Concluding remarks

Taken together, the different aspects approached in this last section demonstrate that the road ahead is ever more exciting, and that the work herein presented is but the first step in a long journey to make physical rehabilitation more accessible, more effective and more efficient.

New approaches to deliver healthcare interventions, namely using technology, can be the solution for many of the problems faced by healthcare systems around the world. Most unfortunately, we have been stricken by the COVID-19 pandemic, which wreaked havoc in all areas of society. Much has changed since we started this work. As part of the adaptation to this new reality, we were forced to re-think healthcare delivery models. Tele-health, and tele-rehabilitation as a subset of tele-health, are now in the spotlight.

The work presented herein shows that tele-rehabilitation is a possibility within our grasp, one that is worth pursuing and integrating within our therapeutic arsenal. We sincerely hope that the work we are doing will help to push the frontiers of tele-herabilitation in particular, and telemedicine in general, for the betterment of the human race.

References

1. UN-DESA. *World Population Ageing 2017*. *World Population Ageing 2017* (2017) doi:ST/ESA/SER.A/348.
2. Woolf, A. D. & Pfleger, B. Burden of major musculoskeletal conditions. *Bull. World Health Organ.* **81**, 646–656 (2003).
3. Litwic, A., Edwards, M. H., Dennison, E. M. & Cooper, C. Epidemiology and burden of osteoarthritis. *Br. Med. Bull.* (2013) doi:10.1093/bmb/lds038.
4. Zhang, W. *et al.* OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. *Osteoarthr. Cartil.* (2008) doi:10.1016/j.joca.2007.12.013.
5. Kurtz, S., Ong, K., Lau, E., Mowat, F. & Halpern, M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J. Bone Joint Surg. Am.* **89**, 780–5 (2007).
6. OECD. *Health at a Glance 2017*. (2017). doi:10.1787/health_glance-2017-en.
7. Singh, J. A. Epidemiology of knee and hip arthroplasty: a systematic review. *Open Orthop. J.* **5**, 80–5 (2011).
8. Okoro, T., Lemmey, A. B., Maddison, P. & Andrew, J. G. An appraisal of rehabilitation regimes used for improving functional outcome after total hip replacement surgery. *Sports Med. Arthrosc. Rehabil. Ther. Technol.* **4**, 5 (2012).
9. Coulter, C. L., Scarvell, J. M., Neeman, T. M. & Smith, P. N. Physiotherapist-directed rehabilitation exercises in the outpatient or home setting improve strength, gait speed and cadence after elective total hip replacement: A systematic review. *J. Physiother.* **59**, 219–226 (2013).
10. Minns Lowe, C. J., Barker, K. L., Dewey, M. & Sackley, C. M. Effectiveness of physiotherapy exercise after knee arthroplasty for osteoarthritis: Systematic review and meta-analysis of randomised controlled trials. *Br. Med. J.* (2007) doi:10.1136/bmj.39311.460093.BE.
11. Artz, N. *et al.* Effectiveness of physiotherapy exercise following total knee replacement: Systematic review and meta-analysis. *BMC Musculoskelet. Disord.* **16**, (2015).
12. Joice, M. G., Bhowmick, S. & Amanatullah, D. F. Perioperative Physiotherapy in Total Knee Arthroplasty. *Orthopedics* **40**, e765–e773 (2017).
13. Artz, N. *et al.* Physiotherapy Provision Following Discharge after Total Hip and Total Knee Replacement: A Survey of Current Practice at High-Volume NHS Hospitals in England and Wales. *Musculoskeletal Care* **11**, 31–38 (2013).
14. Oatis, C. A. *et al.* Variations in delivery and exercise content of physical therapy rehabilitation following total knee replacement surgery: a cross- sectional observational study. *Int. J. Phys. Med. Rehabil.* 1–18 (2014) doi:10.4172/2329-9096.S5-002.Variations.
15. Minns Lowe, C. J., Barker, K. L., Dewey, M. E. & Sackley, C. M. Effectiveness of physiotherapy exercise following hip arthroplasty for osteoarthritis: A systematic review of clinical trials. *BMC Musculoskelet. Disord.* **10**, 1–14 (2009).
16. Pozzi, F., Snyder-Mackler, L. & Zeni, J. Physical exercise after knee arthroplasty: A systematic review of controlled trials. *Eur. J. Phys. Rehabil. Med.* **49**, 877–892 (2013).
17. Westby, M. D., Brittain, A. & Backman, C. L. Expert Consensus on Best Practices for Post-Acute Rehabilitation After Total Hip and Knee Arthroplasty: A Canada and United States Delphi Study. *Arthritis Care Res. (Hoboken).* **66**, 411–423 (2014).
18. Minns Lowe, C. J., Davies, L., Sackley, C. M. & Barker, K. L. Effectiveness of land-based physiotherapy exercise following hospital discharge following hip arthroplasty for osteoarthritis: An updated systematic review. *Physiother. (United Kingdom)* **101**, 252–265 (2015).

19. OECD. *Fiscal Sustainability of Health Systems: Bridging Health and Finance Perspectives September*. *Fiscal Sustainability of Health Systems* (2015) doi:10.1039/c1em10819k.
20. Theodoros, D. & Russell, T. Telerehabilitation: current perspectives. *Stud. Health Technol. Inform.* **131**, 191–209 (2008).
21. Cottrell, M. A., Galea, O. A., O'Leary, S. P., Hill, A. J. & Russell, T. G. Real-time telerehabilitation for the treatment of musculoskeletal conditions is effective and comparable to standard practice: A systematic review and meta-analysis. *Clin. Rehabil.* 026921551664514 (2016) doi:10.1177/0269215516645148.
22. Shukla, H., Nair, S. R., Shaikh, J. S., Thakker, D. & Sharma, D. Role of telerehabilitation in patients followin g total knee arthrop lasty: Evidence from systematic literature review. *Value Heal.* **17 (3)**, A182 (2014).
23. Russell, T. G., Buttrum, P., Wootton, R. & Jull, G. A. Internet-based outpatient telerehabilitation for patients following total knee arthroplasty: A randomized controlled trial. *J. Bone Jt. Surg. - Ser. A* (2011) doi:10.2106/JBJS.I.01375.
24. Moffet, H. *et al.* In-Home Telerehabilitation Compared with Face-to-Face Rehabilitation After Total Knee Arthroplasty. *J. Bone Jt. Surgery-American Vol.* **97**, 1129–1141 (2015).
25. Tousignant, M. *et al.* A randomized controlled trial of home telerehabilitation for post-knee arthroplasty. *J. Telemed. Telecare* **17**, 195–198 (2011).
26. Boissy, P. *et al.* Conditions of Use, Reliability, and Quality of Audio/Video-Mediated Communications During In-Home Rehabilitation Teletreatment for Postknee Arthroplasty. *Telemed. e-Health* **22**, 637–649 (2016).
27. Antón, D., Nelson, M., Russell, T., Goñi, A. & Illarramendi, A. Validation of a Kinect-based telerehabilitation system with total hip replacement patients. *J. Telemed. Telecare* **22**, 192–197 (2016).
28. Piqueras, M. *et al.* Effectiveness of an interactive virtual telerehabilitation system in patients after total knee arthroplasty: A randomized controlled trial. *J. Rehabil. Med.* **45**, 392–396 (2013).
29. Smittenaar, P. *et al.* Translating Comprehensive Conservative Care for Chronic Knee Pain Into a Digital Care Pathway: 12-Week and 6-Month Outcomes for the Hinge Health Program. *JMIR Rehabil. Assist. Technol.* (2017) doi:10.2196/rehab.7258.
30. Mecklenburg, G., Smittenaar, P., Erhart-Hledik, J. C., Perez, D. A. & Hunter, S. Effects of a 12-week digital care program for chronic knee pain on pain, mobility, and surgery risk: Randomized controlled trial. *J. Med. Internet Res.* (2018) doi:10.2196/jmir.9667.
31. Chughtai, M. *et al.* The Role of Virtual Rehabilitation in Total and Unicompartmental Knee Arthroplasty. *J. Knee Surg.* (2019) doi:10.1055/s-0038-1637018.
32. Baltaci, G., Harput, G., Haksever, B., Ulusoy, B. & Ozer, H. Comparison between Nintendo Wii Fit and conventional rehabilitation on functional performance outcomes after hamstring anterior cruciate ligament reconstruction: Prospective, randomized, controlled, double-blind clinical trial. *Knee Surgery, Sport. Traumatol. Arthrosc.* **21**, 880–887 (2013).
33. Baltaci, G., Harput, G., Haksever, B., Ulusoy, B. & Ozer, H. Comparison between Nintendo Wii Fit and conventional rehabilitation on functional performance outcomes after hamstring anterior cruciate ligament reconstruction: Prospective, randomized, controlled, double-blind clinical trial. *Knee Surgery, Sport. Traumatol. Arthrosc.* (2013) doi:10.1007/s00167-012-2034-2.
34. European Commission. The 2018 Ageing Report. *Eur. Econ.* (2017) doi:10.2765/286359.
35. Bento, V. F., Cruz, V. T., Ribeiro, D. D. & Cunha, J. P. The vibratory stimulus as a neurorehabilitation tool for stroke patients: Proof of concept and tolerability test. *NeuroRehabilitation* **30**, 287–293 (2012).
36. Wolf, S. L., Lecraw, D. E., Barton, L. A. & Jann, B. B. Forced use of hemiplegic upper

extremities to reverse the effect of learned nonuse among chronic stroke and head-injured patients. *Exp. Neurol.* (1989) doi:10.1016/S0014-4886(89)80005-6.
37. Tedim Cruz, V. *et al.* A novel system for automatic classification of upper limb motor function after stroke: An exploratory study. *Med. Eng. Phys.* **36**, 1704–1710 (2014).
38. Bento, V. A. F. SWORD – Um dispositivo vibratório vestível para uma reabilitação mais eficiente em doentes com AVC. (2012).
39. Cruz, V. T. *et al.* Motor task performance under vibratory feedback early poststroke: Single center, randomized, cross-over, controled clinical trial. *Sci. Rep.* **4**, 1–9 (2014).
40. Cramer, S. C. Repairing the human brain after stroke: I. Mechanisms of spontaneous recovery. *Annals of Neurology* (2008) doi:10.1002/ana.21393.
41. Nelson, L. A. The Role of Biofeedback in Stroke Rehabilitation: Past and Future Directions. *Top. Stroke Rehabil.* (2007) doi:10.1310/tsr1404-59.
42. Parker, J., Mountain, G. & Hammerton, J. A review of the evidence underpinning the use of visual and auditory feedback for computer technology in post-stroke upper-limb rehabilitation. *Disabil. Rehabil. Assist. Technol.* (2011) doi:10.3109/17483107.2011.556209.
43. Wittmann, F., Lambercy, O. & Gassert, R. Magnetometer-based drift correction during rest in IMU arm motion tracking. *Sensors (Switzerland)* (2019) doi:10.3390/s19061312.
44. Correia, F. D. *et al.* Motor Task Performance under Visual and Auditory Feedback Post Stroke: A Randomised Crossover Trial. *Int. J. Neurorehabilitation* **04**, (2017).
45. James, S. L. *et al.* Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017. *Lancet* **392**, 1789–1858 (2018).
46. Fransen, M. *et al.* Exercise for osteoarthritis of the knee. *Cochrane Database of Systematic Reviews* (2015) doi:10.1002/14651858.CD004376.pub3.
47. Fransen, M., McConnell, S., Hernandez-Molina, G. & Reichenbach, S. Exercise for osteoarthritis of the hip. *Cochrane Database Syst. Rev.* (2014) doi:10.1002/14651858.CD007912.pub2.
48. Gordon, R. & Bloxham, S. A Systematic Review of the Effects of Exercise and Physical Activity on Non-Specific Chronic Low Back Pain. *Healthcare* (2016) doi:10.3390/healthcare4020022.
49. Littlewood, C., Ashton, J., Chance-Larsen, K., May, S. & Sturrock, B. Exercise for rotator cuff tendinopathy: A systematic review. *Physiotherapy* (2012) doi:10.1016/j.physio.2011.08.002.
50. Sharif, B., Kopec, J. A., Wong, H. & Anis, A. H. Distribution and Drivers of Average Direct Cost of Osteoarthritis in Canada From 2003 to 2010. *Arthritis Care Res.* (2017) doi:10.1002/acr.22933.
51. Services, C. for M. and M. Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services. Final rule. *Fed. Regist.* **80**, 73273–73554 (2015).
52. European Commission. The impact of ageing on public expenditure: projectories for the EU25 member States on pensions, health care, long-term care, education and unemployment transfers (2004-2050). *Health Care (Don. Mills).* (2006) doi:D:\BDB\General \1226_annex.pdf.
53. de Meijer, C., Wouterse, B., Polder, J. & Koopmanschap, M. The effect of population aging on health expenditure growth: A critical review. *European Journal of Ageing* (2013) doi:10.1007/s10433-013-0280-x.
54. Bijlsma, J. W. J., Berenbaum, F. & Lafeber, F. P. J. G. Osteoarthritis: An update with relevance for clinical practice. *Lancet* **377**, 2115–2126 (2011).
55. Laires, P. A. *et al.* The impact of osteoarthritis on early exit from work: Results from a population-based study. *BMC Public Health* (2018) doi:10.1186/s12889-018-5381-1.

56. Hootman, J. M., Helmick, C. G., Barbour, K. E., Theis, K. A. & Boring, M. A. Updated Projected Prevalence of Self-Reported Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation Among US Adults, 2015–2040. *Arthritis Rheumatol.* (2016) doi:10.1002/art.39692.
57. Kim, C. *et al.* Prevalence of radiographic and symptomatic hip osteoarthritis in an urban United States community: The Framingham osteoarthritis study. *Arthritis Rheumatol.* (2014) doi:10.1002/art.38795.
58. Branco, J. C. *et al.* Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: Results from EpiReumaPt- a national health survey. *RMD Open* (2016) doi:10.1136/rmdopen-2015-000166.
59. Turkiewicz, A. *et al.* Prevalence of knee pain and knee OA in southern Sweden and the proportion that seeks medical care. *Rheumatol. (United Kingdom)* (2014) doi:10.1093/rheumatology/keu409.
60. Felson, D. T. *et al.* The prevalence of knee osteoarthritis in the elderly. the framingham osteoarthritis study. *Arthritis Rheum.* (1987) doi:10.1002/art.1780300811.
61. Allen, K. D. & Golightly, Y. M. State of the evidence. *Current Opinion in Rheumatology* (2015) doi:10.1097/BOR.0000000000000161.
62. Song, J., Chang, R. W. & Dunlop, D. D. Population impact of arthritis on disability in older adults. *Arthritis Care Res.* (2006) doi:10.1002/art.21842.
63. Hiligsmann, M. *et al.* Health economics in the field of osteoarthritis: An Expert's consensus paper from the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO). *Semin. Arthritis Rheum.* (2013) doi:10.1016/j.semarthrit.2013.07.003.
64. Glyn-Jones, S. *et al.* Osteoarthritis - Seminar. *Lancet* (2015) doi:10.1016/S0140-6736(14)60802-3.
65. Mork, P. J., Holtermann, A. & Nilsen, T. I. L. Effect of body mass index and physical exercise on risk of knee and hip osteoarthritis: Longitudinal data from the Norwegian HUNT Study. *J. Epidemiol. Community Health* (2012) doi:10.1136/jech-2011-200834.
66. Tanamas, S. *et al.* Does knee malalignment increase the risk of development and progression of knee osteoarthritis? A systematic review. *Arthritis Care Res.* (2009) doi:10.1002/art.24336.
67. Woolf, A. D. & Pfleger, B. Burden of major musculoskeletal conditions. *Bulletin of the World Health Organization* (2003) doi:S0042-96862003000900007 [pii].
68. Altman, R. *et al.* The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hip. *Arthritis Rheum.* (1991) doi:10.1002/art.1780340502.
69. Altman, R. *et al.* Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee. *Arthritis Rheum.* (1986) doi:10.1002/art.1780290816.
70. Reichenbach, S., Nüesch, E., Trelle, S., Jüni, P. & Rutjes, A. W. Joint lavage for osteoarthritis of the knee. *Cochrane Database Syst. Rev.* (2010) doi:10.1002/14651858.cd007320.pub2.
71. Pivec, R., Johnson, A. J., Mears, S. C. & Mont, M. A. Hip arthroplasty. *Lancet* **380**, 1768–1777 (2012).
72. Young, E., Mccormack, V. & Swanson, M. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man. 15th Annual Report 2018. Available at http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2015th%20Annual%20Report%202018.pdf. Accessed November 18, 2018. **1821**, (2018).
73. Murphy, L. & Helmick, C. G. The Impact of osteoarthritis in the United States: A population-health perspective: A population-based review of the fourth most common cause of hospitalization in U.S. adults. *Orthopaedic Nursing* (2012) doi:10.1097/NOR.0b013e31824fcd42.
74. Dakin, H., Gray, A., Fitzpatrick, R., MacLennan, G. & Murray, D. Rationing of total knee

replacement: A cost-effectiveness analysis on a large trial data set. *BMJ Open* (2012) doi:10.1136/bmjopen-2011-000332.
75. Daigle, M. E., Weinstein, A. M., Katz, J. N. & Losina, E. The cost-effectiveness of total joint arthroplasty: A systematic review of published literature. *Best Practice and Research: Clinical Rheumatology* (2012) doi:10.1016/j.berh.2012.07.013.
76. Carr, A. J. *et al.* Knee replacement. *Lancet* **379**, 1331–1340 (2012).
77. Fawsitt, C. G. *et al.* Choice of Prosthetic Implant Combinations in Total Hip Replacement: Cost-Effectiveness Analysis Using UK and Swedish Hip Joint Registries Data. *Value Heal.* (2019) doi:10.1016/j.jval.2018.08.013.
78. Pennington, M., Grieve, R., Black, N. & Van der Meulen, J. H. Cost-Effectiveness of five commonly used prosthesis brands for total knee replacement in the UK: A study using the NJR Dataset. *PLoS One* (2016) doi:10.1371/journal.pone.0150074.
79. Park, K. K., Chang, C. B., Kang, Y. G., Seong, S. C. & Kim, T. K. Correlation of maximum flexion with clinical outcome after total knee replacement in Asian patients. *J. Bone Jt. Surg. - Br. Vol.* **89-B**, 604–608 (2007).
80. Bade, M. J., Kittelson, J. M., Kohrt, W. M. & Stevens-Lapsley, J. E. Predicting functional performance and range of motion outcomes after total knee arthroplasty. *Am. J. Phys. Med. Rehabil.* **93**, 579–85 (2014).
81. Miner, A. L., Lingard, E. A., Wright, E. A., Sledge, C. B. & Katz, J. N. Knee range of motion after total knee arthroplasty: How important is this as an outcome measure? *J. Arthroplasty* **18**, 286–294 (2003).
82. Dayton, M. R., Judd, D. L., Hogan, C. A. & Stevens-Lapsley, J. E. Performance-Based Versus Self-Reported Outcomes Using the Hip Disability and Osteoarthritis Outcome Score after Total Hip Arthroplasty. *Am. J. Phys. Med. Rehabil.* (2016) doi:10.1097/PHM.0000000000000357.
83. Mizner, R. L. *et al.* Measuring Functional Improvement After Total Knee Arthroplasty Requires Both Performance-Based and Patient-Report Assessments. A Longitudinal Analysis of Outcomes. *J. Arthroplasty* (2011) doi:10.1016/j.arth.2010.06.004.
84. Stratford, P. W. & Kennedy, D. M. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. *J. Clin. Epidemiol.* (2006) doi:10.1016/j.jclinepi.2005.07.012.
85. Wittink, H., Rogers, W., Sukiennik, A. & Carr, D. B. Physical functioning: Self-report and performance measures are related but distinct. *Spine (Phila. Pa. 1976).* (2003) doi:10.1097/01.BRS.0000085304.01483.17.
86. Stevens-Lapsley, J. E., Schenkman, M. L. & Dayton, M. R. Comparison of Self-Reported Knee Injury and Osteoarthritis Outcome Score to Performance Measures in Patients After Total Knee Arthroplasty. *PM R* **3**, 541–549 (2011).
87. Dobson, F. *et al.* OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. *Osteoarthr. Cartil.* (2013) doi:10.1016/j.joca.2013.05.002.
88. Sands, G. *et al.* Improving patients' experience and outcome of total joint replacement: the RESTORE programme. *Program. Grants Appl. Res.* (2016) doi:10.3310/pgfar04120.
89. Van Der Wees, P. J. *et al.* Patient-reported health outcomes after total hip and knee surgery in a Dutch University Hospital Setting: Results of twenty years clinical registry. *BMC Musculoskelet. Disord.* (2017) doi:10.1186/s12891-017-1455-y.
90. Xie, F. *et al.* Evaluation of health outcomes in osteoarthritis patients after total knee replacement: A two-year follow-up. *Health Qual. Life Outcomes* (2010) doi:10.1186/1477-7525-8-87.
91. Ng, C. Y., Ballantyne, J. A. & Brenkel, I. J. Quality of life and functional outcome after primary total hip replacement. *J. Bone Joint Surg. Br.* (2007) doi:10.1302/0301-620x.89b7.18482.

92. Laasik, R. *et al.* Return to work after primary total hip arthroplasty: a nationwide cohort study. *Acta Orthop.* (2019) doi:10.1080/17453674.2019.1591081.
93. Ethgen, O., Bruyere, O., Richy, F., Dardennes, C. & Reginster, J.-Y. Health-Related Quality of Life in Total Hip and Total Knee Arthroplasty. *The Journal of Bone and Joint Surgery* 963-.
94. Bruyère, O. *et al.* Health-related quality of life after total knee or hip replacement for osteoarthritis: a 7-year prospective study. *Arch. Orthop. Trauma Surg.* **132**, 1583–1587 (2012).
95. Dailiana, Z. H. *et al.* Patient-reported quality of life after primary major joint arthroplasty: A prospective comparison of hip and knee arthroplasty. *BMC Musculoskelet. Disord.* **16**, 10–17 (2015).
96. Bahardoust, M., Hajializade, M., Amiri, R., Mousazadeh, F. & Pisoudeh, K. Evaluation of health-related quality of life after total hip arthroplasty: A case-control study in the Iranian population. *BMC Musculoskelet. Disord.* (2019) doi:10.1186/s12891-019-2428-0.
97. Keswani, A. *et al.* Discharge Destination After Total Joint Arthroplasty: An Analysis of Postdischarge Outcomes, Placement Risk Factors, and Recent Trends. *J. Arthroplasty* **31**, 1155–1162 (2016).
98. Paxton, E. W. *et al.* Total joint replacement: A multiple risk factor analysis of physical activity level 1–2 years postoperatively. *Acta Orthop.* (2016) doi:10.1080/17453674.2016.1193663.
99. Wu, J. Q., Mao, L. B. & Wu, J. Efficacy of exercise for improving functional outcomes for patients undergoing total hip arthroplasty: A meta-analysis. *Medicine (Baltimore).* (2019) doi:10.1097/MD.0000000000014591.
100. Petterson, S. C. *et al.* Improved function from progressive strengthening interventions after total knee arthroplasty: A randomized clinical trial with an imbedded prospective cohort. *Arthritis Care Res.* (2009) doi:10.1002/art.24167.
101. Bade, M. J. & Stevens-Lapsley, J. E. Early High-Intensity Rehabilitation Following Total Knee Arthroplasty Improves Outcomes. *J. Orthop. Sport. Phys. Ther.* **41**, 932–941 (2011).
102. JM, M. & MP, G. Impairment of muscle performance before and following total hip replacement. *Int. J. Ther. Rehabil.* (2007) doi:10.12968/ijtr.2007.14.2.23515.
103. Vissers, M. M. *et al.* Recovery of physical functioning after total hip arthroplasty: systematic review and meta-analysis of the literature. *Phys. Ther.* **91**, 615–29 (2011).
104. Beswick, A. D., Wylde, V., Gooberman-Hill, R., Blom, A. & Dieppe, P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of Prospective studies in unselected patients. *BMJ Open* (2012) doi:10.1136/bmjopen-2011-000435.
105. Rossi, M. D., Hasson, S., Kohia, M., Pineda, E. & Bryan, W. Mobility and perceived function after total knee arthroplasty. *J. Arthroplasty* (2006) doi:10.1016/j.arth.2005.02.013.
106. Mikkelsen, L. R., Mikkelsen, S. S. & Christensen, F. B. Early, intensified home-based exercise after total hip replacement - A pilot study. *Physiother. Res. Int.* **17**, 214–226 (2012).
107. Ribinik, P. *et al.* Physical and Rehabilitation Medicine (PRM) care pathways: 'Patients after total knee arthroplasty'. *Ann. Phys. Rehabil. Med.* **55**, 533–539 (2012).
108. Ribinik, P. *et al.* Physical and Rehabilitation Medicine (PRM) care pathways: 'Patients after total knee arthroplasty'. *Ann. Phys. Rehabil. Med.* (2012) doi:10.1016/j.rehab.2012.02.002.
109. Blom, A. W. *et al.* Improving patients' experience and outcome of total joint replacement: the RESTORE programme. *Program. Grants Appl. Res.* **4**, 1–508 (2016).
110. Granja, C., Janssen, W. & Johansen, M. A. Factors determining the success and failure of ehealth interventions: Systematic review of the literature. *Journal of Medical Internet Research* (2018) doi:10.2196/10235.
111. Dinesen, B. *et al.* Personalized telehealth in the future: A global research agenda. *Journal of Medical Internet Research* (2016) doi:10.2196/jmir.5257.

112. Dahlberg, L. E., Grahn, D., Dahlberg, J. E. & Thorstensson, C. A. A Web-Based Platform for Patients With Osteoarthritis of the Hip and Knee: A Pilot Study. *JMIR Res. Protoc.* (2016) doi:10.2196/resprot.5665.
113. Coulter, C., Perriman, D. M., Neeman, T. M., Smith, P. N. & Scarvell, J. M. Supervised or Unsupervised Rehabilitation After Total Hip Replacement Provides Similar Improvements for Patients: A Randomized Controlled Trial. *Arch. Phys. Med. Rehabil.* (2017) doi:10.1016/j.apmr.2017.03.032.
114. Mikkelsen, L. R. *et al.* Effect of early supervised progressive resistance training compared to unsupervised home-based exercise after fast-track total hip replacement applied to patients with preoperative functional limitations. A single-blinded randomised controlled trial. *Osteoarthr. Cartil.* **22**, 2051–2058 (2014).
115. Klement, M. R., Rondon, A. J., McEntee, R. M., Greenky, M. R. & Austin, M. S. Web-Based, Self-Directed Physical Therapy After Total Knee Arthroplasty Is Safe and Effective for Most, but Not All, Patients. *J. Arthroplasty* (2019) doi:10.1016/j.arth.2018.11.040.
116. Hansen, S., Aaboe, J., Mechlenburg, I., Overgaard, S. & Mikkelsen, L. R. Effects of supervised exercise compared to non-supervised exercise early after total hip replacement on patient-reported function, pain, health-related quality of life and performance-based function – a systematic review and meta-analysis of randomized co. *Clin. Rehabil.* (2019) doi:10.1177/0269215518791213.
117. Giggins, O. M., Persson, U. M. C. & Caulfield, B. Biofeedback in rehabilitation. *J. Neuroeng. Rehabil.* **10**, 1 (2013).
118. Timmermans, A. A. A. *et al.* Effects of task-oriented robot training on arm function, activity, and quality of life in chronic stroke patients: A randomized controlled trial. *J. Neuroeng. Rehabil.* (2014) doi:10.1186/1743-0003-11-45.
119. Iosa, M., Hesse, S., Oliviero, A. & Paolucci, S. New Technologies for Stroke Rehabilitation. *Stroke Res. Treat.* (2013) doi:10.1155/2013/815814.
120. Raaben, M., Vogely, H. C. & Blokhuis, T. J. Real-time visual biofeedback to improve therapy compliance after total hip arthroplasty: A pilot randomized controlled trial. *Gait Posture* (2018) doi:10.1016/j.gaitpost.2018.01.038.
121. Pfeufer, D. *et al.* Training with biofeedback devices improves clinical outcome compared to usual care in patients with unilateral TKA: a systematic review. *Knee Surgery, Sport. Traumatol. Arthrosc.* (2018) doi:10.1007/s00167-018-5217-7.
122. Christiansen, C. L., Bade, M. J., Davidson, B. S., Dayton, M. R. & Stevens-Lapsley, J. E. Effects of Weight-Bearing Biofeedback Training on Functional Movement Patterns Following Total Knee Arthroplasty: A Randomized Controlled Trial. *J. Orthop. Sport. Phys. Ther.* (2015) doi:10.2519/jospt.2015.5593.
123. Fung, V., Ho, A., Shaffer, J., Chung, E. & Gomez, M. Use of Nintendo Wii Fit™ In the rehabilitation of outpatients following total knee replacement: A preliminary randomised controlled trial. *Physiother. (United Kingdom)* **98**, 183–188 (2012).
124. Zeni, J., Abujaber, S., Flowers, P., Pozzi, F. & Snyder-Mackler, L. Biofeedback to Promote Movement Symmetry After Total Knee Arthroplasty: A Feasibility Study. *J. Orthop. Sport. Phys. Ther.* (2013) doi:10.2519/jospt.2013.4657.
125. Magdalena Wilk-Franczuk, Jerzy Zemła & Śliwiński, Z. The application of biofeedback exercises in patients following arthroplasty of the knee with the use of total endoprosthesis. *Med Sci Monit* **16**, CR423-6 (2010).
126. Oh, H.-T. & Hwangbo, G. The effects of proprioception exercise with and without visual feedback on the pain and balance in patients after total knee arthroplasty. *J. Phys. Ther. Sci.* (2018) doi:10.1589/jpts.30.124.

127. Shanb, A.-S. A. & Youssef, E. F. EFFECTS OF ADDING BIOFEEDBACK TRAINING TO ACTIVE EXERCISES AFTER TOTAL KNEE ARTHROPLASTY. *J. Musculoskelet. Res.* (2014) doi:10.1142/s0218957714500018.
128. Wang, T. J. *et al.* Biofeedback relaxation for pain associated with continuous passive motion in Taiwanese patients after total knee arthroplasty. *Res. Nurs. Heal.* (2015) doi:10.1002/nur.21633.
129. Paxton, R. J. *et al.* A Feasibility Study for Improved Physical Activity After Total Knee Arthroplasty. *J. Aging Phys. Act.* **26**, 7–13 (2018).
130. Christensen, J. C. *et al.* Visual knee-kinetic biofeedback technique normalizes gait abnormalities during high-demand mobility after total knee arthroplasty. *Knee* (2018) doi:10.1016/j.knee.2017.11.010.
131. Hardt, S. *et al.* Improved early outcome after TKA through an app-based active muscle training programme—a randomized-controlled trial. *Knee Surgery, Sport. Traumatol. Arthrosc.* (2018) doi:10.1007/s00167-018-4918-2.
132. Kuiken, T. A., Amir, H. & Scheidt, R. A. Computerized biofeedback knee goniometer: Acceptance and effect on exercise behavior in post-total knee arthroplasty rehabilitation. *Arch. Phys. Med. Rehabil.* (2004) doi:10.1016/j.apmr.2003.08.088.
133. Blasco, J. M. *et al.* The efficacy of virtual reality tools for total knee replacement rehabilitation: A systematic review. *Physiother. Theory Pract.* (2019) doi:10.1080/09593985.2019.1641865.
134. Su, C. H. Developing and evaluating effectiveness of 3D game-based rehabilitation system for Total Knee Replacement Rehabilitation patients. *Multimed. Tools Appl.* (2016) doi:10.1007/s11042-015-2820-1.
135. Roig-Casasús, S., Blasco, J. M., López-Bueno, L. & Blasco-Igual, M. C. Balance Training with a Dynamometric Platform Following Total Knee Replacement: A Randomized Controlled Trial. *J. Geriatr. Phys. Ther.* (2018) doi:10.1519/JPT.0000000000000121.
136. Dursun, N., Dursun, E. & Kili, Z. Electromyographic biofeedback-controlled exercise versus conservative care for patellofemoral pain syndrome. *Arch. Phys. Med. Rehabil.* (2001) doi:10.1053/apmr.2001.26253.
137. Yip, S. L. M. & Ng, G. Y. F. Biofeedback supplementation to physiotherapy exercise programme for rehabilitation of patellofemoral pain syndrome: A randomized controlled pilot study. *Clin. Rehabil.* (2006) doi:10.1177/0269215506071259.
138. Draper, V. Electromyographic biofeedback and recovery of quadriceps femoris muscle function following anterior cruciate ligament reconstruction. *Phys. Ther.* (1990) doi:10.1093/ptj/70.1.11.
139. Draper, V. & Ballard, L. Electrical stimulation versus electromyographic biofeedback in the recovery of quadriceps femoris muscle function following anterior cruciate ligament surgery. *Phys. Ther.* (1991).
140. Christanell, F., Hoser, C., Huber, R., Fink, C. & Luomajoki, H. The influence of electromyographic biofeedback therapy on knee extension following anterior cruciate ligament reconstruction: A randomized controlled trial. *Sport. Med. Arthrosc. Rehabil. Ther. Technol.* (2012) doi:10.1186/1758-2555-4-41.
141. Durmuş, D., Alayli, G. & Cantürk, F. Effects of quadriceps electrical stimulation program on clinical parameters in the patients with knee osteoarthritis. *Clin. Rheumatol.* (2007) doi:10.1007/s10067-006-0358-3.
142. Anwer, S., Quddus, N., Miraj, M. & Equebal, A. Effectiveness of electromyographic biofeedback training on quadriceps muscle strength in osteoarthritis of knee. *Hong Kong Physiother. J.* (2011) doi:10.1016/j.hkpj.2011.06.006.
143. Levitt, R., Deisinger, J. A., Remondet Wall, J., Ford, L. & Cassisi, J. E. EMG feedback-assisted

postoperative rehabilitation of minor arthroscopic knee surgeries. *J. Sports Med. Phys. Fitness* (1995).
144. Wasielewski, N. J., Parker, T. M. & Kotsko, K. M. Evaluation of electromyographic biofeedback for the quadriceps femoris: A systematic review. *Journal of Athletic Training* (2011) doi:10.4085/1062-6050-46.5.543.
145. Eichler, S. *et al.* Telerehabilitation as a supplement to usual aftercare in patients after total knee or hip replacement - A randomized controlled study for the effectiveness of a telemedical assisted movement therapy in orthopaedic rehabilitation (Preprint). *JMIR Rehabil. Assist. Technol.* (2019) doi:10.2196/14236.
146. Ficklscherer, A. *et al.* Testing the feasibility and safety of the Nintendo Wii gaming console in orthopedic rehabilitation: A pilot randomized controlled study. *Arch. Med. Sci.* **12**, 1273–1278 (2016).
147. Levinger, P. *et al.* A real time biofeedback using Kinect and Wii to improve gait for post-total knee replacement rehabilitation: A case study report. *Disabil. Rehabil. Assist. Technol.* (2016) doi:10.3109/17483107.2015.1080767.
148. Wang, Q., Markopoulos, P., Yu, B., Chen, W. & Timmermans, A. Interactive wearable systems for upper body rehabilitation: A systematic review. *Journal of NeuroEngineering and Rehabilitation* (2017) doi:10.1186/s12984-017-0229-y.
149. Bolink, S. A. A. N. *et al.* Assessment of physical function following total hip arthroplasty: Inertial sensor based gait analysis is supplementary to patient-reported outcome measures. *Clin. Biomech.* (2016) doi:10.1016/j.clinbiomech.2015.11.014.
150. Youn, I. H., Youn, J. H., Zeni, J. A. & Knarr, B. A. Biomechanical gait variable estimation using wearable sensors after unilateral total knee arthroplasty. *Sensors (Switzerland)* (2018) doi:10.3390/s18051577.
151. Chiang, C. Y., Chen, K. H., Liu, K. C., Hsu, S. J. P. & Chan, C. T. Data collection and analysis using wearable sensors for monitoring knee range of motion after total knee arthroplasty. *Sensors (Switzerland)* (2017) doi:10.3390/s17020418.
152. Giggins, O. M., Sweeney, K. T. & Caulfield, B. Rehabilitation exercise assessment using inertial sensors: A cross-sectional analytical study. *J. Neuroeng. Rehabil.* (2014) doi:10.1186/1743-0003-11-158.
153. Jeldi, A. J. *et al.* Upright Time and Sit-To-Stand Transition Progression After Total Hip Arthroplasty: An Inhospital Longitudinal Study. *J. Arthroplasty* (2016) doi:10.1016/j.arth.2015.09.024.
154. Kwasnicki, R. M. *et al.* A wearable mobility assessment device for total knee replacement: Alongitudinal feasibility study. *Int. J. Surg.* (2015) doi:10.1016/j.ijsu.2015.04.032.
155. Lin, J. F. S. & Kulić, D. Human pose recovery using wireless inertial measurement units. *Physiol. Meas.* (2012) doi:10.1088/0967-3334/33/12/2099.
156. Chapman, R. M., Moschetti, W. E. & Van Citters, D. W. Stance and swing phase knee flexion recover at different rates following total knee arthroplasty: An inertial measurement unit study. *J. Biomech.* (2019) doi:10.1016/j.jbiomech.2018.12.027.
157. Calliess, T. *et al.* Clinical evaluation of a mobile sensor-based gait analysis method for outcome measurement after knee arthroplasty. *Sensors (Switzerland)* (2014) doi:10.3390/s140915953.
158. Bahadori, S., Immins, T. & Wainwright, T. W. A review of wearable motion tracking systems used in rehabilitation following hip and knee replacement. *J. Rehabil. Assist. Technol. Eng.* **5**, 205566831877181 (2018).
159. Raaben, M., Vogely, H. C. & Blokhuis, T. J. Real-time visual biofeedback to improve therapy compliance after total hip arthroplasty: A pilot randomized controlled trial. *Gait Posture* (2018) doi:10.1016/j.gaitpost.2018.01.038.

160. Argent, R. *et al.* Wearable sensor-based exercise biofeedback for orthopaedic rehabilitation: A mixed methods user evaluation of a prototype system. *Sensors (Switzerland)* (2019) doi:10.3390/s19020432.
161. Roos, E. M. & Lohmander, L. S. The Knee injury and Osteoarthritis Outcome Score (KOOS): From joint injury to osteoarthritis. *Health and Quality of Life Outcomes* (2003) doi:10.1186/1477-7525-1-64.
162. de la Torre-Díez, I., López-Coronado, M., Vaca, C., Aguado, J. S. & de Castro, C. Cost-Utility and Cost-Effectiveness Studies of Telemedicine, Electronic, and Mobile Health Systems in the Literature: A Systematic Review. *Telemed. e-Health* **21**, 81–85 (2015).
163. Tousignant, M. *et al.* Cost analysis of in-home telerehabilitation for post-knee arthroplasty. *J. Med. Internet Res.* **17**, (2015).
164. Haines, T. & Bowles, K. A. Cost-effectiveness of using a motion-sensor biofeedback treatment approach for the management of sub-acute or chronic low back pain: Economic evaluation alongside a randomised trial. *BMC Musculoskelet. Disord.* (2017) doi:10.1186/s12891-016-1371-6.
165. Parent, E. & Moffet, H. Comparative responsiveness of locomotor tests and questionnaires used to follow-early recovery after total knee arthroplasty. *Arch. Phys. Med. Rehabil.* **83**, 70–80 (2002).
166. Lindemann, U. *et al.* Gait analysis and WOMAC are complementary in assessing functional outcome in total hip replacement. *Clin. Rehabil.* (2006) doi:10.1191/0269215506cr958oa.
167. Wright, A. A., Cook, C. E., Baxter, G. D., Dockerty, J. D. & Abbott, J. H. A Comparison of 3 Methodological Approaches to Defining Major Clinically Important Improvement of 4 Performance Measures in Patients With Hip Osteoarthritis. *J. Orthop. Sport. Phys. Ther.* **41**, 319–327 (2011).
168. Poitras, S., Wood, K. S., Savard, J., Dervin, G. F. & Beaule, P. E. Predicting early clinical function after hip or knee arthroplasty. *Bone Joint Res.* **4**, 145–151 (2015).
169. Nankaku, M. *et al.* Preoperative Prediction of Ambulatory Status at 6 Months After Total Hip Arthroplasty. *Phys. Ther.* **93**, 88–93 (2013).
170. Podsiadlo, D. & Richardson, S. The timed 'Up & Go': a test of basic functional mobility for frail elderly persons. *J. Am. Geriatr. Soc.* **39**, 142–148 (1991).
171. Klässbo, M., Larsson, E. & Mannevik, E. Hip disability and osteoarthritis outcome score: An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. *Scand. J. Rheumatol.* **32**, 46–51 (2003).
172. Nilsdotter, A. K., Lohmander, L. S., Klässbo, M. & Roos, E. M. Hip disability and osteoarthritis outcome score (HOOS) - Validity and responsiveness in total hip replacement. *BMC Musculoskelet. Disord.* **4**, 1–8 (2003).
173. Ornetti, P. *et al.* Cross-cultural adaptation and validation of the French version of the Hip disability and Osteoarthritis Outcome Score (HOOS) in hip osteoarthritis patients. *Osteoarthr. Cartil.* **18**, 522–529 (2010).
174. Kennedy, D. M., Stratford, P. W., Wessel, J., Gollish, J. D. & Penney, D. Assessing stability and change of four performance measures: a longitudinal study evaluating outcome following total hip and knee arthroplasty. *BMC Musculoskelet Disord* **6**, 3 (2005).
175. Gupta, S. Intention-to-treat concept: A review. *Perspect. Clin. Res.* (2011) doi:10.4103/2229-3485.83221.
176. Ranganathan, P., Pramesh, C. & Aggarwal, R. Common pitfalls in statistical analysis: Intention-to-treat versus per-protocol analysis. *Perspect. Clin. Res.* (2016) doi:10.4103/2229-3485.184823.
177. Foucher, K. C. Identifying clinically meaningful benchmarks for gait improvement after total hip

arthroplasty. *J. Orthop. Res.* (2016) doi:10.1002/jor.22996.
178. Hesse, S. *et al.* Treadmill Training with Partial Body-Weight Support after Total Hip Arthroplasty: A Randomized Controlled Trial. *Arch. Phys. Med. Rehabil.* (2003) doi:10.1016/S0003-9993(03)00434-9.
179. Suetta, C. *et al.* Resistance training in the early postoperative phase reduces hospitalization and leads to muscle hypertrophy in elderly hip surgery patients - A controlled, randomized study. *J. Am. Geriatr. Soc.* (2004) doi:10.1111/j.1532-5415.2004.52557.x.
180. Rahmann, A. E., Brauer, S. G. & Nitz, J. C. A Specific Inpatient Aquatic Physiotherapy Program Improves Strength After Total Hip or Knee Replacement Surgery: A Randomized Controlled Trial. *Arch. Phys. Med. Rehabil.* (2009) doi:10.1016/j.apmr.2008.12.011.
181. Di Monaco, M., Vallero, F., Tappero, R. & Cavanna, A. Rehabilitation after total hip arthroplasty: A systematic review of controlled trials on physical exercise programs. *Eur. J. Phys. Rehabil. Med.* (2009) doi:R33092038 [pii].
182. Wijnen, A. *et al.* The therapeutic validity and effectiveness of physiotherapeutic exercise following total hip arthroplasty for osteoarthritis: A systematic review. *PLoS One* (2018) doi:10.1371/journal.pone.0194517.
183. Freter, S. H. & Fruchter, N. Relationship between timed 'up and go' and gait time in an elderly orthopaedic rehabilitation population. *Clin. Rehabil.* (2000) doi:10.1191/026921500675545616.
184. Imada, A., Nelms, N., Halsey, D. & Blankstein, M. Physical therapists collect different outcome measures after total joint arthroplasty as compared to most orthopaedic surgeons: a New England study. *Arthroplast. Today* (2018) doi:10.1016/j.artd.2017.08.003.
185. Galea, M. P. *et al.* A targeted home- and center-based exercise program for people after total hip replacement: A randomized clinical trial. *Arch. Phys. Med. Rehabil.* **89**, 1442–1447 (2008).
186. Okoro, T. *et al.* Does an early home-based progressive resistance training program improve function following total hip replacement? Results of a randomized controlled study. *BMC Musculoskelet. Disord.* **17**, (2016).
187. Coulter, C., Perriman, D. M., Neeman, T. M., Smith, P. N. & Scarvell, J. M. Supervised or Unsupervised Rehabilitation After Total Hip Replacement Provides Similar Improvements for Patients: A Randomized Controlled Trial. *Arch. Phys. Med. Rehabil.* **98**, 2253–2264 (2017).
188. Nankaku, M. *et al.* Hip external rotator exercise contributes to improving physical functions in the early stage after total hip arthroplasty using an anterolateral approach: a randomized controlled trial. *Disabil. Rehabil.* (2016) doi:10.3109/09638288.2015.1129453.
189. Steffen, T. M., Hacker, T. A. & Mollinger, L. Age- and gender-related test performance in community-dwelling elderly people: Six-Minute Walk Test, Berg Balance Scale, Timed Up & Go Test, and gait speeds. *Phys. Ther.* (2002) doi:10.1093/ptj/82.2.128.
190. Lusardi, M. M., Pellecchia, G. L. & Schulman, M. Functional Performance in Community Living Older Adults. *J. Geriatr. Phys. Ther.* (2003) doi:10.1519/00139143-200312000-00003.
191. Naylor, J. M., Harmer, A. R., Heard, R. C. & Harris, I. A. Patterns of recovery following knee and hip replacement in an Australian cohort. *Aust. Heal. Rev.* (2009) doi:10.1071/AH090124.
192. Kennedy, D. M., Stratford, P. W., Hanna, S. E., Wessel, J. & Gollish, J. D. Modeling early recovery of physical function following hip and knee arthroplasty. *BMC Musculoskelet. Disord.* (2006) doi:10.1186/1471-2474-7-100.
193. Charbonnier, C. *et al.* Analysis of hip range of motion in everyday life: A pilot study. *HIP Int.* (2015) doi:10.5301/hipint.5000192.
194. Sashika, H., Matsuba, Y. & Watanabe, Y. Home program of physical therapy: Effect on disabilities of patients with total hip arthroplasty. *Arch. Phys. Med. Rehabil.* (1996) doi:10.1016/S0003-9993(96)90111-2.

195. Heiberg, K. E., Bruun-Olsen, V., Ekeland, A. & Mengshoel, A. M. Effect of a walking skill training program in patients who have undergone total hip arthroplasty: Followup one year after surgery. *Arthritis Care Res.* (2012) doi:10.1002/acr.20681.
196. Umpierres, C. S. *et al.* Rehabilitation following total hip arthroplasty evaluation over short follow-up time: Randomized clinical trial. *J. Rehabil. Res. Dev.* (2014) doi:10.1682/JRRD.2014.05.0132.
197. Trudelle-Jackson, E., Emerson, R. & Smith, S. Outcomes of Total Hip Arthroplasty: A Study of Patients One Year Postsurgery. *J. Orthop. Sport. Phys. Ther.* (2002) doi:10.2519/jospt.2002.32.6.260.
198. Tannast, M. *et al.* Noninvasive three-dimensional assessment of femoroacetabular impingement. *J. Orthop. Res.* (2007) doi:10.1002/jor.20309.
199. Roos, E. M., Roos, H. P., Lohmander, L. S., Ekdahl, C. & Beynnon, B. D. Knee Injury and Osteoarthritis Outcome Score (KOOS)—Development of a Self-Administered Outcome Measure. *J. Orthop. Sport. Phys. Ther.* **28**, 88–96 (1998).
200. Alviar, M. J. *et al.* Do patient-reported outcome measures in hip and knee arthroplasty rehabilitation have robust measurement attributes? A systematic review. *J. Rehabil. Med.* **43**, 572–583 (2011).
201. Monticone, M., Ferrante, S., Salvaderi, S., Motta, L. & Cerri, C. Responsiveness and minimal important changes for the knee injury and osteoarthritis outcome score in subjects undergoing rehabilitation after total knee arthroplasty. *Am. J. Phys. Med. Rehabil.* (2013) doi:10.1097/PHM.0b013e31829f19d8.
202. Yuksel, E., Kalkan, S., Cekmece, S., Unver, B. & Karatosun, V. Assessing Minimal Detectable Changes and Test-Retest Reliability of the Timed Up and Go Test and the 2-Minute Walk Test in Patients With Total Knee Arthroplasty. *J. Arthroplasty* (2017) doi:10.1016/j.arth.2016.07.031.
203. Mizner, R. L., Petterson, S. C. & Snyder-Mackler, L. Quadriceps Strength and the Time Course of Functional Recovery After Total Knee Arthroplasty. *J. Orthop. Sport. Phys. Ther.* (2005) doi:10.2519/jospt.2005.35.7.424.
204. Stratford, P. W., Kennedy, D. M. & Robarts, S. F. Modelling knee range of motion post arthroplasty: Clinical applications. *Physiother. Canada* (2010) doi:10.3138/physio.62.4.378.
205. Mutsuzaki, H., Takeuchi, R., Mataki, Y. & Wadano, Y. Target range of motion for rehabilitation after total knee arthroplasty. *J. Rural Med.* **12**, 33–37 (2017).
206. López-Liria, R. *et al.* Home-based versus hospital-based rehabilitation program after total knee replacement. *Biomed Res. Int.* **2015**, (2015).
207. Bade, M. J., Kohrt, W. M. & Stevens-Lapsley, J. E. Outcomes Before and After Total Knee Arthroplasty Compared to Healthy Adults. *J. Orthop. Sport. Phys. Ther.* (2010) doi:10.2519/jospt.2010.3317.
208. Moffet, H. *et al.* Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single-blind randomized controlled trial. *Arch. Phys. Med. Rehabil.* **85**, 546–556 (2004).
209. Judd DL, Wolfe P, LeDoux CV, Hogan C, Dayton MR, S.-L. J. Trajectories of functional performance and muscle strength recovery differ after total knee and total hip replacement: a performance-based, longitudinal study. *Int J Rehabil Res.* **42**, 211–216 (2019).
210. El Bitar, Y. F., Illingworth, K. D., Scaife, S. L., Horberg, J. V. & Saleh, K. J. Hospital Length of Stay following Primary Total Knee Arthroplasty: Data from the Nationwide Inpatient Sample Database. *J. Arthroplasty* (2015) doi:10.1016/j.arth.2015.05.003.
211. Brooke, J. SUS - A quick and dirty usability scale. in *Usability Evaluation in Industry* (1996). doi:10.1002/hbm.20701.
212. Manual do Trabalho e Emprego, 30, 15/8/2014.

213. *Decreto-Lei 106/98 de 24 de Abril*.
214. Brown, S. Preserving the human touch in medicine in a digital age. *CMAJ* (2019) doi:10.1503/cmaj.109-5757.
215. Topol, E. J. High-performance medicine: the convergence of human and artificial intelligence. *Nature Medicine* (2019) doi:10.1038/s41591-018-0300-7.
216. Burge, E., Monnin, D., Berchtold, A. & Allet, L. Cost-Effectiveness of Physical Therapy Only and of Usual Care for Various Health Conditions: Systematic Review. *Phys. Ther.* (2016) doi:10.2522/ptj.20140333.
217. Jiang, F. *et al.* Artificial intelligence in healthcare: Past, present and future. *Stroke and Vascular Neurology* (2017) doi:10.1136/svn-2017-000101.
218. James, S. L. *et al.* Global, regional, and national incidence, prevalence, and years lived with disability for 354 Diseases and Injuries for 195 countries and territories, 1990-2017: A systematic analysis for the Global Burden of Disease Study 2017. *Lancet* (2018) doi:10.1016/S0140-6736(18)32279-7.
219. Grant, H. J., Arthur, A. & Pichora, D. R. Evaluation of interventions for rotator cuff pathology: A systematic review. *J. Hand Ther.* (2004) doi:10.1197/j.jht.2004.02.013.
220. Seida, J. C. *et al.* Systematic review: Nonoperative and operative treatments for rotator cuff tears. *Annals of Internal Medicine* (2010) doi:10.7326/0003-4819-153-4-201008170-00263.
221. Thomson, S., Jukes, C. & Lewis, J. Rehabilitation following surgical repair of the rotator cuff: A systematic review. *Physiotherapy (United Kingdom)* (2016) doi:10.1016/j.physio.2015.08.003.
222. Littlewood, C. *et al.* Rehabilitation following rotator cuff repair: a systematic review. *Shoulder Elb.* (2015) doi:10.1177/1758573214567702.
223. Laible, C., Stein, D. A. & Kiridly, D. N. Mensical Repair. *Jaaos* 204–213 (1948).
224. Cavanaugh, J. T. & Killian, S. E. Rehabilitation following meniscal repair. *Current Reviews in Musculoskeletal Medicine* (2012) doi:10.1007/s12178-011-9110-y.
225. O'Donnell, K., Freedman, K. B. & Tjoumakaris, F. P. Rehabilitation Protocols after Isolated Meniscal Repair: A Systematic Review. *American Journal of Sports Medicine* (2017) doi:10.1177/0363546516667578.
226. Chen, W.-H., Tsai, W.-C., Wang, H.-T., Wang, C.-H. & Tseng, Y.-T. Can early rehabilitation after osteoarthritis reduce knee and hip arthroplasty risk? *Medicine (Baltimore).* (2019) doi:10.1097/md.0000000000015723.
227. O'Connell, N. E., Cook, C. E., Wand, B. M. & Ward, S. P. Clinical guidelines for low back pain: A critical review of consensus and inconsistencies across three major guidelines. *Best Practice and Research: Clinical Rheumatology* (2016) doi:10.1016/j.berh.2017.05.001.
228. Littlewood, C., May, S. & Walters, S. Epidemiology of Rotator Cuff Tendinopathy: A Systematic Review. *Shoulder Elb.* (2013) doi:10.1111/sae.12028.
229. Beaudreuil, J., Dhénain, M., Coudane, H. & Mlika-Cabanne, N. Clinical practice guidelines for the surgical management of rotator cuff tears in adults. *Orthopaedics and Traumatology: Surgery and Research* (2010) doi:10.1016/j.otsr.2010.02.002.
230. Gebremariam, L., Hay, E. M., Koes, B. W. & Huisstede, B. M. Effectiveness of surgical and postsurgical interventions for the subacromial impingement syndrome: A systematic review. *Archives of Physical Medicine and Rehabilitation* (2011) doi:10.1016/j.apmr.2011.06.006.
231. Pedowitz, R. A. *et al.* Optimizing the management of rotator cuff problems. *J. Am. Acad. Orthop. Surg.* (2011) doi:10.5435/00124635-201106000-00007.
232. Ridley, T. J., McCarthy, M. A., Bollier, M. J., Wolf, B. R. & Amendola, A. Age Differences in the Prevalence of Isolated Medial and Lateral Meniscal Tears in Surgically Treated Patients. *Iowa Orthop. J.* (2017).
233. Abrams, G. D. *et al.* Trends in meniscus repair and meniscectomy in the United States, 2005-

2011. *Am. J. Sports Med.* (2013) doi:10.1177/0363546513495641.
234. Englund, M. The Role of the Meniscus in Osteoarthritis Genesis. *Medical Clinics of North America* (2009) doi:10.1016/j.mcna.2008.08.005.
235. Thorlund, J. B., Juhl, C. B., Roos, E. M. & Lohmander, L. S. Arthroscopic surgery for degenerative knee: Systematic review and meta-analysis of benefits and harms. *British Journal of Sports Medicine* (2015) doi:10.1136/bjsports-2015-h2747rep.
236. Kise, N. J. *et al.* Exercise therapy versus arthroscopic partial meniscectomy for degenerative meniscal tear in middle aged patients: Randomised controlled trial with two year follow-up. *Br. J. Sports Med.* (2016) doi:10.1136/bjsports-2016-i3740rep.

ANEXES

Annex I: Published Paper "Home-based rehabilitation with a novel digital biofeedback system versus conventional in-person rehabilitation after total knee replacement: a feasibility study."

Annex II: Published Paper "Medium-term outcomes after Total Knee Replacement: follow up results of a feasibility study comparing digital versus conventional home-based rehabilitation."

Annex III: Published Paper "Digital versus conventional rehabilitation after total hip arthroplasty."

Annex IV: E-Poster certificate "Home-based rehabilitation with SWORD Phoenix versus standard of care after total knee replacement: a randomized controlled study."

Annex V: Scientific Program and Certificate for the Lectures presented at the 13th International Society of Physical and Rehabilitation Medicine World Congress, Kobe, 9-12 June 2019

Annex VI: Best Innovation Award ISPRM 2018

Annex VII: HOOS Scale (Portuguese version)

Annex VIII: KOOS Scale (Portuguese version)

Annex IX: Participant information and Informed Consent Form

Annex X: Data Protection Authority Authorization

Annex XI: Ethics Committee Authorization

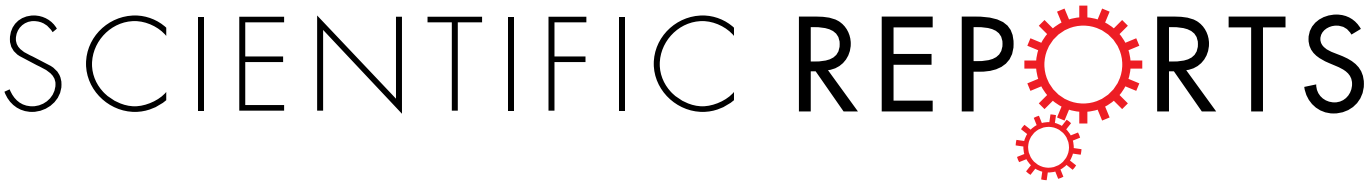
Annex I

PUBLISHED PAPER

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V.

Home-based rehabilitation with a novel digital biofeedback system versus conventional in-person rehabilitation after total knee replacement: a feasibility study.

Sci Rep 2018; Jul 26; 8(19):11299. Doi: 10.1038/s41598-018-29668-0



OPEN

Home-based Rehabilitation With A Novel Digital Biofeedback System versus Conventional In-person Rehabilitation after Total Knee Replacement: a feasibility study

Received: 9 April 2018
Accepted: 16 July 2018
Published online: 26 July 2018

Fernando Dias Correia[1,2], André Nogueira[1], Ivo Magalhães[1], Joana Guimarães[1], Maria Moreira[1], Isabel Barradas[1], Laetitia Teixeira[3,4,5], José Tulha[6], Rosmaninho Seabra[6], Jorge Lains[7] & Virgilio Bento[1,8]

In-person home-based rehabilitation and telerehabilitation can be as effective as clinic-based rehabilitation after total knee arthroplasty (TKA), but require heavy logistics and are highly dependent on human supervision. New technologies that allow independent home-based rehabilitation without constant human supervision may help solve this problem. This was a single-center, feasibility study comparing a digital biofeedback system that meets these needs against conventional in-person home-based rehabilitation after TKA over an 8-week program. Primary outcome was the change in the Timed Up and Go score between the end of the program and baseline. Fifty-nine patients completed the study (30 experimental group; 29 conventional rehabilitation). The study demonstrated a superiority of the experimental group for all outcomes. Adverse events were similar in both groups. This is the first study to demonstrate that a digital rehabilitation solution can achieve better outcomes than conventional in-person rehabilitation, while less demanding in terms of human resources.

With the aging population, there has been a substantial increase in the demand for Total Knee Arthroplasty (TKA). The incidence in TKA has nearly doubled[1] from 2000 to 2013, and will continue to rise in the next decades. In the US, it has been estimated that by 2030, the demand for primary TKA will increase by 673% and for revision TKA by 601% compared to 2005[2]. This will translate into around 3.48 million primary and 268.000 revision procedures[2].

TKA is associated with significant pain relief, functional improvements and an increase in the quality of life[3–5]. Physical rehabilitation improves results after TKA[6], but the provision of these services varies widely in content and duration[7,8]. In the current context of increasing demand and a pressing need to contain expenditure[9], ensuring access to effective rehabilitation while minimizing costs is both a priority and a challenge.

Currently, there are no universally accepted guidelines for rehabilitation after TKA[10,11]. There is, however, evidence favoring therapeutic exercise as the primary component[10] and that progression upon achievement of milestones and higher intensity lead to better outcomes[12,13], even if optimal dose and progression timings are unknown[11].

A recent Delphi panel on rehabilitation after TKA recommended that rehabilitation should be started within 3 weeks of discharge[11]. There was no consensus on the duration, frequency, and number of treatment sessions. The greatest support was for 4 to 12 weeks of supervised rehabilitation, 2 to 3 times per week[11].

[1]SWORD Health, Porto, Portugal. [2]Neurology Department, Hospital de Santo António- Centro Hospitalar do Porto, Porto, Portugal. [3]Department of Population Studies, Abel Salazar Institute of Biomedical Sciences, Porto, Portugal. [4]CINTESIS, Abel Salazar Institute of Biomedical Sciences, University of Porto, Porto, Portugal. [5]EPIUnit - Instituto de Saúde Pública, Universidade do Porto, Porto, Portugal. [6]Orthopaedics Department, Hospital da Prelada- Domingos Braga da Cruz, Porto, Portugal. [7]Rovisco Pais Medical and Rehabilitation Centre, Tocha, Portugal. [8]University Institute of Maia - ISMAI, Maia, Portugal. Correspondence and requests for materials should be addressed to F.D.C. (email: fanacorreia@gmail.com)

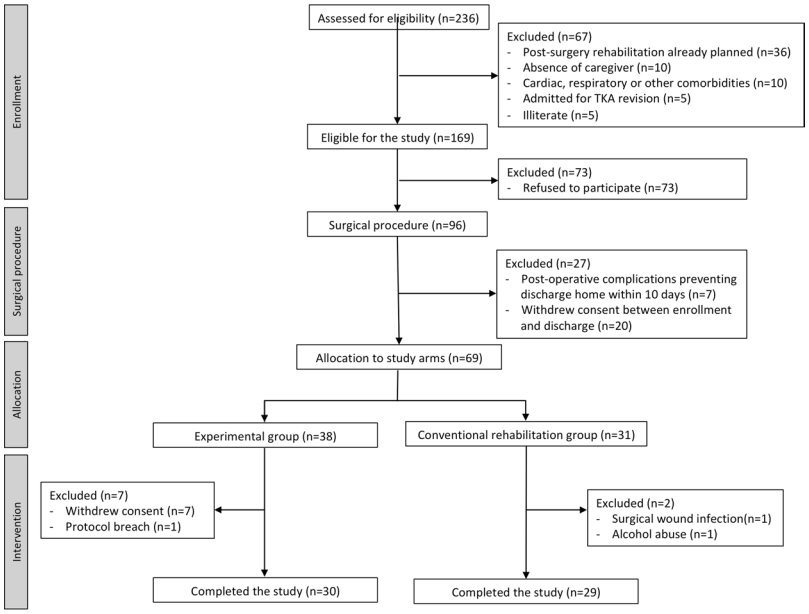


Figure 1. Study CONSORT diagram.

Regarding rehabilitation setting, home and clinic-based rehabilitation protocols have generated similar improvements[14–19]. This is in line with the recent trends in healthcare delivery, towards home-based care[20] aiming to improve cost-effectiveness.

Home-based approaches in rehabilitation, however, are very demanding both in terms of logistics and in human resources, which are scarce and costly. In an attempt to maximize access and minimize costs, tele-rehabilitation solutions have been developed and tested. For rehabilitation after knee or hip replacement, these have demonstrated similar outcomes in comparison to standard rehabilitation[21–27], and there is preliminary evidence that these solutions may be cost-effective[28]. However, these solutions still require human supervision, either during home-based sessions or during complementary supervised sessions, limiting widespread availability.

Technological solutions that empower patients and allow home-based rehabilitation to take place without the need for real-time human supervision could be the key to improve effectiveness and lower costs. While there have been some advances in novel technologies for neurological rehabilitation, there is scant validation on solutions for musculoskeletal disorders, apart from those based on electromyography feedback[29–31]. For lower limb disorders, there is only preliminary validation of the Nintendo® Wii® Fit console as an adjunct to conventional physiotherapy after TKA[32,33] or anterior cruciate ligament reconstruction[33,34]. Apart from this, we have found no validation for camera-based systems and only one study published on a solution based on inertial motion trackers[23]. This study included 142 patients, which were randomized to receive a 2-week program after surgery (10 sessions) with this system or conventional rehabilitation. The outcomes were similar in both groups, but the intervention duration was too short to draw definitive conclusions[23].

We have tested a novel digital biofeedback system for home-based physical rehabilitation (SWORD). Using inertial motion trackers, this system digitizes patient motion and provides real-time feedback on performance through a mobile app. It also includes a web-based platform that allows the clinical team to prescribe, monitor and adapt the rehabilitation process remotely. This way, the system allows patients to perform independent rehabilitation sessions at home without the need for constant therapist supervision, ensuring remote monitoring throughout the rehabilitation program.

The present study was a single-center, parallel-group, feasibility study designed to compare the clinical outcomes of a home-based program using this system against conventional in-person home-based rehabilitation after TKA, as well as assess patient uptake and safety of this novel feedback system. We hypothesize that the clinical outcomes of such a program will be at least similar to those of traditional rehabilitation.

Results

Two hundred and thirty six patients were assessed for eligibility between December 2016 and October 2017. Figure 1 shows the CONSORT diagram for the study. The study inclusion rate was of 29%. Between initial assessment and allocation to one of two study arms, a total of 93 patients refused to participate or withdrew consent, corresponding to 56% of all screening failures.

Sixty-nine patients were included and allocated to one of two study groups, according to their address of residence (37 on the experimental group and 32 on the conventional rehabilitation group). On the experimental group, 7 patients withdrew consent on the first week of the study, and one additional patient was excluded due to a protocol breach (additional physical therapy program started) corresponding to a 21% dropout rate in this group. On the conventional rehabilitation group, 2 patients were excluded, corresponding to a 7% dropout rate in this

	Total (n = 69)	Experimental group (n = 38)	Conventional rehabilitation (n = 31)	*p* value
Demographics				
Age (years) mean (sd)	68.5 (7.0)	67.3 (6.8)	70.0 (7.2)	0.116[$]
Gender Female (%)	78.3	84.2	71.0	0.302[#]
Side Right (%)	55.1	63.2	45.2	0.211[#]
Comorbidities & Known risk factors for adverse events				
Body Mass Index mean (sd)	30.9 (4.9)	31.0 (4.5)	30.8 (5.4)	0.837[$]
Smoking (%)	11.6	10.5	12.9	1.000*
Hypertension (%)	69.6	65.8	74.2	0.623[#]
Diabetes (%)	15.9	18.4	12.9	0.743*
Pulmonary disease (%)	13.0	7.9	19.4	0.281*
Cardiac disease (%)	5.8	5.3	6.5	1.000*
Stroke (%)	0.0	0.0	0.0	NA
Renal disease (%)	1.4	0.0	3.2	0.449*
Bleeding disorders (%)	0.0	0.0	0.0	NA
ASA[€] class 3 or 4 (%)	14.5	13.2	16.1	0.745*
Steroids for chronic condition (%)	0.0	0.0	0.0	NA
Previous contralateral knee replacement	24.6	18.4	32.3	0.296[#]
Previous hip replacement	4.3	7.9	0.0	0.247*
Hospital admission and surgical procedure				
Time between admission and surgery (hours)	<24 h	<24 h	<24 h	NA
Operative time (min) mean (sd)	62.6 (11.3)	62.4 (9.87)	62.8 (13.0)	0.887[$]
Minor adverse events before discharge (%)	1.4	0.0	3.2	0.449*
Hospital length of stay (days)				0.953[#]
3 or 4 days (%)	23.2	21.1	25.8	
5 days (%)	23.2	23.7	22.6	
6 days (%)	31.9	34.2	29.0	
7 to 9 days (%)	21.7	21.1	22.6	

Table 1. Baseline characteristics of study participants. [€]American Society of Anesthesiology physical status classification system [#]Chi-Square test; *Fisher's exact test; [$]independent samples T test.

group. In total, 59 patients completed the study (30 patients in the experimental group and 29 in the conventional rehabilitation group).

Study population characterization. Baseline characteristics of study participants regarding demographics, comorbidities and risk factors for adverse events, as well as data on hospitalization and surgery are summarized in Table 1 (total sample and divided by allocation group). There were no differences between the two study groups regarding these characteristics. The baseline assessment of the outcome variables is summarized in Table 2. At baseline, there were no differences between the two study groups regarding the primary outcome variable (TUG) nor regarding knee range of motion. Regarding the KOOS, the population in the experimental group had lower scores in every subscale.

Considering only the patients who completed the study and that were included in the per-protocol analysis (30 patients in the experimental group and 29 in the conventional rehabilitation group), at baseline, there were no differences between the two study groups regarding TUG ($p = 0.129$) and knee range of motion ($p = 0.345$ for lying knee flexion; $p = 0.187$ for sitting knee flexion; $p = 0.147$ for standing knee flexion; $p = 0.425$ for sitting knee extension). Regarding the KOOS, the experimental group had lower scores in every subscale ($p < 0.001$ for Symptoms; $p < 0.001$for Pain; $p = 0.005$ for ADL; $p = 0.006$ for Sports and $p = 0.007$ for QOL) (see also Table 3).

Outcomes assessment. *Change between baseline and the 8-week assessment.* The change was superior in the experimental group in all outcome measures (see Table 3).

Based on the MCID reported in the literature for TUG (2.27 seconds)[35] clinically significant improvements were noted in both groups. The difference between the median changes in the two groups was of 4.9 seconds, favoring the experimental group (i.e. greater improvement in this group). This difference is more than twice the MCID and therefore clinically significant.

Regarding KOOS, the improvement noted in both groups was superior to the 8–10 point MCID[36] in every subscale, denoting clinical significant changes (see Table 3). As with TUG, the difference between the median changes in the two groups was of over 20 points in all subscales except for the Sports subscale (see a Table 3),

	Total (n = 69)	Experimental group (n = 38)	Conventional rehabilitation group (n = 31)	*p* value
Primary Outcome				
TUG (seconds) median (IQR)	16.59 (7.43)	18.19 (7.6)	15.98 (8.6)	0.120*
Secondary Outcomes				
Range of Motion				
mean (sd)				
Lying Knee Flexion	82.9 (16.0)	81.3 (20.2)	84.8 (31.0)	0.366*
Sitting Knee Flexion	88.0 (14.3)	85.8 (15.2)	90.7 (12.8)	0.158#
Standing Knee Flexion	74.8 (18.9)	72.0 (20.5)	78.3 (16.3)	0.172#
Sitting Knee Extension	26.2 (8.8)	27.4 (9.6)	24.8 (7.6)	0.237#
KOOS				
median (IQR)				
Symptoms	39.0 (28.0)	33.4 (14.8)	52.1 (16.4)	<0.001#
Pain	39.0 (16.0)	35.4 (8.7)	47.3 (12.6)	<0.001#
ADL	38.0 (17.0)	34.0 (25.2)	43.0 (24.0)	0.001*
Sports	0.0 (5.0)	0.0 (6.2)	5.0 (10.0)	0.004*
QOL	13.0 (19.0)	13.0 (18.0)	19.0 (31.0)	0.012*

Table 2. Pre-operative assessment of outcome measures in study participants. #Independent samples T test; *Mann-Whitney U Test.

	Baseline assessment		8-week assessment		Change		
Outcome variable	Experimental group (n = 30)	Conventional rehabilitation (n = 29)	Experimental group (n = 30)	Conventional rehabilitation (n = 29)	Experimental group (n = 30)	Conventional rehabilitation (n = 29)	*p* value
Primary outcome							
TUG median (IQR)	18.2 (6.2)	15.3 (8.5)	7.8 (2.7)	10.1 (4.1)	−9.5 (8.0)	−4.6 (8.6)	0.04*
Secondary outcomes							
Range of Motion							
mean (sd)							
Lying knee Flexion	80.7 (12.4)	84.7 (18.7)	100.0 (11.3)	92.6 (13.1)	19.3 (17.0)	7.7 (16.8)	0.012#
Lying Knee Flexion	85.3 (16.0)	90.4 (13.1)	101.5 (9.6)	97.0 (11.3)	16.3 (17.7)	6.7 (13.5)	0.021#
Sitting Knee Flexion	71.6 (20.3)	18.8 (16.6)	95.8 (8.8)	86.1 (10.8)	24.2 (20.9)	7.4 (13.9)	0.001#
Standing Knee Flexion	26.5 (8.4)	24.8 (7.8)	14.5 (8.2)	22.8 (9.6)	−12.1 (11.1)	−1.6 (13.3)	0.002#
KOOS							
median (IQR)							
Symptoms	34.0 (20.0)	50.0 (29.0)	81.0 (14.5)	71.0 (14.0)	50.0 (26.0)	18.0 (21.0)	<0.001*
Pain	33.0 (12.0)	47.0 (24.0)	90.5 (16.0)	78.0 (16.0)	57.0 (16.3)	34.0 (25.0)	<0.001*
ADL	34.0 (18.0)	41.0 (18.0)	90.5 (0.0)	76.0 (5.0)	54.5 (16.5)	36.0 (19.0)	<0.001*
Sports	0.0 (0.0)	5.0 (8.0)	20.0 (19.0)	15.0 (19.0)	20.0 (7.5)	15.0 (15.0)	0.04*
QOL	13.0 (19.0)	25.0 (19.0)	69.0 (0.0)	56.0 (0.0)	56.0 (20.5)	31.0 (31.0)	<0.001*

Table 3. Outcomes assessment - change between 8-weeks assessment and baseline. #Independent samples T test; *Mann-Whitney U Test.

in favor of the experimental group. Again, these differences are superior to the MCID and, hence, clinically significant.

Even though there are no MCID validated for knee range of motion in patients submitted to TKA, a study by Stratford and collaborators[37] reported a MDC90 (Minimal Detectable Change at a 90% confidence interval) of 9.6 degrees for knee flexion and 6.3 degrees for knee extension in patients after TKA. Therefore, significant improvements in knee range of motion were noted only in the experimental group.

Results of the 8-week assessment. In the 8-week assessment, the TUG scores were lower in the experimental group than in the conventional rehabilitation group (median 7.8 seconds; IQR 2.7 versus 10.1 seconds; IQR 3.1) ($p < 0.001$), i.e. patients in the experimental group were faster than the patients in the other group.

The same was observed for knee range of motion, which was higher in experimental group for lying knee flexion ($p = 0.024$); standing knee flexion ($p < 0.001$) and for sitting knee extension ($p = 0.01$) but not for sitting knee flexion ($p = 0.1$).

Outcome variable	Time		Group		Time*Group	
	F(df1,df2)	*p*	F(df1,df2)	*p*	F(df1,df2)	*p*
Patient performance						
TUG[#&]	F(1.7,94.1) = 104.1	<0.001	F(1,57) = 7.6	0.008	F(1.7,94.1) = 17.9	<0.001
Knee range of motion						
Lying Flexion[#&]	F(1.2,71.2) = 29.7	<0.001	F(1,57) = 0.20	0.653	F(1.2,71.2) = 4.2	0.038
Sitting Flexion[&]	F(1.3,74.6) = 23.5	<0.001	F(1,57) = 0.01	0.921	F(1.3,74.6) = 4.2	0.035
Standing Flexion[&]	F(1.3,75.1) = 30.1	<0.001	F(1,57) = 0.55	0.460	F(1.3,75.1) = 8.6	0.002
Sitting Extension[§]	F(2,114) = 14.6	<0.001	F(1,57) = 12.0	0.001	F(2,114) = 8.0	0.001

Table 4. Outcomes assessment - Repeated measures analysis. [#]ln transformation; [§]sqrt transformation; [&]Greenhouse-Geisser correction.

Regarding KOOS, the scores in the experimental group were superior to the conventional rehabilitation group for KOOS Symptoms ($p = 0.001$); KOOS Pain ($p < 0.001$); KOOS ADL ($p = 0.001$) and KOOS QOL ($p < 0.001$), but not for KOOS Sports ($p = 0.094$).

Repeated measures analysis. This analysis was performed only for normally distributed variables - TUG and knee range of motion- after transformation. The results are summarised in Table 4.

While both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time, a main effect of group and an interaction between time and group in favour of the experimental group in all outcomes (see Table 4 and Fig. 2).

Treatment intensity. The total active treatment time was superior in the experimental group, with a median of 31.5 hours (IQR 18.0; range 10.8–69.1) versus 24 hours in the control group ($p = 0.005$). Time spent on additional unsupervised sessions by patients in the control group was not considered, as patients were not requested to register these sessions.

Therapist-patient interaction. In the conventional rehabilitation group, each patient had 24 face-to-face sessions. In the experimental group, each patient had 3 face-to-face contacts with the therapist (on deployment, 4 weeks into the rehabilitation program and on termination), and on average, 0.4 (sd = 0.7; range 0–2) extra contacts for technical assistance. Regarding telephone calls, in addition to the two scheduled calls per protocol (at weeks 2 and 6), each patient received a median of 2.5 extra calls (IQR = 3.0; range 1–12).

Independence of use. In the experimental group, 60% of the patients required the assistance of a caregiver either in motion tracker/strap placement or in the interaction with the app. There was no age difference between autonomous patients (median 65.5 years; IQR 13) or those needing assistance (median 65.5 years; IQR 13) ($p = 0.185$).

Patient satisfaction. In the experimental group, patients were asked to answer the following question at the end of the program "On a scale from 0 to 10, how much would you recommend the system to one of your friends or neighbours?". From the 30 patients, 27 (90.0%) rated the system with 10, one patient rated the system with 9 and two rated the system with 8.

Safety and adverse events. In the experimental group, from the patients who were initially enrolled, adverse events were reported in only one patient (thrombophlebitis), corresponding to an adverse event rate of 2.6%. In the conventional rehabilitation group, from the patients who were initially enrolled, one patient was excluded due to a surgical wound infection requiring readmission to hospital and a revision procedure, and another was excluded for alcohol abuse interfering with the compliance with the rehabilitation program. Inflammatory signs over the surgical wound were reported in three additional patients and thrombophlebitis in one. This corresponds to an adverse event rate of 22.5%. This difference was not significant ($p = 0.065$).

Discussion

Given the paucity of studies in this area, comparison of the results of the present study with similar studies is not possible, except with a study published by Piqueras *et al.*[23], where a solution broadly similar to the SWORD device was tested. We will therefore consider, in addition, other studies published on rehabilitation after TKA[12,13,38], on home versus clinic-based interventions[17] or tele-rehabilitation versus conventional rehabilitation[23,25,26].

In the study by Piqueras *et al.*[23], the outcomes were similar in both groups[23]. However, in this study, the intervention time (10 sessions over 2 weeks) was too short to allow the detection of differences between groups, and treatment intensity was inferior to current recommendations[10,11]. In fact, treatment intensity is highly variable in published studies on rehabilitation after TKA and we have found only one study where treatment intensity was comparable to the one provided to the patients in the present study[12]. This study, by Bade *et al.*[12], compared two different treatment intensities in the rehabilitation after TKA, in an outpatient setting, with the high intensity group performing 25 sessions in 12 weeks, which was similar to the treatment intensity in the conventional rehabilitation group in our study.

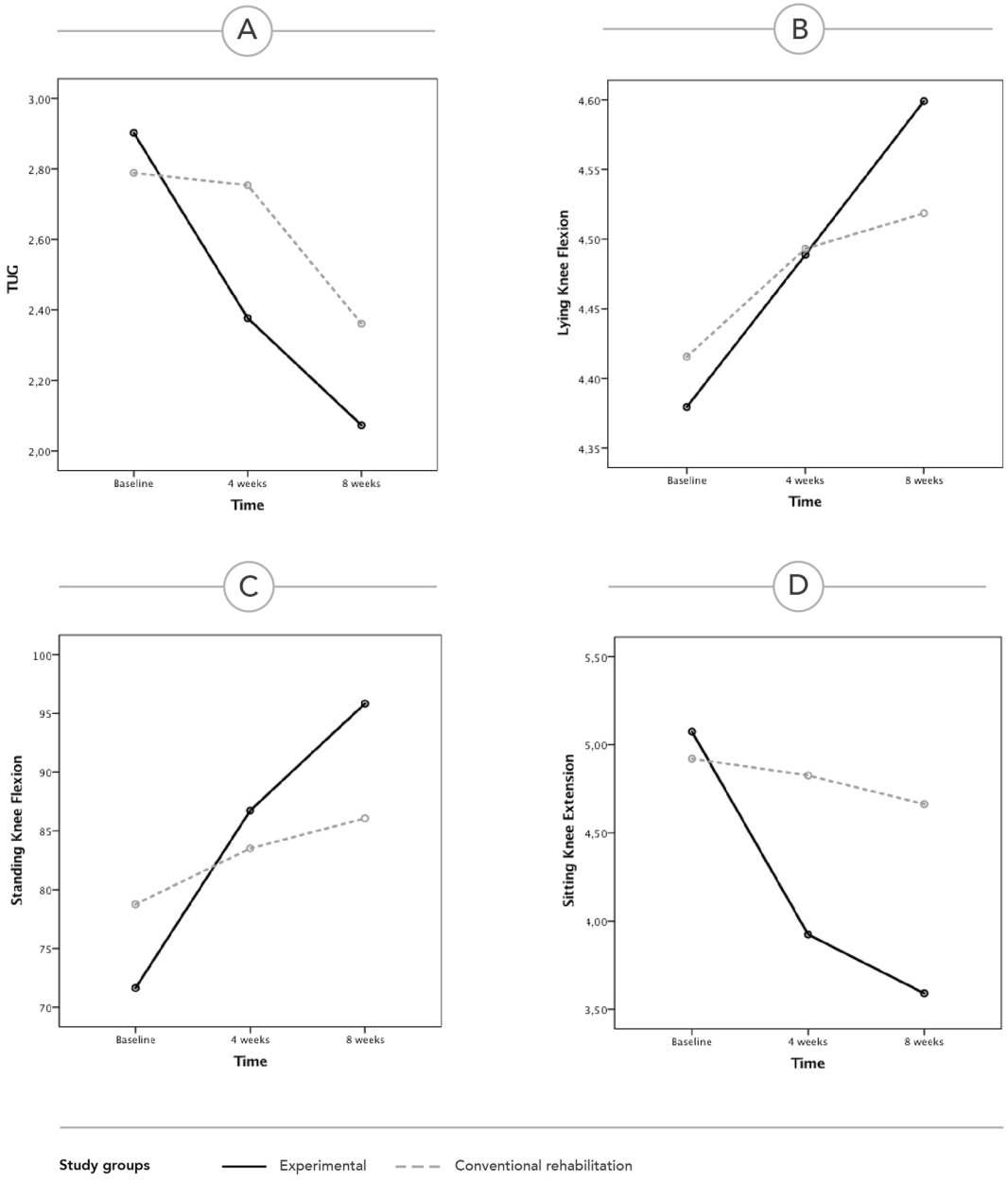


Figure 2. Evolution of the outcomes over time in both groups, based on the repeated measures analysis (estimated marginal means of transformed variables are presented). (**A**) TUG score. (**B**) Lying knee flexion. (**C**) Standing knee flexion. (**D**) Sitting knee extension.

Previous published studies demonstrated similar outcomes for home versus clinic-based rehabilitation[12,13,17,18,38] or tele-rehabilitation versus conventional rehabilitation[23,25,26]. The present study, however, demonstrated a clear superiority of the experimental group for all outcomes (performance tests, knee range of motion and patient reported outcomes) in terms of change between baseline and the 8-week assessment (see Table 3). Plus, for TUG and knee range of motion, this superiority was corroborated by the repeated measures analysis, which clearly demonstrates an association between these outcomes, time and intervention in favor of the experimental group (see Table 4 and Fig. 2).

Given the wide variation in terms of pre- and post- intervention TUG scores in published studies on rehabilitation after TKA[12,13,23,25,38], comparison with published data is difficult. Still, the study by Mizner *et al.*[38] on the time course of functional recovery after TKA reported a mean improvement of 1.7 seconds between the pre-operative and 3 months assessment, and the study by Bade *et al.*[12] reported a mean change of 1.6 seconds in the high intensity rehabilitation group after 3 months. These results are lower than what was observed in our study for both groups. In comparison with the results reported by Petterson *et al.*[13] in a study on progressive strengthening interventions after TKA (4.08 seconds improvement at 3 months), the results of the experimental group are superior whereas the results of the conventional group are comparable. It is however, necessary to stress

that these studies reported the change between baseline and 3 months whereas we are comparing the change between baseline and 8 weeks.

Considering papers published on tele-rehabilitation solutions, the results observed in the experimental group are clearly superior to those reported by Piqueras *et al*. for the tele-rehabilitation group (−5.22 seconds change)[23]- still, with the caveat of the short timeline of the intervention in this study - but lower than those reported by Russel *et al*.[25]. However, in the latter study, the baseline TUG scores were much higher than those observed in our study (mean scores of 28.8 ± 16.6 seconds in the tele-rehabilitation group and 26.8 ± 12.1 seconds in the control group)[25].

Regarding knee range of motion, even if these measures represent poor markers of implant success and patient satisfaction[10,39,40], significant improvements were noted in both groups. The mean change in lying knee flexion observed in the experimental group (19.3) was comparable to that reported in other studies on home- versus clinic-based rehabilitation (15.0–17.0 degrees)[17] and tele-rehabilitation (17.8–19.8)[25] and higher than those reported by Piqueras *et al*. for the tele-rehabilitation group (7.7)[23]. The results in the conventional rehabilitation group were inferior to those reported by these authors, but still with a mean lying flexion angle above 90 degrees at the 8-week assessment (see Table 3). Regarding knee extension, comparison with published studies is more complicated. In this study, knee extension at baseline was much worse- 26.8 degrees (sd = 8.8) than reported by other studies[17,23,25,41]. However, we tested knee extension in a sitting position, which is more demanding than in a supine position, whereas some authors opted for the latter[12,13,38] or simply did not specify patient position[21–23,26].

Regarding KOOS, in the conventional rehabilitation group, the change was comparable to the change reported by Moffet *et al*. for both groups (conventional and tele-rehabilitation) regarding the Symptoms, Sports and QOL subscores (18.0 vs 14.3–16.8 points; 15.0 vs 13.1–14.3; 31.0 vs 33.9–35.6) and higher for Pain and ADL subscores (34.0 vs 23.5–26.7 points; 36.0 vs 26.0–27.2 points)[26]. In the experimental group, the median change in KOOS was significantly higher, both in comparison to the conventional rehabilitation group and in comparison to the results reported by Moffet *et al*., with differences of over 20 points in all subscales except for the Sports subscale (see above and also Table 3)[26].

However, because the scores in the experimental group were lower in all subscales at baseline (see Tables 2 and 3) it can be argued that analyzing the change between the 8-week assessment and baseline may have benefited the SWORD group over the conventional rehabilitation group. However, the 8-week assessment also shows higher scores in the SWORD Phoenix® group in all subscales except for the Sports subscale, leading to the same conclusion. Plus, the scores are also higher than the ones reported by Moffet *et al*. for the tele-rehabilitation group at the 2-month assessment, except for the Sports and QOL subscales[26].

When analyzing these results, it is important to note that this was a feasibility study where patient allocation was performed according to geographical criteria, and not through randomization. Therefore, even if the two groups were similar in terms of demographics, comorbidities, risk factors for adverse and clinical characteristics (except for KOOS), a number of other factors (namely socio-economic) could have influenced the results.

It is also important to consider that treatment intensity was different between both groups, with the experimental group receiving more therapy hours. This is a potential confounding factor, as evidence points to a positive effect of treatment intensity on outcomes[12]. However, the difference between groups does not factor the additional unsupervised sessions that the patients in the conventional rehabilitation group were instructed to perform. Therefore, treatment intensity in the conventional rehabilitation group was likely underestimated. This is an aspect that needs to be controlled in ensuing studies. Still, even if the effect of treatment intensity on clinical outcomes is truly significant, it would mean that the digital biofeedback system enabled patients to increase treatment intensity without a corresponding increase in therapist contact time or supervision needs, which is the exact purpose of such a system.

Beyond this aspect, we hypothesize that the following factors may have played a role in the superiority of the experimental group: (a) the positive impact of a kinematic biofeedback tool on patient performance, especially regarding error correction and stimulation of a greater range of motion; (b) patient empowerment regarding their rehabilitation process; (c) high patient engagement through the use of gamification strategies; (c) the effect of remote monitoring on patient effort (that is, patients knew that their adherence and performance was being registered and monitored) and (d) the availability of objective data for clinical review, enabling data-driven decisions on program changes.

One other potential confounding factor, apart from treatment intensity, was that the rehabilitation protocols used in the study allowed a certain degree of liberty regarding the choice of specific exercises, targets, sets and repetitions. Therefore, inter-therapist variation could have influenced the results. To minimize this, all patients in the experimental group were treated by the same therapist and patients in the conventional rehabilitation group were treated by two different therapists, all equally trained and with similar levels of experience.

The inclusion rate in this study was low (29%), with a total of 93 patients refusing to participate or withdrawing consent. This corresponded to 56% of all screening failures, indicating that this, and not inclusion and exclusion criteria, was the main reason behind the low inclusion rate. In fact, the baseline characteristics of the study population (see Table 1) clearly demonstrate that the patients that were included in the study are a representative sample of a "real-world" scenario. This high refusal rate, (also observed by Piqueras *et al*.[23]) was to be expected, given that this study involved a new technological solution, which inevitably draws skepticism from the patient side, especially given the mean age of study participants (68.5 years; sd = 7.0).

From the patients who were allocated to the experimental group, 7 (18.5%) withdrew consent on the first week of the study. These patients were responsible for the difference in the dropout rates between both groups (21% vs 7%). We speculate that this may represent the difficulties of an aged population in interacting with technological systems, as is also noted by the low percentage of patients who were able to use the system autonomously (40%). This has been one of the main challenges faced by new technologies in this field, and this system is no exception.

Even after many development iterations, these results demonstrate that there is still much room for improvement regarding usability by elderly patients.

Interestingly, even considering that most of the patients needed assistance in using the system, the patient satisfaction score was very high, with 90% of the patients rated the system as 10/10). When patients were asked to elaborate on the reasons for the score, almost all of them referred the ability to perform their sessions at home, whenever was more convenient, as the main reason for satisfaction. We speculate that the convenience of such a system, both for patients and their caregivers, motivates them to find strategies to overcome the difficulties associated with a new technology.

Regarding adverse events, while differences between the two groups were not statistically significant, there was a clear tendency for a greater number of patients reporting inflammatory signs over the surgical wound in the conventional rehabilitation group. We speculate that this might have been related to an underreporting of this particular adverse event in the experimental group. Being a mild situation, with no clinical relevance, and with spontaneous resolution without the need for medical attention, patients in this group may have not noticed this or neglected to report it to their physical therapist.

In conclusion, this study demonstrates that independent-home based rehabilitation after TKA with this novel digital biofeedback system is feasible, safe and effective. Based on the conclusions drawn from this study, larger, multi-centric, randomized controlled studies are now being planned, to confirm these findings. Plus, to our knowledge, this is the first study to demonstrate that a digital solution can achieve better outcomes than conventional home-based rehabilitation, while being far less demanding in terms of human resources. As such, it may represent a viable and cost-effective solution that can have a tremendous impact not only on rehabilitation after TKA but on physical rehabilitation in general, if the findings of the present study are replicated for other disorders.

Methods

System technical specifications. The system is composed of the following components (Fig. 3A–D):

a) **Inertial motion trackers** (Fig. 1A)
Each tracker comprises gyroscopes, accelerometers and magnetometers, allowing 3D movement quantification. The trackers communicate via Bluetooth LE with a tablet computer. The trackers are placed on body segments using Velcro® straps, in specific positions (Fig. 1A):

I. **Red tracker:** over the sternal manubrium
II. **Green tracker:** anterior surface of the hip, midway between the trochanter and the knee
III. **Blue tracker:** over the anterior tibial crest

b) **Mobile App**
Before each exercise, a video demonstration is presented to the patient (Fig. 3B), complemented with an audio explanation. During execution, the patient is given real-time biofeedback through a dedicated interface (Fig. 3C). Only repetitions assessed as correct contribute to reach the session´s goals. These are defined as movements starting at the baseline and reaching or surpassing the specified range of motion without violating movement or posture constraints. If the patient violates a constraint, an error message is displayed, allowing the patient to correct the movement in the following attempts.

c) **Web-based Portal**
The Portal allows clinical teams to prescribe exercises, monitor results and edit prescriptions. To prescribe a session, the clinician selects the exercises, number of sets, number of repetitions and range of motion for each exercise (Fig. 3D). Upon the performance of a session, the results are uploaded to the platform and available for review (Fig. 3E). Based on this information, the clinical team can edit the session remotely.

Primary outcome. The primary endpoint was the change in patient performance at the end of the 8 week rehabilitation period compared to the baseline, measured through the Timed Up and Go Test (TUG).

Secondary outcomes. The secondary endpoints were the change at the end of the 8 week rehabilitation period compared to the baseline regarding: a) patient reported outcomes, measured by the Knee Osteoarthritis Outcome Scale (KOOS); b) knee range of motion in degrees in the following exercises- lying, sitting and standing knee flexion; sitting knee extension.

Location. Patients were recruited at Hospital da Prelada - Dr. Domingos Braga da Cruz, Porto, Portugal

Sample size estimation. Sample size estimation was performed considering the primary outcome measure - TUG - in an equivalence scenario, based on the study published by Mizner *et al.*[38] (baseline TUG sd = 2.4 seconds), where patients performed a rehabilitation protocol broadly comparable to the one used in the present study. A Minimal Clinically Important Difference (MCID) change of 2.27 seconds was considered, based on the study published by Yuksel *et al.*[35] Considering a power of 90%, a two-sided 0.05 significance level and a 15% dropout rate, 55 patients would be necessary to detect a 2.27 second difference between the two groups. Given the wide variation in the standard deviation of the TUG reported by different authors - from 0,5 seconds[42] to 6,3 seconds[23]- we decided to increase sample size to 70 patients, to account for a greater variation than the one reported by Mizner and collaborators.

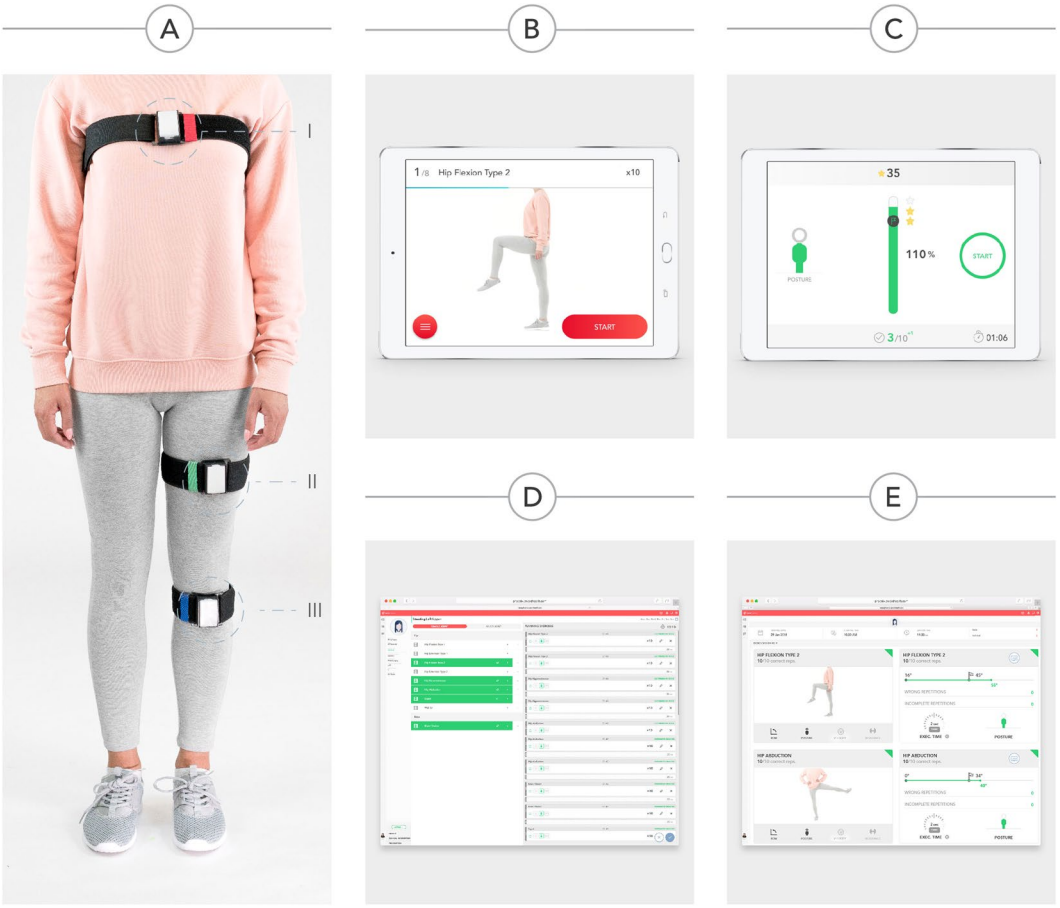


Figure 3. System components. (**A**) Motion Tracker Setup. (**B**) Mobile App: preparation screen. This screen is shown before each exercise, and displays a video of the exercise, as well as audio instructions. (**C**) Mobile App: execution screen. This screen is shown during exercise execution, displaying: (a) timer; (b) progress bar; (c) posture dummy; (d) repetition counter; (e) time left; (**C**) Web Portal - prescription screen. This screen displays the available exercises on the left and the layout of the exercise session on the right. (**E**) Web Portal - results screen. In this screen, the following information is presented: (a) date and time of the session; (b) session duration; (c) pain and fatigue reported by the patient through the app; (b) one card per exercise, showing baseline and target joint angles, wrong and incomplete repetitions, as well as posture errors.

Participants. Patients admitted for TKA between December 19th 2016 and October 16th 2017 were screened for eligibility.

Subjects were included if they were $\geq$ 18 years old and had: (a) clinical and imaging evidence of knee osteoarthritis; (b) indication for TKA according to the patient´s orthopedic surgeon; (c) ability to walk unaided, with unilateral or bilateral support; (d) availability of a caregiver to assist the patient after surgery.

Exclusion criteria were: (a) admitted for revision of TKA; (b) contralateral hip or knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program; (c) aphasia, dementia or psychiatric comorbidity interfering with communication or compliance to the rehabilitation process; (d) respiratory, cardiac, metabolic or other condition incompatible with at least 30 minutes of light to moderate physical activity; (e) major medical complications occurring after surgery that prevented the discharge of the patient within 10 days after the surgery; (f) other medical and/or surgical complications that prevent the patient from complying with a rehabilitation program; (g) blind and/or illiterate patients.

Patient allocation. Patient allocation was performed using patient address as criterion. Subjects residing in areas outside the administrative limits of the city of Oporto were allocated to the experimental group. Conversely, patients residing within the administrative limits of the city were allocated to the conventional rehabilitation group.

Blinding. The nature of the study did not allow blinding of the patients. Patient assessment was performed by one investigator- J.T. - blinded for study groups. Statistical analysis was performed by a blinded statistician - L.T.

Patient assessment. Several studies suggest that the outcomes should be measured not only in terms of range of motion, a poor marker of implant success and patient satisfaction[10,39,40] but also using patient-reported outcomes and a performance test[43,44].

Stage	Weeks	Experimental group	Conventional rehabilitation
1	0–2	—	Soft tissue massage
		—	Active assisted mobilization of the knee to increase range of motion
		—	Gait training with bilateral support
		Open kinetic chain exercises without added resistance: lying, sitting and standing (with support)	Open kinetic chain exercises without added resistance
		Strengthening of hip flexors and extensors	Strengthening of hip flexors and extensors
		Ice pack application after each session and throughout the day as needed	Ice pack application after each session and throughout the day as needed
2	3–6	—	Soft tissue massage
		Exercises with steps	Active assisted mobilization of the knee to increase range of motion
		Open kinetic chain exercises with added resistance, progressing to closed kinetic chain exercises, with strengthening of knee flexors/extensors and knee stabilization	Open kinetic chain exercises with added resistance, progressing to closed kinetic chain exercises, with strengthening of knee flexors/extensors and knee stabilization
		Progression to standing exercises without support	Gait training with progressive withdrawal of external support
		Ice pack application after each session and throughout the day as needed	Ice pack application after each session and throughout the day as needed
4	7–8	Eccentric strengthening exercises	Eccentric strengthening exercises
		Exercises involving steps	Exercises involving steps
		Multi-directional exercises	Weight-bearing exercises
		Ice pack application after each session	Ice pack application after each session

Table 5. Rehabilitation protocols used in the study.

The performance test chosen was the TUG[45], which was validated for patients submitted to TKA by Yuksel *et al.*[35]. The TUG consists on the time that a person takes to rise from a chair, walk three meters, turn around, walk back to the chair, and sit down. For patient reported outcomes, the KOOS scale[46], which was validated for patients submitted to TKA by Alviar *et al.*[47], was chosen. The KOOS consists of 5 subscales: (1) Pain; (2) other Symptoms; (3) Function in daily living (ADL); (4) Function in sport and recreation (Sport/Rec) and (5) knee related Quality of life (QoL). The previous week is the time period considered when answering the questions. Standardized options are given (5 Likert boxes) and each question is assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.

Patients were assessed at baseline (pre-operatively), 4 weeks after initiation of rehabilitation and at the end of the program. Data was collected on: (a) demographics (gender, date of birth); (b) affected side; (c) comorbidities and risk factors for adverse events[48]; (d) TUG; (e) KOOS and (f) active knee range of motion (lying, sitting and standing knee flexion; sitting knee extension) measured automatically by the SWORD device.

Safety and adverse events. Patients in the conventional rehabilitation group were under regular monitoring by a physical therapist, enabling early detection and reporting of adverse events. In the experimental group, safety was evaluated through pain and fatigue scores (graduated from 0 to 10) at the end of each session. These were available for remote monitoring. Patients were also asked to report any adverse events to their physical therapist through a direct telephone contact.

Intervention. Rehabilitation protocols (see Table 5) were designed based on a recent systematic review[10], the results of a Delphi panel on best practices for rehabilitation after TKA[11] and the protocols published by SOFMER, the French Physical and Rehabilitation Medicine Society[49].

Both groups received home-based rehabilitation for 8 weeks starting between day 7 and day 10 after surgery.

The experimental group performed a rehabilitation program solely through the use of the biofeedback system. After an initial deploy and training visit, the program was monitored remotely by the assigned physical therapist. Patients were instructed to perform exercise sessions between five and seven days a week, but were not excluded from the study in case of lower adherence. Total training time was registered automatically by the device. Each patient received a visit from the physical therapist 4 weeks after initiation of the program and then a termination visit. Two interim telephone calls were also scheduled (at 2 and 6 weeks after initiation of the rehabilitation program). Additional telephone or face-to-face visits were performed when required and registered.

The conventional rehabilitation group received a program provided by a physiotherapist, 3 times a week, for 1 hour. Patients were also instructed to perform additional unsupervised sessions in at least two other days of the week. Compliance to these additional sessions was not mandatory.

Statistical analysis. To assess differences in clinical and demographic variables of the patients allocated to the two study groups, independent samples t test or Mann–Whitney U test were used for quantitative variables. For qualitative variables, Chi-squared test or Fisher's exact test were used.

Outcome analysis was performed using a per-protocol analysis. The impact of the interventions in the primary and secondary outcomes was evaluated considering the change between baseline and week 8. Differences between the two study groups were performed using independent samples t test or Mann-Whitney U test. Since outcomes

were measured in three different moments (baseline, 4 weeks and 8 weeks), a repeated measures analysis was also performed, using a 3×2 ANOVA with group as an independent factor and time as a within- subjects factor. When necessary, logarithm or square root transformations were performed to obtain normally distributed variables. In all analysis, a significant level of 0.05 was considered.

Ethics approval of research. The study was approved by the National Data Protection Commission (authorization number 1476/2017) and by the local ethics committee at Hospital da Prelada (Chair: Dr. Juiz Conselheiro Almeida Lopes). The methods were conducted in accordance with the approved guidelines. All patients and caregivers were provided with information about the purpose and procedures of the study and provided written informed consent before inclusion. All patient data was anonimized and linked to the patient by a unique study number that did not contain any personal identifiers.

Clinical Trial Registration. This clinical trial was prospectively registered at www.clinicaltrials.gov with the Unique identifier: NCT03047252. Date of registration: 8 February 2017.

Availability of data and materials. The study protocol is available from www.clinicaltrials.gov. Individual patient data that underlie the results reported in this article was submitted as supplementary information (see Supplementary Dataset 1) which can be accessed through the online version of this paper.

References

1. *Health at a Glance 2015*, https://doi.org/10.1787/health_glance-2015-en (2015).
2. Kurtz, S., Ong, K., Lau, E., Mowat, F. & Halpern, M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. *J. Bone Joint Surg. Am.* **89**, 780–5 (2007).
3. Vissers, M. M. *et al*. Recovery of physical functioning after total hip arthroplasty: systematic review and meta-analysis of the literature. *Phys. Ther.* **91**, 615–29 (2011).
4. Kennedy, D. M., Hanna, S. E., Stratford, P. W., Wessel, J. & Gollish, J. D. Preoperative Function and Gender Predict Pattern of Functional Recovery After Hip and Knee Arthroplasty. *J. Arthroplasty* **21**, 559–566 (2006).
5. Consensus, N. I. H. & Statements, S. NIH Consensus Statement on total knee replacement. *NIH Consens. State. Sci. Statements* **20**, 1–34 (2003).
6. Artz, N. *et al*. Effectiveness of physiotherapy exercise following total knee replacement: systematic review and meta-analysis. *BMC Musculoskelet. Disord.* **16**, 15 (2015).
7. Artz, N. *et al*. Physiotherapy Provision Following Discharge after Total Hip and Total Knee Replacement: A Survey of Current Practice at High-Volume NHS Hospitals in England and Wales. *Musculoskeletal Care* **11**, 31–38 (2013).
8. Oatis, C. A. *et al*. Variations in delivery and exercise content of physical therapy rehabilitation rollowing total knee replacement surgery: a cross- sectional observational study. *Int. J. Phys. Med. Rehabil.* 1–18, https://doi.org/10.4172/2329-9096.S5-002.Variations (2014).
9. Tousignant, M., Boissy, P., Corriveau, H. & Moffet, H. In home telerehabilitation for older adults after discharge from an acute hospital or rehabilitation unit: A proof-of-concept study and costs estimation. *Disabil. Rehabil. Assist. Technol.* **1**, 209–216 (2006).
10. Pozzi, F., Snyder-Mackler, L. & Zeni, J. Physical exercise after knee arthroplasty: A systematic review of controlled trials. *Eur. J. Phys. Rehabil. Med.* **49**, 877–892 (2013).
11. Westby, M. D., Brittain, A. & Backman, C. L. Expert Consensus on Best Practices for Post-Acute Rehabilitation After Total Hip and Knee Arthroplasty: A Canada and United States Delphi Study. *Arthritis Care Res. (Hoboken).* **66**, 411–423 (2014).
12. Bade, M. J. & Stevens-Lapsley, J. E. Early High-Intensity Rehabilitation Following Total Knee Arthroplasty Improves Outcomes. *J. Orthop. Sport. Phys. Ther.* **41**, 932–941 (2011).
13. Petterson, S. C. *et al*. Improved function from progressive strengthening interventions after total knee arthroplasty: A randomized clinical trial with an imbedded prospective cohort. *Arthritis Care Res.* **61**, 174–183 (2009).
14. Kramer, J. F., Speechley, M., Bourne, R., Rorabeck, C. & Vaz, M. Comparison of clinic- and home-based rehabilitation programs after total knee arthroplasty. *Clin. Orthop. Relat. Res.* 225–234, https://doi.org/10.1097/01.blo.0000063600.67412.11 (2003).
15. Madsen, M., Larsen, K., Madsen, I. K., Søe, H. & Hansen, T. B. Late group-based rehabilitation has no advantages compared with supervised home-exercises after total knee arthroplasty. *Dan. Med. J.* **60**, 1–6 (2013).
16. Mitchell, C. *et al*. Costs and effectiveness of pre- and post-operative home physiotherapy for total knee replacement: randomized controlled trial. *J. Eval. Clin. Pract.* **11**, 283–292 (2005).
17. López-Liria, R. *et al*. Home-based versus hospital-based rehabilitation program after total knee replacement. *Biomed Res. Int*. **2015** (2015).
18. Han, A. S. Y. *et al*. Early Rehabilitation After Total Knee Replacement Surgery: A Multicenter, Noninferiority, Randomized Clinical Trial Comparing a Home Exercise Program With Usual Outpatient Care. *Arthritis Care Res. (Hoboken).* **67**, 196–202 (2015).
19. Li, D., Yang, Z., Kang, P. & Xie, X. Home-Based Compared with Hospital-Based Rehabilitation Program for Patients Undergoing Total Knee Arthroplasty for Osteoarthritis. *Am. J. Phys. Med. Rehabil.* **96**, 440–447 (2017).
20. Huckfeldt, P. J., Escarce, J. J., Rabideau, B., Karaca-Mandic, P. & Sood, N. Less intense postacute care, better outcomes for enrollees in medicare advantage than those in fee-for-service. *Health Aff.* **36**, 91–100 (2017).
21. Cottrell, M. A., Galea, O. A., O'Leary, S. P., Hill, A. J. & Russell, T. G. Real-time telerehabilitation for the treatment of musculoskeletal conditions is effective and comparable to standard practice: A systematic review and meta-analysis. *Clin. Rehabil.* 26921551664514, https://doi.org/10.1177/0269215516645148 (2016).
22. Tousignant, M. *et al*. A randomized controlled trial of home telerehabilitation for post-knee arthroplasty. *J. Telemed. Telecare* **17**, 195–198 (2011).
23. Piqueras, M. *et al*. Effectiveness of an interactive virtual telerehabilitation system in patients after total knee arthroplasty: A randomized controlled trial. *J. Rehabil. Med.* **45**, 392–396 (2013).
24. Pastora-Bernal, J. M., Martín-Valero, R., Barón-López, F. J. & Estebanez-Pérez, M. J. Evidence of benefit of telerehabitation after orthopedic surgery: A systematic review. *Journal of Medical Internet Research* **19** (2017).
25. Russell, T. G., Buttrum, P., Wootton, R. & Jull, G. A. Internet-Based Outpatient Telerehabilitation for Patients Following Total Knee Arthroplasty. *J. Bone Jt. Surgery-American Vol.* **93**, 113–120 (2011).
26. Moffet, H. *et al*. In-Home Telerehabilitation Compared with Face-to-Face Rehabilitation After Total Knee Arthroplasty. *J. Bone Jt. Surgery-American Vol.* **97**, 1129–1141 (2015).
27. Shukla, H., Nair, S. R., Shaikh, J. S., Thakker, D. & Sharma, D. Role of telerehabilitation in patients followin g total knee arthrop lasty: Evidence from systematic literature review. *Value Heal.* **17**(3), A182 (2014).
28. Fusco, F. & Turchetti, G. Telerehabilitation after total knee replacement in Italy: Cost-effectiveness and cost-utility analysis of a mixed telerehabilitation-standard rehabilitation programme compared with usual care. *BMJ Open* **6** (2016).
29. Giggins, O. M., Persson, U. & Caulfield, B. Biofeedback in rehabilitation. *J. Neuroeng. Rehabil.* **10**, 60 (2013).

30. Matheve, T., Brumagne, S. & Timmermans, A. A. A. The Effectiveness of Technology-Supported Exercise Therapy for Low BackPain A Systematic Review. *Am. J. Phys. Med. Rehabil.* **96**, 347–356 (2017).
31. Akkaya, N. *et al*. Efficacy of electromyographic biofeedback and electrical stimulation following arthroscopic partial meniscectomy: A randomized controlled trial. *Clin. Rehabil.* **26**, 224–236 (2012).
32. Fung, V., Ho, A., Shaffer, J., Chung, E. & Gomez, M. Use of Nintendo Wii Fit™ In the rehabilitation of outpatients following total knee replacement: A preliminary randomised controlled trial. *Physiother. (United Kingdom)* **98**, 183–188 (2012).
33. Ficklscherer, A. *et al*. Testing the feasibility and safety of the Nintendo Wii gaming console in orthopedic rehabilitation: A pilot randomized controlled study. *Arch. Med. Sci.* **12**, 1273–1278 (2016).
34. Baltaci, G., Harput, G., Haksever, B., Ulusoy, B. & Ozer, H. Comparison between Nintendo Wii Fit and conventional rehabilitation on functional performance outcomes after hamstring anterior cruciate ligament reconstruction: Prospective, randomized, controlled, double-blind clinical trial. *Knee Surgery, Sport. Traumatol. Arthrosc.* **21**, 880–887 (2013).
35. Yuksel, E., Kalkan, S., Cekmece, S., Unver, B. & Karatosun, V. Assessing Minimal Detectable Changes and Test-Retest Reliability of the Timed Up and Go Test and the 2-Minute Walk Test in Patients With Total Knee Arthroplasty. *J. Arthroplasty* **32**, 426–430 (2017).
36. Roos, E. M. & Lohmander, L. S. The Knee injury and Osteoarthritis Outcome Score (KOOS): From joint injury to osteoarthritis. *Health and Quality of Life Outcomes* **1** (2003).
37. Stratford, P. W., Kennedy, D. M. & Robarts, S. F. Modelling knee range of motion post arthroplasty: Clinical applications. *Physiother. Canada* **62**, 378–387 (2010).
38. Mizner, R. L., Petterson, S. C. & Snyder-Mackler, L. Quadriceps Strength and the Time Course of Functional Recovery After Total Knee Arthroplasty. *J. Orthop. Sport. Phys. Ther.* **35**, 424–436 (2005).
39. Blom, A. W. *et al*. Improving patients' experience and outcome of total joint replacement: the RESTORE programme. *Program. Grants Appl. Res.* **4**, 1–508 (2016).
40. Parent, E. & Moffet, H. Comparative responsiveness of locomotor tests and questionnaires used to follow-early recovery after total knee arthroplasty. *Arch. Phys. Med. Rehabil.* **83**, 70–80 (2002).
41. Moffet, H. *et al*. Effectiveness of intensive rehabilitation on functional ability and quality of life after first total knee arthroplasty: A single-blind randomized controlled trial. *Arch. Phys. Med. Rehabil.* **85**, 546–556 (2004).
42. Stevens-Lapsley, J. E., Schenkman, M. L. & Dayton, M. R. Comparison of Self-Reported Knee Injury and Osteoarthritis Outcome Score to Performance Measures in Patients After Total Knee Arthroplasty. *PM R* **3**, 541–549 (2011).
43. Park, K. K., Chang, C. B., Kang, Y. G., Seong, S. C. & Kim, T. K. Correlation of maximum flexion with clinical outcome after total knee replacement in Asian patients. *J. Bone Jt. Surg. - Br. Vol.* **89–B**, 604–608 (2007).
44. Miner, A. L., Lingard, E. A., Wright, E. A., Sledge, C. B. & Katz, J. N. Knee range of motion after total knee arthroplasty: How important is this as an outcome measure? *J. Arthroplasty* **18**, 286–294 (2003).
45. Podsiadlo, D. & Richardson, S. The timed 'Up & Go': a test of basic functional mobility for frail elderly persons. *J. Am. Geriatr. Soc.* **39**, 142–148 (1991).
46. Roos, E. M., Roos, H. P., Lohmander, L. S., Ekdahl, C. & Beynnon, B. D. Knee Injury and Osteoarthritis Outcome Score (KOOS)—Development of a Self-Administered Outcome Measure. *J. Orthop. Sport. Phys. Ther.* **28**, 88–96 (1998).
47. Alviar, M. J. *et al*. Do patient-reported outcome measures in hip and knee arthroplasty rehabilitation have robust measurement attributes? A systematic review. *J. Rehabil. Med.* **43**, 572–583 (2011).
48. Keswani, A. *et al*. Discharge Destination After Total Joint Arthroplasty: An Analysis of Postdischarge Outcomes, Placement Risk Factors, and Recent Trends. *J. Arthroplasty* **31**, 1155–1162 (2016).
49. Ribinik, P. *et al*. Physical and Rehabilitation Medicine (PRM) care pathways: 'Patients after total knee arthroplasty'. *Ann. Phys. Rehabil. Med.* **55**, 533–539 (2012).

Acknowledgements

This work was supported by the European Commission through the Project H2020 SME Instrument Phase 2 - Grant Agreement number 672814.

Author Contributions

Study concept and design: F.D.C., V.B., J.T., R.S., A.N. and L.T. Data acquisition: I.M., J.G., M.M., I.B. Direct supervision of rehabilitation program: I.M., J.G., M.M., I.B. Outcomes assessment: J.T. Analysis and interpretation of data: F.D.C., L.T., A.N. Critical revision of the manuscript for important intellectual content: All authors. Obtained funding: F.D.C., V.B. Administrative, technical and material support: I.M., J.G., M.M., I.B. Study supervision: F.D.C., V.B., J.T., R.S., A.N.

Additional Information

Supplementary information accompanies this paper at https://doi.org/10.1038/s41598-018-29668-0.

Competing Interests: F.D.C. and V.B. have a shareholder position at SWORD Health, a company that develops and commercializes SWORD related products. A.N., I.M., J.G., M.M., I.B. are employees of SWORD Health but do not have shareholder positions. L.T. and J.L. receive honoraria from SWORD Health. J.T. and R.S. have no conflicts of interest to report.

Publisher's note: Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Annex II

PUBLISHED PAPER

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Molinos M, Teixeira L, Tulha J, Seabra R, Lains J, Bento V.

Medium-term outcomes after Total Knee Replacement: follow up results of a feasibility study comparing digital versus conventional home-based rehabilitation.

JMIR Rehabil Assist Technol. 2019 Feb 28;6(1):e13111. doi: 10.2196/13111

Original Paper

Medium-Term Outcomes of Digital Versus Conventional Home-Based Rehabilitation After Total Knee Arthroplasty: Prospective, Parallel-Group Feasibility Study

Fernando Dias Correia[1,2], MD; André Nogueira[1], MPhysio, MBA; Ivo Magalhães[1], MPhysio; Joana Guimarães[1], MPhysio; Maria Moreira[1], MPhysio; Isabel Barradas[1], MPhysio; Maria Molinos[1], PhD; Laetitia Teixeira[3,4,5], PhD; José Tulha[6], MD; Rosmaninho Seabra[6], MD; Jorge Lains[7], MD; Virgílio Bento[1,8], PhD

[1]SWORD Health, Porto, Portugal

[2]Neurology Department, Hospital de Santo António, Centro Hospitalar do Porto, Porto, Portugal

[3]Department of Population Studies, Abel Salazar Institute of Biomedical Sciences, Porto, Portugal

[4]Centro de Investigação em Tecnologias e Serviços de Saúde (CINTESIS), Abel Salazar Institute of Biomedical Sciences, University of Porto, Porto, Portugal

[5]Epidemiology Research Unit, Instituto de Saúde Pública, Universidade do Porto, Porto, Portugal

[6]Orthopaedics Department, Hospital da Prelada - Dr. Domingos Braga da Cruz, Porto, Portugal

[7]Physical Rehabilitation Medicine Department, Rovisco Pais Medical and Rehabilitation Centre, Tocha, Portugal

[8]Engineering Department, University Institute of Maia - ISMAI, Maia, Portugal

Corresponding Author:
Fernando Dias Correia, MD
SWORD Health
Rua de Sá da Bandeira 651, 1ºDTO
Porto, 4000-437
Portugal
Phone: 351 966 557 789
Email: fanacorreia@gmail.com

Abstract

Background: Physical rehabilitation is recommended after total knee arthroplasty (TKA). With the expected increase in TKA over the next few decades, it is important to find new ways of delivering cost-effective interventions. Technological interventions have been developed with this intent, but only preliminary evidence exists regarding their validity, with short follow-up times.

Objective: This study aimed to present the follow-up results of a feasibility study comparing two different home-based programs after TKA: conventional face-to-face sessions and a digital intervention performed through the use of an artificial intelligence-powered biofeedback system under remote clinical monitoring.

Methods: The digital intervention uses a motion tracker allowing 3D movement quantification, a mobile app and a Web portal. This study presents the results of the previous single-center, prospective, parallel-group, feasibility study including an 8-week active treatment stage and further assessments at 3 and 6 months post-TKA. Primary outcome was the Timed Up and Go score, and secondary outcomes were the Knee Osteoarthritis Outcome Scale (KOOS) score and knee range of motion.

Results: A total of 59 patients completed the study (30 in the digital intervention group and 29 in the conventional rehabilitation group) and follow-up assessments. During the active treatment stage, patients in the digital intervention group demonstrated high engagement and satisfaction levels, with an 82% retention rate. Both groups attained clinically relevant improvements from baseline to 6 months post-TKA. At the end of the 8-week program, clinical outcomes were superior in the digital intervention group. At the 3- and 6-month assessments, the outcomes remained superior for the Timed Up and Go score (P<.001) and all KOOS subscale scores (at 3 months, P<.001 overall; at 6 months, KOOS Symptoms: P=.006, Pain: P=.002, Activities of Daily Living: P=.001, Sports: P=.003, and Quality of Life: P=.001). There was progressive convergence between both groups in terms of the knee range of motion, which remained higher for standing flexion in the digital intervention group than the conventional group at 6 months (P=.01). For the primary outcome, at 6 months, the median difference between groups was 4.87 seconds (95% CI 1.85-7.47), in favor of the digital intervention group.

Conclusions: The present study demonstrates that this novel digital intervention for independent home-based rehabilitation after TKA is feasible, engaging, and capable of maximizing clinical outcomes in comparison to conventional rehabilitation in the short and medium term; in addition, this intervention is far less demanding in terms of human resources.

Trial Registration: ClinicalTrials.gov NCT03047252; https://clinicaltrials.gov/ct2/show/NCT03047252

(JMIR Rehabil Assist Technol 2019;6(1):e13111) doi:10.2196/13111

KEYWORDS

knee; TKA; home-based telerehabilitation; digital physiotherapist; artificial intelligence; eHealth

Introduction

Total knee arthroplasty (TKA) is the third most commonly performed surgery in the United States, with over 700,000 procedures performed annually [1]. According to the Centers for Medicare & Medicaid Services, the average Medicare expenditure for surgery, hospitalization, and recovery after TKA ranges from US $16,500 to $33,000 [2]. As a consequence of population aging, the incidence of TKA is expected to increase, leading to an exponential growth in costs [3]. Reducing costs of care is thus a priority, with several initiatives already in place, such as the implementation of Bundled Payment options and the Comprehensive Care for Joint Replacement models [4,5]. These are examples of a broader trend favoring discharge from hospital to home, as opposed to more costly facility-based care [6].

Physical rehabilitation, the evidence-based [7] standard of care immediately following TKA, is being increasingly delivered to TKA recipients at home. Indeed, current evidence indicates that home-based care is a viable, more cost-effective alternative to conventional outpatient rehabilitation [8-12].

In the in-home setting, telerehabilitation, involving continuous monitoring from physical therapists, has shown to be very well accepted by patients [13,14], with results comparable to conventional outpatient physical therapy [13,15,16] or face-to-face home rehabilitation [17]. Besides reducing health costs, telerehabilitation enhances therapy uptake while allowing professionals to remotely adjust rehabilitation programs. In recent years, more advanced technological solutions have emerged, which further enhance patient's autonomy and minimize real-time human supervision. These solutions incorporate biofeedback systems with the intent of increasing both patient performance and adherence [18].

Although there is preliminary evidence of the benefits of such technologies [18], they are generally poorly interactive, include complex machinery, and still show a low evidence level, with no long-term validation available yet [18]. Alternatively, smart portable biofeedback systems coupled with motion-tracking sensors are appealing sophisticated solutions that hold great promise in the upcoming age of artificial intelligence-guided therapies [19]. Promising as these may be, we found only one randomized controlled trial (n=142) testing an interactive telerehabilitation solution based on inertial motion trackers after TKA [16]; however, in that study, the intervention was too short (2 weeks) to draw definitive conclusions, and the outcomes were similar in both groups (system against conventional rehabilitation) [16].

In a previous study, we tested an artificial intelligence-powered digital system for home-based physical rehabilitation that uses inertial motion trackers in order to digitize patient motion and provide real-time feedback on performance through a mobile app. This system also includes a Web-based platform that allows the clinical team to monitor each patient's progress and adapt the programs remotely, with the help of machine-learning algorithms. In this single-center, parallel-group, feasibility study (Trial registration: Clinicaltrial.gov NCT03047252; n=59), we compared the digital intervention to conventional face-to-face home-based rehabilitation after TKA, over an 8-week program, to test patient acceptance, engagement, and compliance and assess its clinical impact. The digital intervention was generally very well accepted, with high compliance and satisfaction levels, and the clinical outcomes were superior to those of the conventional rehabilitation group, in terms of change between the baseline and the end of the program [20]. In the present study, we assessed the medium-term results (3 and 6 months post-TKA) of both rehabilitation programs.

Methods

A complete description of the methods can be found in the previously paper published by Correia et al [20]. An abridged version is presented here.

Sample Size Estimation

Sample size estimation was performed considering the primary outcome measure Timed Up and Go (TUG) test score, based on the study by Mizner et al [21] (baseline TUG SD 2.4 seconds), where patients performed a rehabilitation protocol broadly comparable to the one used in the present study. A minimal clinically important difference (MCID) change of 2.27 seconds was considered, based on the study published by Yuksel et al [22]. Considering a power of 90%, a two-sided significance level of .05, and a dropout rate of 15%, 55 patients would be needed to detect a 2.27-second difference between the two groups. Given the wide variation in the SD of the TUG reported by different authors—from 0.5 seconds [23] to 6.3 seconds [16]—we decided to increase the sample size to 70 patients in order to account for a greater variation than the one reported by Mizner et al .

Eligibility Criteria

All consecutive patients admitted to Hospital da Prelada, Porto, Portugal, for primary TKA, between December 19, 2016, and January 16, 2018, were screened for eligibility. Subjects were included if they were ≥18 years old and had clinical and imaging evidence of hip or knee osteoarthritis, indication for TKA

according to the patient's orthopedic surgeon, the ability to walk (unaided or with assistive device), and a caregiver available to assist the patient after surgery.

Exclusion Criteria

The exclusion criteria were as follows: admitted for revision TKA; contralateral knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program; aphasia, dementia, or psychiatric comorbidity interfering with communication or compliance to the rehabilitation process; respiratory, cardiac, metabolic, or other conditions incompatible with at least 30 minutes of light-to-moderate physical activity; major medical complications occurring after surgery, which prevented discharge of the patient within 10 days after the surgery; other medical or surgical complications that prevent the patient from complying with a rehabilitation program; and presence of blindness or illiteracy.

Allocation

Patients were assessed preoperatively and subsequently scheduled for elective TKA. On discharge, patients were allocated to one of two groups, using patient address as criterion. Subjects residing in areas outside the administrative limits of the city of Oporto were allocated to the digital intervention group. Conversely, patients residing within the administrative limits of the city were allocated to the conventional rehabilitation group.

Blinding

The nature of the study did not allow blinding of patients. Patient assessment was performed by one trained investigator (JT) who was blinded to the study groups. Statistical analysis was performed by a blinded statistician (LT).

Intervention

Both groups received an 8-week rehabilitation program starting on the day after discharge (7-10 days after surgery). The conventional rehabilitation group received a home-based supervised program provided by a physiotherapist, 3 times a week, for 1 hour (total of 24 hours of active treatment time).

The digital intervention group received an initial onboarding visit from the assigned physical therapist, who trained the patient or caregiver to use the system and then performed a supervised session with the patient, ensuring that the patient was able to interact with the system independently or with assistance from a caregiver. From then onward, patients performed the rehabilitation program solely through the use of the biofeedback system, under remote monitoring from the physical therapist. Patients were asked to perform independent sessions at least 5 times per week with a minimum duration of 30 minutes (ideally, total of 20 hours of active treatment time), but were not excluded in case of lower intensity.

Ethics Approval of Research

The study was approved by the National Data Protection Commission (authorization number 1476/2017) and the local ethics committee at Hospital da Prelada. The methods were conducted in accordance with the approved guidelines. All patients and caregivers were informed about the purpose and procedures of the study; they provided written informed consent before inclusion. All patient data were anonymized and linked to the patient by a unique study number that did not contain any personal identifiers.

Outcome Assessments

In our previous report, outcomes were measured 4 weeks into the rehabilitation program and at the end of the rehabilitation program (week 8) [20]. For this study, patients were reassessed at 3 and 6 months postsurgery (± 10 work days) through face-to-face visits.

Several studies suggest that the outcomes should be measured not only in terms of range of motion (ROM) [24-27], but also using patient-reported outcomes and a performance-based test [28,29].

The primary outcome was the TUG score [30], which measures the time that a person takes to rise from a chair, walk 3 meters, turn around, walk back to the chair, and sit down. This test was chosen because it is simple and practical, has high interrater reliability [31], and has been demonstrated to predict both short- [32] and long-term [33] function following knee arthroplasty.

The secondary outcomes were patient-reported outcomes, measured by the Knee Osteoarthritis Outcome Scale (KOOS) and knee ROM in degrees. The KOOS scale [34] was validated by Alviar et al for patients undergoing TKA [35]. The KOOS consists of 5 subscales: (1) pain, (2) other symptoms, (3) function in daily living (activities of daily living [ADL]), (4) function in sport and recreation, and (5) knee-related quality of life (QoL). Standardized options were given (5 Likert boxes), and each question was assigned a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for each subscale.

Regarding knee ROM, since the system used in this study was a validated medical device for joint angle measurement, with a reported root mean square error of 3.5º in comparison to standard goniometry in the technical file, knee ROM was measured automatically by the system. Active ROM was measured in the following movements: lying, sitting, standing knee flexion, and sitting knee extension. For each exercise, the patient was asked to perform three repetitions, and the best value of the three was recorded.

Individual patient data that underlie the results reported in this article were submitted as supplementary information (Multimedia Appendix 1), which can be accessed through the online version of this paper.

Statistical Analysis

Outcome analysis was performed using a per-protocol analysis. The impact of the interventions on the primary and secondary outcomes was evaluated while considering the change between the baseline and 3 and 6 months. Differences between the two study groups were performed using the independent samples *t* test or Mann-Whitney *U* test. The 95% CIs were determined using Hodges-Lehman estimator. Since outcomes were measured at three different time points (baseline, 3 months, and 6 months), a repeated measures of analysis was performed using a 3 × 2 analysis of variance with group as an independent factor and

time as a within-subject factor. When necessary, logarithm or square root transformations were performed to obtain normally distributed variables. In all analysis, a significance level of 0.05 was considered.

System Technical Specifications

The system is composed of the following components (Figure 1).

Inertial Motion Trackers

Each tracker comprises gyroscopes, accelerometers, and magnetometers, allowing 3D movement quantification. The trackers communicate via Bluetooth low energy with a tablet computer. The trackers are placed on body segments using Velcro straps in specific positions.

Mobile App

Before each exercise, a video demonstration is presented to the patient (Figure 1) along with an audio explanation. During execution, the patient is given real-time visual and audio biofeedback through a dedicated interface (Figure 1). In each repetition, the patient is asked to fill a progress bar, earning a maximum of three stars if he/she surpasses the target range of motion. To do so, the patient must keep within prespecified movement and posture constraints (eg, excessive abduction in a straight leg raise is not allowed). If the patient performs a movement error or assumes an incorrect posture, an error message is displayed, with audio and video information on the specific error performed, thus allowing correction in the following attempts.

Web-Based Portal

The portal allows clinical teams to prescribe exercises, monitor results, and edit prescriptions (Figure 1).

Figure 1. System components. (A) Motion tracker setup. (I) Red tracker: over the sternal manubrium. (II) Green tracker: anterior surface of the hip. (III) Blue tracker: over the anterior tibial crest. (B) Mobile App: preparation screen. This screen is shown before each exercise and displays a video of the exercise as well as audio instructions. (C) Mobile App: execution screen. (D) Web Portal - prescription screen. This screen displays the available exercises on the left and the layout of the exercise session on the right. (E) Web Portal - results screen. In this screen, the following information is presented: date and time of the session; session duration; pain and fatigue reported by the patient through the app; and one card per exercise, showing baseline and target joint angles, wrong and incomplete repetitions, and posture errors.

Figure 1A

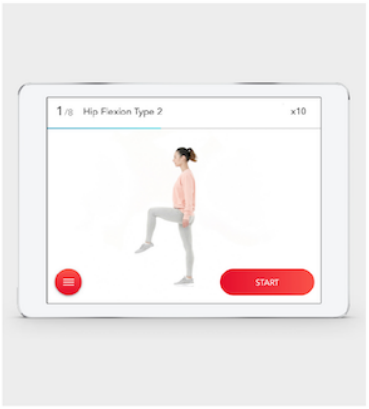


Figure 1B

Figure 1C

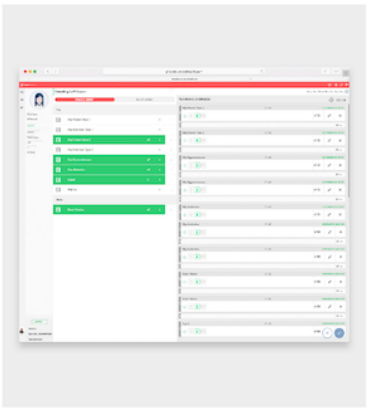


Figure 1D

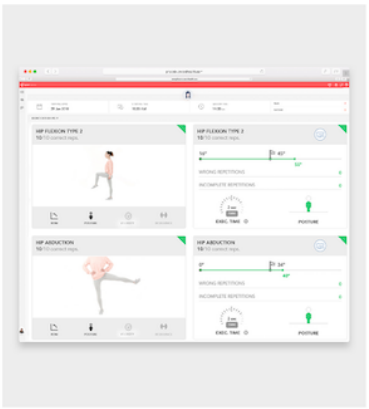


Figure 1E

Results

In total, 59 patients completed the previous 8-week intervention study [20] (30 patients in the digital intervention group and 29 in the conventional rehabilitation group), and there was no loss to follow-up in this study. The CONSORT (Consolidated Standards of Reporting Trials) diagram is presented in Figure 2.

Baseline Sample Characterization

Baseline characteristics of the study participants regarding demographics, comorbidities, and risk factors for adverse events as well as data on hospitalization and surgery are presented in Table 1. There were no differences between the two study groups regarding the abovementioned characteristics. In terms of primary and secondary outcomes, there were no differences between the two study groups regarding TUG and knee ROM (Tables 1 and 2). Regarding the KOOS, the digital intervention group had lower scores in every subscale [20] (Table 3).

Figure 2. Study CONSORT diagram. CONSORT: Consolidated Standards of Reporting Trials; TKA: total knee arthroplasty.

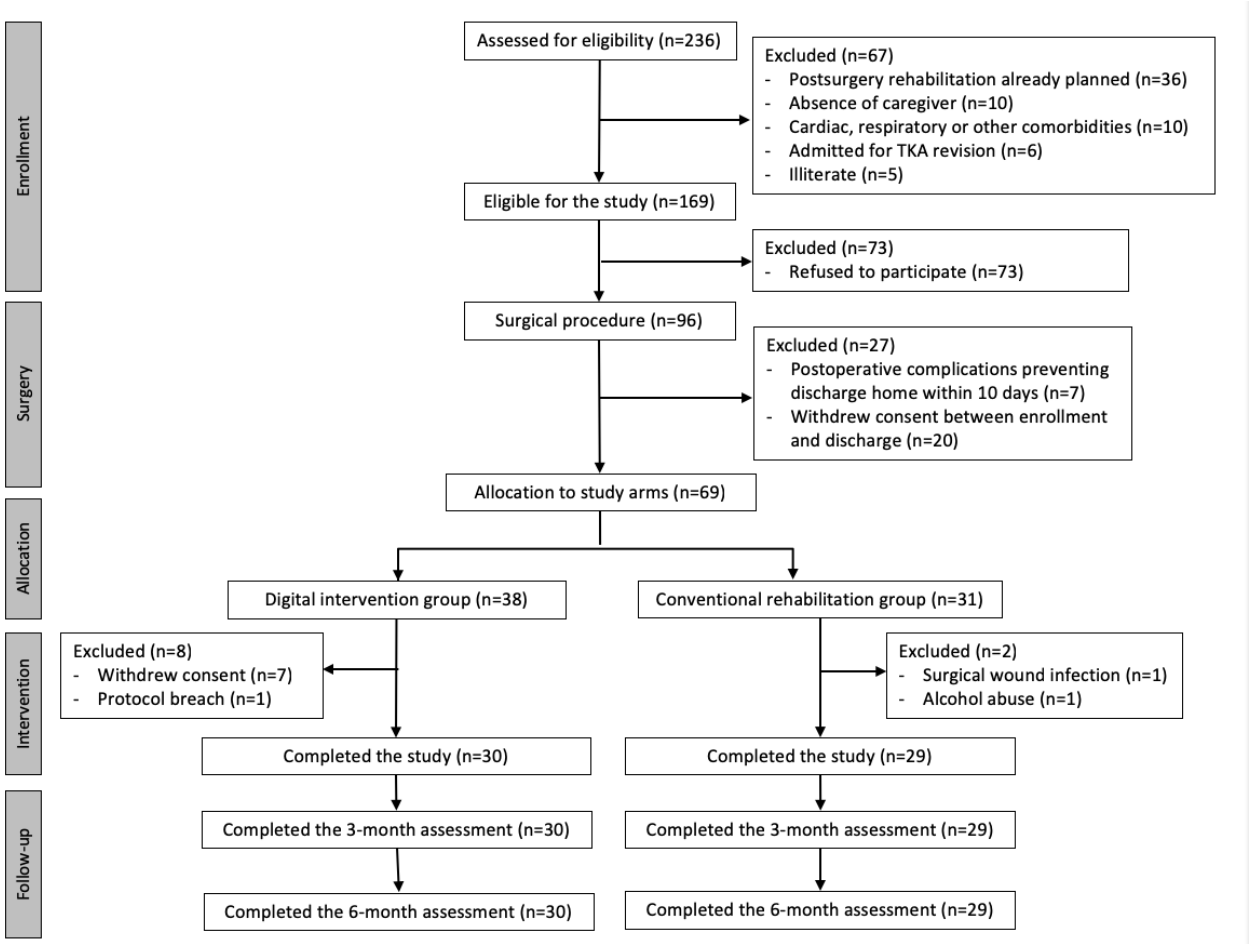


Table 1. Baseline characteristics of the study participants.

Characteristics	Total (N=69)	Digital intervention group (N=38)	Conventional rehabilitation group (N=31)	*P* value[a]
Demographics				
Age (years), mean (SD)	68.5 (7.0)	67.3 (6.8)	70.0 (7.2)	0.12[b]
Gender, female, n (%)	54 (78.3)	32 (84.2)	22 (71.0)	0.30[c]
Operated knee - right, n (%)	38 (55.1)	23 (63.2)	14 (45.2)	0.21[c]
Comorbidities and known risk factors for adverse events				
Body mass index, mean (SD)	30.9 (4.9)	31.0 (4.5)	30.8 (5.4)	0.84[b]
Smoking, n (%)	8 (11.6)	4 (10.5)	4 (12.9)	1.00[d]
Hypertension, n (%)	48 (69.6)	25 (65.8)	23 (74.2)	0.62[c]
Diabetes, n (%)	11 (15.9)	7 (18.4)	4 (12.9)	0.74[d]
Pulmonary disease, n (%)	9 (13.0)	3 (7.9)	6 (19.4)	0.28[d]
Cardiac disease, n (%)	4 (5.8)	2 (5.3)	2 (6.5)	1.00[d]
Stroke, n (%)	0 (0)	0 (0)	0 (0)	N/A[e]
Renal disease, n (%)	2 (1.4)	0 (0)	1 (3.2)	0.45[d]
Bleeding disorders, n (%)	0 (0)	0 (0)	0 (0)	N/A
ASA[f] class 3 or 4[g], n (%)	10 (14.5)	5 (13.2)	5 (16.1)	0.74[d]
Steroids for chronic condition, n (%)	0 (0)	0 (0)	0 (0)	N/A
Previous contralateral knee replacement, n (%)	17 (24.6)	7 (18.4)	10 (32.3)	0.30[c]
Previous hip replacement, n (%)	3 (4.3)	3 (7.9)	0 (0)	0.25[d]
Hospital admission and surgical procedure				
Time between admission and surgery (hours)	<24	<24	<24	N/A
Operative time (min), mean (SD)	62.6 (11.3)	62.4 (9.87)	62.8 (13.0)	0.89[b]
Minor adverse events before discharge, n (%)	1 (1.4)	0 (0)	1 (3.2)	0.45[d]
Hospital length of stay (days), median (interquartile range)	6 (1.0)	6 (1.0)	6 (2.0)	0.83[c]

[a]Mann-Whitney *U* test.

[b]Independent samples *t* test.

[c]Chi square test.

[d]Fisher exact test.

[e]N/A: not applicable.

[f]ASA: American Society of Anesthesiology.

[g]American Society of Anesthesiology physical status classification system.

Table 2. Results of the secondary outcome measure (Knee Osteoarthritis Outcome Score).

Outcome variables	Digital intervention group, median (IQR[a])	Control group, median (IQR)	*P* value[b]	Estimate difference between groups[c]	95% CI[c]
Baseline					
Symptoms	34.0 (20.0)	50.0 (29.0)	<.001	–18.0	–25.0 to –17.0
Pain	33.0 (12.0)	47.0 (24.0)	<.001	–11.0	–19.0 to –6.0
ADL[d]	34.0 (18.0)	41.0 (18.0)	.005	–9.0	–15.0 to –3.0
Sports	0.0 (0.0)	5.0 (8.0)	.006	0.0	–5.0 to 0
Quality of life	13.0 (19.0)	25.0 (19.0)	.007	–12.0	–18.0 to 0
At 3 months					
Symptoms	87.5 (11.8)	82.0 (19.5)	.01	9.0	0-15.0
Pain	95.5 (11.8)	86.0 (22.5)	<.001	11.0	5.0-17.0
ADL	93.0 (8.0)	87.0 (22.5)	.001	7.0	3.0-15.0
Sports	30.0 (11.3)	20.0 (7.5)	.001	10.0	5.0-15.0
Quality of life	81.0.0 (14.5)	56.0 (25.0)	<.001	19.0	12.0-25.0
Change from baseline to 3 months					
Symptoms	51.5 (24.25)	25.0 (27.0)	<.001	25.0	15.0-35.0
Pain	58.0 (12.0)	31.0 (23.5)	<.001	23.0	15.0-31.0
ADL	57.5 (17.8)	35.0 (16.5)	<.001	20.0	13.0-27.0
Sports	30.0 (11.3)	15.0 (10.0)	<.001	10.0	10.9-15.0
Quality of life	65.0 (22.0)	44.0 (21.0)	<.001	25.0	18.0-37.0
At 6 months					
Symptoms	96.0 (15.0)	86.0 (22.0)	.006	7.0	3.0-14.0
Pain	100.0 (8.0)	86.0 (23.5)	.002	11.0	3.0-16.0
ADL	97.0 (6.0)	87.0 (14.5)	.001	7.0	4.0-13.0
Sports	42.5 (36.3)	20.0 (22.5)	.003	15.0	5.0-30.0
Quality of life	94.0 (12.0)	63.0 (37.5)	.001	25.0	12.0-32.0
Change from baseline to 6 months					
Symptoms	60.5 (25.8)	29.0 (33.5)	<.001	25.0	15.0-36.0
Pain	61.0 (11.8)	39.0 (24.0)	<.001	20.0	14.0-28.0
ADL	58.0 (17.5)	43.0 (23.0)	<.001	19.0	11.0-26.0
Sports	40.0 (35.0)	15.0 (27.5)	<.001	20.0	10.0-30.0
Quality of life	81.0 (20.0)	43.0 (40.5)	<.001	36.5	24.0-49.0

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]Hodges-Lehman estimator.

[d]ADL: activities of daily living.

Table 3. Results of the primary outcome measure (Timed Up and Go score).

Time point	Digital intervention group, median (IQR[a])	Control group, median (IQR)	*P* value[b]	Estimated difference between groups[c]	95% CI[c]
Baseline	18.19 (6.2)	15.27 (8.5)	.13	2.02	–0.78 to 4.44
3 months	7.83 (2.4)	10.3 (3.5)	<.001	–2.50	–1.43 to –3.80
Change from baseline to 3 months	–10.28 (5.9)	–5.23 (8.5)	.004	–4.48	–1.64 to –7.37
6 months	6.86 (1.6)	8.74 (4.0)	<.001	–1.95	–1.24 to –2.90
Change from baseline to 6 months	–10.47 (7.2)	–5.08 (9.3)	.003	–4.87	–1.85 to –7.47

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]Hodges-Lehman estimator.

Usability, Satisfaction, and Compliance Analysis in the Digital Intervention Group

Seven patients withdrew consent in the first week of the study, due to the inability to interact with the system. Of the remaining 30 patients, 18 (60%) required assistance of a caregiver for motion tracker placement or interacting with the app. There was no age difference between autonomous patients or those needing assistance (*P*=.19).

Only 4 patients (13%) did not comply with the recommended session frequency of 5 times per week.

Total active treatment time was superior in the digital intervention group (*P*=.005), with a median of 31.5 hours (interquartile range 18.0 hours; range 10.8-69.1 hours).

Patients had three face-to-face contacts with the therapist (one deployment session, one contact at 4 weeks, and one contact at the end of the 8-week program) and, on average, 0.4 (SD 0.7; range 0-2) additional face-to-face contacts as well as a median of 2.5 extra calls (interquartile range 3.0; range 1-12) for technical assistance.

Twenty-seven patients rated their satisfaction as 10/10, one with 9/10, and two with 8/10.

Clinical Outcomes

The TUG scores were better (*P*<.001) in the digital intervention group (Table 3) in both 3- and 6-month assessments.

Concerning KOOS, the scores in the digital intervention group were higher than those in the conventional rehabilitation group for all subscales at both 3 and 6 months after TKA (Table 2).

Knee ROM was higher for sitting knee flexion (*P*=.046), sitting knee extension (*P*=.002), and standing knee flexion (*P*<.001) in the digital intervention group than in the conventional group at 3 months. At the 6-month assessment, only the standing knee flexion ROM remained significantly high (*P*=.01; Table 4).

Change Between Baseline and the 3- and 6-Month Assessments

At 3 months, the change in all outcome measures was superior in the digital intervention group and at the 6 months, this was true for the primary outcome (TUG), the KOOS score, and knee flexion while standing (Tables 2-4).

Based on the MCID reported in the literature for TUG (2.27 seconds) [22], clinically significant improvements were noted in both groups at 3 and 6 months, with participants taking 58% and 33% less time to complete the test in the digital intervention and control groups, respectively, at 6 months after surgery.

The difference between the median changes in the two groups was clinically significant, more than doubling the MCID (4.48 seconds at 3 months and 4.87 seconds at 6 months) in favor of the digital intervention group.

Regarding KOOS scores, the improvement noted in both groups was superior to the minimal important changes reported for the KOOS scores in subjects undergoing rehabilitation after TKA [36] (Symptoms: 10.7 points; Pain: 16.7 points; ADL: 18.4 points; Sports: 12.5 points; QoL: 15.6 points) in all subscales, denoting clinically relevant changes from baseline, 3 months, and 6 months after TKA (Table 2). The difference between the median changes in the two groups was also statistically and clinically significant in all subscales, again favoring the digital intervention group, except for the Sports subscale at the 3-month assessment, where the difference between the groups was lower than the minimal important change for this subscale (10.0 points; 95% CI 10.9-15.0).

Table 4. Results of the secondary outcome measures (knee range of motion).

Outcome variables	Digital intervention group, mean (SD)	Control group, mean (SD)	*P* value[a]	Estimate difference between groups	95% CI
Baseline					
Lying flexion	80.7 (12.4)	84.7 (18.7)	.34	4.0	–12.2 to 4.3
Sitting flexion	85.3 (16.0)	90.4 (13.1)	.19	5.1	–12.8 to 2.5
Standing flexion	71.6 (20.3)	78.8 (16.6)	.15	7.2	–16.8 to 2.6
Sitting extension	26.5 (8.4)	24.8 (7.8)	.43	1.7	–2.5 to 6.0
At 3 months					
Lying flexion	100.1 (12.6)	93.3 (13.6)	.052	6.8	–0.04 to 13.62
Sitting flexion	102.5 (13.1)	96 (11.3)	.046	6.5	0.10-12.89
Standing flexion	95.6 (10.2)	84.9 (10.4)	<.001	10.7	5.22-16.08
Sitting extension	11.8 (8.3)	19 (8.8)	.002	–7.2	2.73-11.65
Change from baseline to 3 months					
Lying flexion	19.4 (15.5)	8.7 (15.1)	.009	10.7	2.8-18.7
Sitting flexion	17.3 (20.1)	5.7 (14.7)	.01	11.6	2.4-20.8
Standing flexion	23.9 (17.6)	6.1 (14.1)	<.001	17.8	9.5-26.2
Sitting extension	–14.8 (9.0)	–5.9 (11.6)	.002	-8.9	–3.5 to –14.3
At 6 months					
Lying flexion	103.4 (10.6)	101.5 (13.3)	.55	1.9	–4.38 to 8.15
Sitting flexion	102.5 (10.8)	102.2 (12.3)	.93	0.3	–5.77 to 6.29
Standing flexion	97.4 (9.9)	89.9 (11.7)	.01	7.5	1.78-13.08
Sitting extension	7.1 (6.6)	9.7 (5.8)	.12	–2.6	–5.83 to 0.64
Change from baseline to 6 months					
Lying flexion	22.7 (12.9)	16.8 (17.4)	.15	5.8	–2.1 to 13.8
Sitting flexion	17.2 (19.1)	11.9 (13.9)	.22	5.4	–3.4 to 14.1
Standing flexion	25.7 (20.1)	11.2 (14.0)	.002	14.6	5.5-23.6
Sitting extension	–19.4 (8.4)	–15.1 (8.7)	.06	–4.3	–8.8 to 0.2

[a]Independent samples *t* test.

For knee ROM in patients undergoing TKA, there are no minimal important changes validated so far. The only comparable metric was reported in a study by Stratford and collaborators [37], which reported a minimal detectable change at a 90% CI of 9.6º for knee flexion and 6.3º for knee extension in patients after TKA. Hence, at 3 months, only the digital intervention group showed clinically relevant improvements in the knee ROM as compared to baseline assessment; however, this was true for both groups 6 months after TKA (Table 4). The difference in median changes revealed the superiority of the digital intervention over conventional rehabilitation at 3 months. At 6 months, only the mean change in the standing flexion knee ROM was significantly higher and clinically meaningful in the digital intervention group (14.6º; 95% CI: 5.5-23.6).

Repeated Measures Analysis

This analysis was performed only for the normally distributed variables TUG and ROM after transformation. The results are summarized in Table 5.

For TUG, the repeated measures analysis revealed a main effect of time ($F_{2.2,124.5}$=76.406, P<.001), a main effect of group ($F_{1,57}$=9.346, P=.003), and an interaction between time and group ($F_{2.2,124.5}$=7.807, P<.001) in favor of the digital intervention group (Table 5, Figure 3).

Regarding knee ROM, the repeated measures analysis revealed a main effect of time and an interaction between time and group in the four knee ROMs measured, again in favor of the digital intervention group (Table 5, Figure 3).

Adverse Events

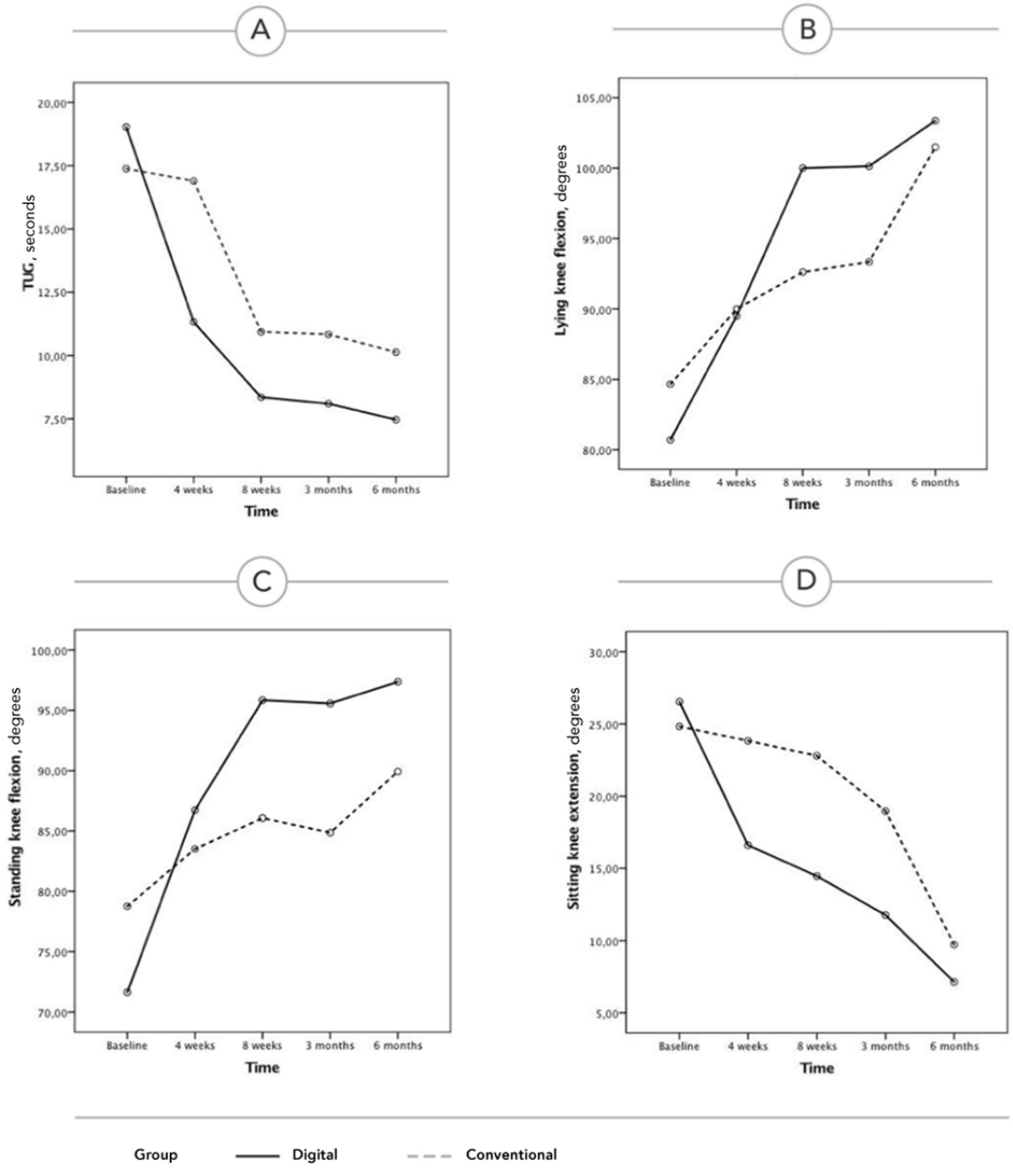
No adverse events were reported in any of the study groups in the period between the end of the active treatment stage and the 6-month assessment. In particular, there were no falls in any of the groups, readmissions to hospital for any reason, or TKA revision.

Table 5. Repeated measures analysis. Greenhouse-Geisser correction was used for all variables.

Outcome variables	Time			Group			Time*Group		
	$F_{df1,df2}$	*F* value	*P* value	$F_{df1,df2}$	*F* value	*P* value	$F_{df1,df2}$	*F* value	*P* value
Patient performance									
Timed Up and Go[a]	$F_{2.2,124.5}$	76.406	<.001	$F_{1,57}$	9.346	0.003	$F_{2.2,124.5}$	7.801	<.001
Knee range of motion									
Lying flexion	$F_{2.6,150.9}$	42.3	<.001	$F_{1,57}$	0.8	0.375	$F_{2.6,150.9}$	4.29	0.008
Sitting flexion	$F_{2.2,126.2}$	24.8	<.001	$F_{1,57}$	0.27	0.604	$F_{2.2,126.2}$	3.98	0.02
Sitting extension	$F_{3.0,169.4}$	50.9	<.001	$F_{1,57}$	11.4	0.001	$F_{3.2,169.4}$	5.6	0.001
Standing flexion	$F_{2.0,116.2}$	37	<.001	$F_{1,57}$	3.88	0.054	$F_{2.2,116.2}$	9.17	<.001

[a]Logarithmic transformation.

Figure 3. Evolution of the outcomes over time in both groups, based on the repeated measures analysis (estimated marginal means of transformed variables are presented). (A) Timed Up and Go score. (B) Lying knee flexion. (C) Standing knee flexion. (D) Sitting knee extension. TUG: Timed Up and Go.



Discussion

The feasibility study was designed to assess both patient acceptance, engagement, and satisfaction with a novel digital intervention for rehabilitation after TKA and to estimate the clinical impact of the intervention in comparison to conventional face-to-face rehabilitation.

In terms of patient acceptance, the enrollment rate of this study was very low (29%), with patient refusal or consent withdrawal corresponding to more than half the screening failures. This was expected, given the relatively high mean age of the study participants (68.5 years; SD 7.0 years) and is a common issue in this field [16], likely representing patients' skepticism toward new technological solutions as well as suspicion of possible hidden costs. This limitation can be overcome by ensuring better training and broader involvement of clinical teams (both doctors and nurses) that approach the patient upon admission.

From the patients initially allocated to the digital intervention, there was an 18% dropout rate in the first week, and 60% of the remaining patients needed assistance from a caregiver. Even if the number of additional face-to-face contacts for technical assistance was low, the number of extra calls for this reason was relatively high. This represents important usability issues faced by these new technologies in an older population and shows that there is room for improvement, namely, in facilitating tracker setup and removing physical interactions with the tablet. Nonetheless, in the patients who completed the 8-week program, user compliance with the program was very high, with only 4 patients using the system less than 5 days per week. Patient satisfaction was also very high. These are very promising results in terms of engagement, and they validate the gamification strategies in use.

Regarding clinical outcomes, the present study demonstrates clinically relevant improvements of all outcome measures in both groups at 3 and 6 months after TKA. We speculate that the good results obtained in both groups may be related to an early and intensive rehabilitation program.

When comparing the results obtained in the two groups, it is important to note that the study was sufficiently powered to detect clinically meaningful changes between the two groups, with posthoc analysis showing a statistical power of 95%.

Overall, this study demonstrates that the greater benefits observed in the digital intervention group for all outcome measures at the end of the 8-week assessment period were maintained at 3 and 6 months for the primary outcome (TUG) and KOOS score, with a convergence in terms of knee ROM (except for standing knee flexion). We speculate that maximizing short-term outcomes may also maximize medium-term (and possibly, long-term) outcomes. In addition, we speculate that one particular factor—patient empowerment regarding the rehabilitation journey—is maximized with an independent home-based program, possibly leading to a more active lifestyle and maintenance of some of the exercises included in the program. This may have, in turn, maximized the results. These aspects warrant further investigation in upcoming studies.

Regarding TUG, participants in the digital intervention group experienced a median change of 10.47 seconds (58% change from baseline) in the TUG test 6 months after surgery, while the control group experienced a median change of 5.08 seconds (33% change from baseline).

However, it must be noted that baseline TUG values in the present study were much higher than those reported by other authors, with preoperative values between 8 and 12 seconds, which in turn yield poor changes from baseline to the intervention time (approximately 8%-30% improvement) [21,38-40]. We could only find one randomized controlled trial (n=142) [16] with comparable baseline values for TUG (control: 22.8 seconds; SD 11.33 seconds and experimental: 18.9 seconds; SD 7.34 seconds). This study also compared an interactive virtual rehabilitation system for rehabilitation after TKA with conventional rehabilitation. However, in this study, the difference from baseline to 3 months was greater for the conventional rehabilitation group (10.86 seconds, SD 8.72 seconds; approximately 48% change) than for the digital intervention group (7 seconds, SD 6.31 seconds; approximately 37% change).

It is also important to note that the mean value reported for TUG at the 6-month follow-up assessment in the digital intervention group (6.9 seconds, SD 1.6 seconds) is similar to the value reported for healthy older individuals (50-85 years of age) by Bade et al (5.6 seconds, SD 1.0 seconds) and much lower than the value reported by the same authors for patients treated with conventional physiotherapy 6 months after TKA (9.1 seconds, SD 2.4 seconds) [41]. In the conventional group, the results at the 6-month assessment are in line with those reported by Bade et al [41].

Overall, the TUG analysis shows that important benefits were attained in both study groups; the results of the conventional group were in line with those reported by other authors, and those of the digital intervention group were superior to the results reported in the literature.

Concerning KOOS, Stevens-Lapsley et al [23] published a retrospective cohort evaluation on the self-reported and performance-based assessments of knee recovery following TKA. The scores obtained in this study for both groups surpassed those reported by these authors for KOOS subscales Symptoms, Pain, and ADL at all time points, but not for the KOOS subscale Sports. This could be explained by the fact that, in this study, baseline scores in the Sports subscale were much lower. Regarding the QoL subscale, the scores for the Sports subscale in the conventional rehabilitation group were slightly lower than those reported by Stevens-Lapsley et al [23] (3 months: 56.0 [SD 25] vs 63.3 [SD 2.98]; 6 months: 63.0 [SD 37.5] vs 66.96 [SD 3.01]), whereas the digital intervention group achieved much higher scores (3 months: 81 [SD 14.5]; 6 months: 94.0 [12.0]).

Overall, the results of the KOOS subscale scores demonstrate that for the comparison group, the clinical improvements were in line with those published by other authors, and results in the digital intervention group were much higher than those reported by other authors.

Regarding knee ROM outcomes, the results of knee flexion at 6 months in both groups were comparable to those reported in other studies (97º to 116º) [37], while active knee extension values were much lower than those found in the literature [37,41,42]. This latter difference could be a result of the more demanding position used to measure knee extension—sitting as compared to lying supine—which ultimately hampered direct comparison of the results.

Overall, differences between the intervention groups were not so evident, with results from all exercises converging at the 6-month assessment and entering a typical plateau phase, except for standing flexion, which showed higher amplitudes in the digital intervention group. However, importantly, short-term assessments (8 weeks and 3 months) revealed a much quicker improvement in the digital intervention group, potentially minimizing the time spent in rehabilitation after TKA surgery.

This study has several limitations that need to be acknowledged. First, it was a quasi-randomized study, where patient allocation was performed using a geographical criterion. Therefore, a number of factors (namely, socioeconomic) that were not controlled or addressed may have influenced the results. Nonetheless, both groups were similar in terms of baseline characteristics, except for KOOS scores, which were lower in the digital intervention group. It could be argued that the difference may be related to different health perceptions between the two groups, but the reason is not clear. Future studies should consider that pure randomization allows for a better control of these aspects.

Second, this was a single-center study performed in a low-volume orthopedic hospital, and all patients were admitted for elective surgery, which may not reflect the reality of other hospitals. In addition, the average length of stay (ie, 6 days) is higher than that reported in other studies [43], probably due to the inexistence of a fast-track protocol for TKA. The results reported here therefore need to be confirmed in multicentric trials in larger hospitals before generalization.

Third, the low inclusion rate may have represented a selection bias toward more technologically prone patients/caregivers, which needs to be properly addressed in future trials.

Fourth, treatment intensity was higher in the digital intervention group, which may have potentiated clinical results in this group. Nonetheless, even if this is the case, it is noteworthy that the superiority was maintained at the 3- and 6-month assessments.

Fifth, even though no serious adverse events were reported until the 6-month assessment, the absence of minor adverse events is more difficult to explain and was most likely due to an underreporting of these events. In future studies, besides direct telephone contact and specific questioning of adverse events in assessment appointments, event logs should be delivered to the patients to avoid underreporting.

In conclusion, the present study demonstrates that this novel digital intervention for rehabilitation after TKA is feasible and associated with high patient compliance and satisfaction. Like other novel technological approaches, it is still met with some skepticism by older patients, and usability still needs to be improved to ensure greater independence by users. This study also demonstrates that the digital intervention can maximize both short- and medium-term outcomes in comparison to conventional rehabilitation. As this approach is far less demanding in terms of human resources, this might be the first step toward a paradigm shift to artificial intelligence-assisted personalized electronic rehabilitation. These promising results warrant larger multicentric randomized controlled studies that address the study limitations to ensure widespread validation of this novel approach.

Acknowledgments

This work was supported by the European Commission through the Project H2020 SME Instrument Phase 2 (Grant Agreement number 672814). The study sponsor, SWORD Health, was involved in study design, data collection, and interpretation and writing of the manuscript. Two authors, JT and RS, served as independent controllers of the study. The decision to submit the manuscript for publication was made by these two independent authors.

Authors' Contributions

Study concept and design: FDC, VB, JT, RS, AN, and LT. Data acquisition: IM, JG, M Moreira, and IB. Direct supervision of the rehabilitation program: IM, JG, M Moreira, and IB. Outcome assessment: JT. Analysis and interpretation of data: FDC, LT, M Molinos, and AN. Critical revision of the manuscript for important intellectual content: All authors. Obtained funding: FDC and VB. Administrative, technical, and material support: IM, JG, M Moreira, M Molinos, and IB. Study supervision: FDC, VB, JT, RS, and AN.

Conflicts of Interest

FDC and VB have a shareholder position at SWORD Health, a company that develops and commercializes SWORD-related products. AN, IM, JG, M Moreira, M Molinos, and IB are employees of SWORD Health but do not have shareholder positions. LT and JL receive honoraria from SWORD Health. JT and RS have no conflicts of interest to report.

Multimedia Appendix 1

Raw data for outcome measures.

[XLSX File (Microsoft Excel File), 71KB - rehab_v6i1e13111_app1.xlsx]

References

1. McDermott K, Freeman W, Elixhauser A. Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality; 2018 Apr. Overview of Operating Room Procedures During Inpatient Stays in U.S. Hospitals, 2014 URL: https://www.hcup-us.ahrq.gov/reports/statbriefs/sb233-Operating-Room-Procedures-United-States-2014.jsp [accessed 2018-12-11] [WebCite Cache ID 76KfjN9U3]
2. Centers for Medicare & Medicaid Innovation (cms.gov). Comprehensive Care for Joint Replacement Model URL: https://innovation.cms.gov/initiatives/cjr [accessed 2018-11-25] [WebCite Cache ID 76KgFI1C9]
3. Kurtz SM, Ong KL, Lau E, Bozic KJ. Impact of the economic downturn on total joint replacement demand in the United States: updated projections to 2021. J Bone Joint Surg Am 2014 Apr 16;96(8):624-630. [doi: 10.2106/JBJS.M.00285] [Medline: 24740658]
4. Maniya OZ, Mather RC, Attarian DE, Mistry B, Chopra A, Strickland M, et al. Modeling the Potential Economic Impact of the Medicare Comprehensive Care for Joint Replacement Episode-Based Payment Model. J Arthroplasty 2017 Dec;32(11):3268-3273.e4. [doi: 10.1016/j.arth.2017.05.054] [Medline: 28669568]
5. Siddiqi A, White PB, Mistry JB, Gwam CU, Nace J, Mont MA, et al. Effect of Bundled Payments and Health Care Reform as Alternative Payment Models in Total Joint Arthroplasty: A Clinical Review. J Arthroplasty 2017 Dec;32(8):2590-2597. [doi: 10.1016/j.arth.2017.03.027] [Medline: 28438453]
6. Jubelt LE, Goldfeld KS, Chung W, Blecker SB, Horwitz LI. Changes in Discharge Location and Readmission Rates Under Medicare Bundled Payment. JAMA Intern Med 2016 Jan;176(1):115-117 [FREE Full text] [doi: 10.1001/jamainternmed.2015.6265] [Medline: 26595453]
7. Joice MG, Bhowmick S, Amanatullah DF. Perioperative Physiotherapy in Total Knee Arthroplasty. Orthopedics 2017 May 22;40(5):e765-e773. [doi: 10.3928/01477447-20170518-03] [Medline: 28530765]
8. Rajan RA, Pack Y, Jackson H, Gillies C, Asirvatham R. No need for outpatient physiotherapy following total knee arthroplasty: a randomized trial of 120 patients. Acta Orthop Scand 2004 Feb;75(1):71-73. [doi: 10.1080/00016470410001708140] [Medline: 15022811]
9. Kramer JF, Speechley M, Bourne R, Rorabeck C, Vaz M. Comparison of clinic- and home-based rehabilitation programs after total knee arthroplasty. Clin Orthop Relat Res 2003 May(410):225-234. [doi: 10.1097/01.blo.0000063600.67412.11] [Medline: 12771834]
10. Büker N, Akkaya S, Akkaya N, Gökalp O, Kavlak E, Ok N, et al. Comparison of effects of supervised physiotherapy and a standardized home program on functional status in patients with total knee arthroplasty: a prospective study. J Phys Ther Sci 2014 Oct;26(10):1531-1536 [FREE Full text] [doi: 10.1589/jpts.26.1531] [Medline: 25364104]
11. Han ASY, Nairn L, Harmer AR, Crosbie J, March L, Parker D, et al. Early rehabilitation after total knee replacement surgery: a multicenter, noninferiority, randomized clinical trial comparing a home exercise program with usual outpatient care. Arthritis Care Res (Hoboken) 2015 Feb;67(2):196-202 [FREE Full text] [doi: 10.1002/acr.22457] [Medline: 25220488]
12. Falvey JR, Bade MJ, Forster JE, Burke RE, Jennings JM, Nuccio E, et al. Home-Health-Care Physical Therapy Improves Early Functional Recovery of Medicare Beneficiaries After Total Knee Arthroplasty. J Bone Joint Surg Am 2018 Oct 17;100(20):1728-1734. [doi: 10.2106/JBJS.17.01667] [Medline: 30334882]
13. Russell TG, Buttrum P, Wootton R, Jull GA. Internet-based outpatient telerehabilitation for patients following total knee arthroplasty: a randomized controlled trial. J Bone Joint Surg Am 2011 Jan 19;93(2):113-120. [doi: 10.2106/JBJS.I.01375] [Medline: 21248209]
14. Moffet H, Tousignant M, Nadeau S, Mérette C, Boissy P, Corriveau H, et al. Patient Satisfaction with In-Home Telerehabilitation After Total Knee Arthroplasty: Results from a Randomized Controlled Trial. Telemed J E Health 2017 Dec;23(2):80-87. [doi: 10.1089/tmj.2016.0060] [Medline: 27529575]
15. Bini SA, Mahajan J. Clinical outcomes of remote asynchronous telerehabilitation are equivalent to traditional therapy following total knee arthroplasty: A randomized control study. J Telemed Telecare 2016 Mar 03. [doi: 10.1177/1357633X16634518] [Medline: 26940798]
16. Piqueras M, Marco E, Coll M, Escalada F, Ballester A, Cinca C, et al. Effectiveness of an interactive virtual telerehabilitation system in patients after total knee arthoplasty: a randomized controlled trial. J Rehabil Med 2013 Apr;45(4):392-396 [FREE Full text] [doi: 10.2340/16501977-1119] [Medline: 23474735]
17. Moffet H, Tousignant M, Nadeau S, Mérette C, Boissy P, Corriveau H, et al. In-Home Telerehabilitation Compared with Face-to-Face Rehabilitation After Total Knee Arthroplasty: A Noninferiority Randomized Controlled Trial. J Bone Joint Surg Am 2015 Jul 15;97(14):1129-1141. [doi: 10.2106/JBJS.N.01066] [Medline: 26178888]
18. Pfeufer D, Gililland J, Böcker W, Kammerlander C, Anderson M, Krähenbühl N, et al. Training with biofeedback devices improves clinical outcome compared to usual care in patients with unilateral TKA: a systematic review. Knee Surg Sports Traumatol Arthrosc 2018 Oct 17. [doi: 10.1007/s00167-018-5217-7] [Medline: 30334150]
19. Bahadori S, Immins T, Wainwright TW. A review of wearable motion tracking systems used in rehabilitation following hip and knee replacement. Journal of Rehabilitation and Assistive Technologies Engineering 2018 Jun 18;5:205566831877181. [doi: 10.1177/2055668318771816]

20. Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, et al. Home-based Rehabilitation With A Novel Digital Biofeedback System versus Conventional In-person Rehabilitation after Total Knee Replacement: a feasibility study. Sci Rep 2018 Jul 26;8(1):11299 [FREE Full text] [doi: 10.1038/s41598-018-29668-0] [Medline: 30050087]
21. Mizner RL, Petterson SC, Snyder-Mackler L. Quadriceps strength and the time course of functional recovery after total knee arthroplasty. J Orthop Sports Phys Ther 2005 Jul;35(7):424-436. [doi: 10.2519/jospt.2005.35.7.424] [Medline: 16108583]
22. Yuksel E, Kalkan S, Cekmece S, Unver B, Karatosun V. Assessing Minimal Detectable Changes and Test-Retest Reliability of the Timed Up and Go Test and the 2-Minute Walk Test in Patients With Total Knee Arthroplasty. J Arthroplasty 2017 Dec;32(2):426-430. [doi: 10.1016/j.arth.2016.07.031] [Medline: 27639305]
23. Stevens-Lapsley JE, Schenkman ML, Dayton MR. Comparison of self-reported knee injury and osteoarthritis outcome score to performance measures in patients after total knee arthroplasty. PM R 2011 Jun;3(6):541-549. [doi: 10.1016/j.pmrj.2011.03.002] [Medline: 21665167]
24. Blom AW, Artz N, Beswick AD, Burston A, Dieppe P, Elvers KT, et al. Improving patients' experience and outcome of total joint replacement: the RESTORE programme. Programme Grants for Applied Research 2016 Aug;4(12):508. [doi: 10.3310/pgfar04120] [Medline: 27559567]
25. Parent E, Moffet H. Comparative responsiveness of locomotor tests and questionnaires used to follow early recovery after total knee arthroplasty. Arch Phys Med Rehabil 2002 Jan;83(1):70-80. [doi: 10.1053/apmr.2002.27337] [Medline: 11782835]
26. Lindemann U, Becker C, Unnewehr I, Muche R, Aminin K, Dejnabadi H, et al. Gait analysis and WOMAC are complementary in assessing functional outcome in total hip replacement. Clin Rehabil 2006 May;20(5):413-420. [doi: 10.1191/0269215506cr958oa] [Medline: 16774092]
27. Pozzi F, Snyder-Mackler L, Zeni J. Physical exercise after knee arthroplasty: a systematic review of controlled trials. Eur J Phys Rehabil Med 2013 Dec;49(6):877-892 [FREE Full text] [Medline: 24172642]
28. Park KK, Chang CB, Kang YG, Seong SC, Kim TK. Correlation of maximum flexion with clinical outcome after total knee replacement in Asian patients. J Bone Joint Surg Br 2007 May;89(5):604-608. [doi: 10.1302/0301-620X.89B5.18117] [Medline: 17540744]
29. Miner AL, Lingard EA, Wright EA, Sledge CB, Katz JN, Kinemax Outcomes Group. Knee range of motion after total knee arthroplasty: how important is this as an outcome measure? J Arthroplasty 2003 Apr;18(3):286-294. [doi: 10.1054/arth.2003.50046] [Medline: 12728419]
30. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. J Am Geriatr Soc 1991 Feb;39(2):142-148. [Medline: 1991946]
31. Yeung TSM, Wessel J, Stratford PW, MacDermid JC. The timed up and go test for use on an inpatient orthopaedic rehabilitation ward. J Orthop Sports Phys Ther 2008 Jul;38(7):410-417. [doi: 10.2519/jospt.2008.2657] [Medline: 18591756]
32. Poitras S, Wood KS, Savard J, Dervin GF, Beaule PE. Predicting early clinical function after hip or knee arthroplasty. Bone Joint Res 2015 Sep;4(9):145-151 [FREE Full text] [doi: 10.1302/2046-3758.49.2000417] [Medline: 26336897]
33. Bade MJ, Kittelson JM, Kohrt WM, Stevens-Lapsley JE. Predicting functional performance and range of motion outcomes after total knee arthroplasty. Am J Phys Med Rehabil 2014 Jul;93(7):579-585 [FREE Full text] [doi: 10.1097/PHM.0000000000000065] [Medline: 24508937]
34. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)--development of a self-administered outcome measure. J Orthop Sports Phys Ther 1998 Aug;28(2):88-96. [doi: 10.2519/jospt.1998.28.2.88] [Medline: 9699158]
35. Alviar MJ, Olver J, Brand C, Tropea J, Hale T, Pirpiris M, et al. Do patient-reported outcome measures in hip and knee arthroplasty rehabilitation have robust measurement attributes? A systematic review. J Rehabil Med 2011 Jun;43(7):572-583 [FREE Full text] [doi: 10.2340/16501977-0828] [Medline: 21607295]
36. Monticone M, Ferrante S, Salvaderi S, Motta L, Cerri C. Responsiveness and minimal important changes for the Knee Injury and Osteoarthritis Outcome Score in subjects undergoing rehabilitation after total knee arthroplasty. Am J Phys Med Rehabil 2013 Oct;92(10):864-870. [doi: 10.1097/PHM.0b013e31829f19d8] [Medline: 23900017]
37. Stratford PW, Kennedy DM, Robarts SF. Modelling knee range of motion post arthroplasty: clinical applications. Physiother Can 2010;62(4):378-387 [FREE Full text] [doi: 10.3138/physio.62.4.378] [Medline: 21886379]
38. Bade MJ, Stevens-Lapsley JE. Early high-intensity rehabilitation following total knee arthroplasty improves outcomes. J Orthop Sports Phys Ther 2011 Dec;41(12):932-941. [doi: 10.2519/jospt.2011.3734] [Medline: 21979411]
39. Petterson SC, Mizner RL, Stevens JE, Raisis L, Bodenstab A, Newcomb W, et al. Improved function from progressive strengthening interventions after total knee arthroplasty: a randomized clinical trial with an imbedded prospective cohort. Arthritis Rheum 2009 Feb 15;61(2):174-183 [FREE Full text] [doi: 10.1002/art.24167] [Medline: 19177542]
40. Paxton RJ, Forster JE, Miller MJ, Gerron KL, Stevens-Lapsley JE, Christiansen CL. A Feasibility Study for Improved Physical Activity After Total Knee Arthroplasty. J Aging Phys Act 2018 Jan 01;26(1):7-13. [doi: 10.1123/japa.2016-0268] [Medline: 28338406]
41. Bade MJ, Kohrt WM, Stevens-Lapsley JE. Outcomes before and after total knee arthroplasty compared to healthy adults. J Orthop Sports Phys Ther 2010 Sep;40(9):559-567 [FREE Full text] [doi: 10.2519/jospt.2010.3317] [Medline: 20710093]

42. Mutsuzaki H, Takeuchi R, Mataki Y, Wadano Y. Target range of motion for rehabilitation after total knee arthroplasty. J Rural Med 2017 May;12(1):33-37 [FREE Full text] [doi: 10.2185/jrm.2923] [Medline: 28593015]
43. El Bitar YF, Illingworth KD, Scaife SL, Horberg JV, Saleh KJ. Hospital Length of Stay following Primary Total Knee Arthroplasty: Data from the Nationwide Inpatient Sample Database. J Arthroplasty 2015 Oct;30(10):1710-1715. [doi: 10.1016/j.arth.2015.05.003] [Medline: 26009468]

Abbreviations

ASA: American Society of Anesthesiology
ADL: activities of daily living
CONSORT: Consolidated Standards of Reporting Trials
IQR: interquartile range
KOOS: Knee Osteoarthritis Outcome Scale
MCID: minimal clinically important difference
QoL: quality of life
ROM: range of motion
TKA: total knee arthroplasty
TUG: Timed Up and Go

Edited by G Eysenbach; submitted 12.12.18; peer-reviewed by R Grainger, D Pfeufer, N Bashi; comments to author 28.01.19; revised version received 30.01.19; accepted 17.02.19; published 28.02.19

Please cite as:
Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Molinos M, Teixeira L, Tulha J, Seabra R, Lains J, Bento V
Medium-Term Outcomes of Digital Versus Conventional Home-Based Rehabilitation After Total Knee Arthroplasty: Prospective, Parallel-Group Feasibility Study
JMIR Rehabil Assist Technol 2019;6(1):e13111
URL: http://rehab.jmir.org/2019/1/e13111/
doi:10.2196/13111
PMID:

Annex III

PUBLISHED PAPER

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Molinos M, Teixeira L, Pires J, Seabra R, Lains J, Bento V.

Digital versus conventional rehabilitation after total hip arthroplasty: a single-center; parallel-group pilot study

JMIR Rehabil Assist Technol 2019;6(1):e14523 doi: 10.2196/14523

Original Paper

Digital Versus Conventional Rehabilitation After Total Hip Arthroplasty: A Single-Center, Parallel-Group Pilot Study

Fernando Dias Correia[1], MD; André Nogueira[2], MPhysio; Ivo Magalhães[2], MPhysio; Joana Guimarães[2], MPhysio; Maria Moreira[2], MPhysio; Isabel Barradas[2], MPhysio; Maria Molinos[2], PhD; Laetitia Teixeira[3,4,5], PhD; Joaquim Pires[6], MD; Rosmaninho Seabra[6], MD; Jorge Lains[7], MD; Virgílio Bento[8], PhD

[1]Neurology Department, Hospital de Santo António-Centro Hospitalar do Porto, Porto, Portugal
[2]SWORD Health, Porto, Portugal
[3]Department of Population Studies, Abel Salazar Institute of Biomedical Sciences, Porto, Portugal
[4]Centro de Investigação em Tecnologias e Serviços de Saúde, Abel Salazar Institute of Biomedical Sciences, University of Porto, Porto, Portugal
[5]EPIUnit, Instituto de Saúde Pública, Universidade do Porto, Porto, Portugal
[6]Orthopaedics Department, Hospital da Prelada-Domingos Braga da Cruz, Porto, Portugal
[7]Physical Rehabilitation Medicine Department, Rovisco Pais Medical and Rehabilitation Centre, Tocha, Portugal
[8]Engineering Department, Instituto Universitário da Maia, Maia, Porto, Portugal

Corresponding Author:
Fernando Dias Correia, MD
Neurology Department
Hospital de Santo António-Centro Hospitalar do Porto
Largo Professor Abel Salazar
4099-001
Porto,
Portugal
Phone: 351 966557789
Email: fanacorreia@gmail.com

Abstract

Background: The demand for total hip arthroplasty (THA) is rising. In the face of rapidly increasing health care costs, ensuring widespread, cost-effective rehabilitation is a priority. Technologies allowing independent home-based rehabilitation may be the key to facilitate access, improve effectiveness, and lower costs of care.

Objective: The aim of this study was to assess the feasibility of a novel artificial intelligence–powered digital biofeedback system following THA and compare the clinical outcomes against supervised conventional rehabilitation.

Methods: This was a single-center, parallel-group pilot study, with an 8-week intervention program. Patients were assessed at baseline, during the program (at 4 and 8 weeks), and 3 and 6 months after surgery. The primary outcome was the Timed Up and Go (TUG) score and secondary outcomes were the Hip dysfunction and Osteoarthritis Outcome Scale (HOOS; a patient-reported outcome) and hip range of motion (ROM).

Results: A total of 66 patients were included: 35 digital physiotherapy (PT) versus 31 conventional. There were no differences at baseline between groups except for lower HOOS quality of life (QoL) subscale scores in the digital PT group. Clinically relevant improvements were noted in both groups at all time points. The digital PT group showed a retention rate of 86% (30/35). Per-protocol analysis revealed a superiority of the digital PT group for all outcome measures. Intention-to-treat analysis revealed the superiority of the digital PT group at all time points for TUG (change between baseline and 4 and 8 weeks: $P<.001$; change between baseline and 3 and 6 months: $P=.001$ and $P=.005$, respectively), with a difference between median changes of −4.79 seconds (95% CI −7.24 to −1.71) at 6 months post-THA. Between baseline and month 6, results were also superior in the digital PT group for the HOOS sports and QoL subscales and all ROM except for standing flexion.

Conclusions: This study demonstrates this novel solution holds promise in rehabilitation after THA, ensuring better clinical outcomes than conventional rehabilitation while reducing dependence on human resources.

Trial Registration: ClinicalTrials.gov NCT03045549; https://clinicaltrials.gov/ct2/show/NCT03045549

(JMIR Rehabil Assist Technol 2019;6(1):e14523) doi:10.2196/14523

KEYWORDS

THA; THR; digital physiotherapy; telerehabilitation; biofeedback; motion trackers; AI-powered rehabilitation

Introduction

The demand for total hip arthroplasty (THA) is rising [1,2]. By 2030, primary THA in the United States is estimated to increase by 174% and revision THA by 137% compared to 2005 [2], to approximately 572,000 primary and 96,700 revision procedures per year [2].

The efficacy of THA is well documented [3-5], and rehabilitation is key to optimize outcomes [6,7]. Furthermore, studies indicate that more intensive and early progressive exercise leads to better outcomes [8,9], greater satisfaction and adherence [10,11], and reduction of complications and expenses [11,12]. In an expert consensus on best practices for rehabilitation after THA, the greatest support was for 4 to 8 weeks of therapeutic exercise, two to three times per week [13].

In the face of rapidly increasing health care costs, ensuring widespread cost-effective rehabilitation is a priority, but putting this into effect constitutes a challenge, both in terms of logistics and costs.

In recent years, telerehabilitation solutions (ie, rehabilitation services delivered at home from a remote location through a telecommunication system and information technology [14]) have been developed that allow professionals to remotely monitor rehabilitation programs [15-17]. These solutions have demonstrated a potential to reduce health care costs associated with supervision, facility provision, and transport of patients [18-21], while yielding similar, but not superior, clinical outcomes as conventional physical therapy post-THA [22,23].

Using a different approach, several authors have compared unsupervised home-based programs with physiotherapist-led outpatient rehabilitation programs, with both cases showing similar results for patients who comply with their program [21,24-26]. However, in studies comparing supervised with unsupervised training, or no recommended training at all, there is high variability in adherence rates, which is a well-accepted key determinant to therapy success [27-29], ranging from 23% to 85% [8,27,30,31].

More advanced technological solutions have emerged that incorporate biofeedback systems with the intent of increasing both patient performance and adherence [17,32,33] to maximize outcomes. Promising as these may be, they are generally poorly interactive and show low-level evidence, with no long-term validation studies available.

In a previous study, we tested a novel digital biofeedback system based on inertial motion trackers that enables independent home-based physical rehabilitation with remote monitoring from a clinical team after total knee arthroplasty (TKA) [34]. In this study (N=59; NCT03047252), we compared the digital system to conventional, face-to-face, home-based rehabilitation post-TKA over an 8-week program. The results demonstrated that this solution was safe and very well-accepted, with high adherence and satisfaction levels and, most importantly, that the clinical outcomes were superior to conventional rehabilitation [34]. These encouraging results prompted further studies, with the intent of validating this solution in other therapeutic scenarios.

The aim of this single-center, parallel-group pilot study is to assess patient uptake and system safety in patients undergoing THA, as well as to compare the clinical outcomes of a home-based program using this digital physiotherapy (PT) system against conventional, in-person, home-based rehabilitation after THA.

Methods

Study Design

This was a single-center, parallel-group pilot study. It was designed to assess patient uptake and safety of a digital physiotherapy system, as well as to compare the clinical outcomes of a home-based program using a home-based digital program compared with conventional, in-person, home-based rehabilitation after THA.

Study Timeline

All consecutive patients admitted for THA between December 19, 2016 and January 16, 2018, were screened preoperatively and postoperatively for eligibility at Hospital da Prelada, Porto, Portugal, by the two orthopedic surgeons that oversaw the study (JP and RS). Completion date for the 6-month follow-up assessment was July 16, 2018.

Inclusion and Exclusion Criteria

All patients included in this study were referred to post-THA rehabilitation by two independent physicians. Patients were included if they were (1) aged 18 years or older and had (2) clinical and imaging (CT) evidence of hip osteoarthritis as assessed by the orthopedic surgeon, (3) indication for THA according to the patient´s orthopedic surgeon, (4) ability to walk (unaided or with assistive device), and (5) availability of a caregiver to assist the patient after surgery.

Exclusion criteria were (1) admitted for revision THA; (2) contralateral hip or knee osteoarthritis severely limiting patient mobility and ability to comply with a rehabilitation program; (3) aphasia, dementia, or psychiatric comorbidity interfering with communication or adherence to the rehabilitation process; (4) respiratory, cardiac, metabolic, or other condition incompatible with at least 30 minutes of light to moderate physical activity; (5) major medical complications occurring after surgery that prevented the discharge of the patient within 10 days after the surgery; (6) other medical or surgical complications that prevent the patient from complying with a rehabilitation program; and (7) blindness or illiteracy.

Patient Allocation

Patients were recruited at Hospital da Prelada, Porto, Portugal. Patient allocation was performed using patient address as the criterion. Those patients residing in areas outside the administrative limits of the city of Oporto were allocated to the digital PT group, whereas those residing within the city limits were allocated to the conventional rehabilitation group. Patient allocation was performed centrally by one investigator (FDC) and communicated to the responsible physiotherapist only after patient enrollment.

Blinding

The nature of the study did not allow blinding of the patients. Patient assessment was performed by two investigators (JP and RS), who were blinded to the study groups. Statistical analysis was performed by a blinded statistician (LT).

Intervention

After the initial assessment, all patients were submitted to elective THA. Surgical technique was the same for all patients—direct lateral approach under regional anesthesia.

Between day 1 postop and hospital discharge, all patients were taught how to safely get in and out of bed and were asked to perform alternate ankle flexion and extension exercises regularly. All patients performed initial gait training with canes.

After hospital discharge, both groups received an 8-week rehabilitation program starting between day 7 and day 10 after surgery (see Multimedia Appendix 1). These were designed based on the results of a Delphi panel on best practices for rehabilitation after THA [13] and the protocols published by SOFMER, the French Physical and Rehabilitation Medicine Society [35].

In the digital PT group, patients received an initial visit from the physical therapist to assess specific needs and to teach patients and caregivers how to set up and use the system. Patients then performed exercise sessions independently, using the system, under asynchronous remote monitoring from the physical therapist (see Multimedia Appendix 1 for more details). Patients were instructed to exercise 5 to 7 days per week, minimum 30-minute sessions, but they were not excluded in case of lower adherence. Each patient received a telephone call on weeks 2 and 6 to check on patient adaptation, review the program, and assess adverse events; a face-to-face visit on week 4 to perform an in-depth review of the program; and a termination visit to collect the system. Additional visits were performed when required.

The conventional rehabilitation group received a home-based supervised program provided by a physiotherapist, three times a week, for 1 hour (see Multimedia Appendix 1 for more details). Patients were also instructed to perform additional sessions on at least two other days of the week. These were nonmandatory, and no record of these sessions was kept.

Outcomes Assessment

Total Therapist Time

Total therapist time was calculated in both groups, considering the time spent on face-to-face contacts and spent in travel and on calls. For the digital intervention group, time spent per patient in the Web-based portal was also calculated.

Safety and Adverse Events

In the digital PT group, patients were asked to rate pain and fatigue on a scale from zero to 10 at the end of each session. These were available for remote monitoring through the portal. Patients were also given the direct contact of the assigned physical therapist to report adverse events: pain during exercise, falls, and other medical complications (eg, inflammatory signs or infection on the surgical wound or operated member; thrombophlebitis).

Patients in the conventional rehabilitation group performed supervised sessions by a physical therapist, enabling early adverse event detection and reporting.

Primary and Secondary Outcomes

For primary outcome, we chose a performance test—the Timed Up and Go (TUG) test [36], which measures patient mobility and consists of the time it takes to rise from a chair, walk 3 meters, turn around, walk back to the chair, and sit down. This test is among the most recommended outcome measures to routinely assess or monitor outcomes after primary THA [13]. It is simple, practical, and quick and easy to administer, plus it has been demonstrated to predict both short- [37] and long-term [38] function following hip arthroplasty. Importantly, it has also shown excellent interrater (intraclass correlation [ICC] ≥0.9) and very good test-retest (ICC 0.8-0.89) reliability in patients with elective hip replacement (N=100) [39], and higher sensitivity to change in performance after THA than other commonly used self-reported measures, such as the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Lower Extremity Functional Scale (LEFS) [40]. Moreover, Podsiadlo and Richardson [36] confirmed its content validity in elderly persons (N=60), in that it evaluated a well-recognized series of maneuvers used in daily life.

Secondary outcomes were (1) patient-reported outcomes, measured by the Hip dysfunction and Osteoarthritis Outcome Scale (HOOS) [41] and (2) hip range of motion (ROM).

The HOOS consists of five subscales: (1) pain, (2) symptoms, (3) function in activities of daily living (ADL), (4) function in sport and recreation (sport), and (5) hip-related quality of life (QoL). Patients are asked to answer this disease-specific questionnaire, based on the previous week, with standardized options for each question (each is assigned a score from 0-4). A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale. This scale has shown high test-retest reproducibility for people with hip disability with or without hip osteoarthritis, with ICC ranging from 0.75 to 0.97 for all subscales [41]. The HOOS content validity was tested by Nilsdotter and colleagues [42] in patients assigned to THA (n=90), by asking them to rate the importance of each item. All items were considered to be of at least some importance by more than 67% of the patients, the limit set to justify inclusion into the HOOS. All items included in the pain (10/10), ADL (17/17), sport (5/5), QoL (4/4), and most items included in symptoms (4/5), were considered at least somewhat important by more than 80% of patients.

The SWORD device was used in both groups to measure active hip ROM. This device has been certified for use as an angle-measurement tool, with a reported root mean square error of 3.5° compared with standard goniometry in the technical file. Active hip ROM was measured in degrees in the following exercises: lying and standing hip flexion, lying and standing hip abduction, and standing hip hyperextension. For each exercise, the patient was asked to perform three repetitions by itself; the best value of the three was recorded.

Patients were assessed at baseline (preoperatively), 4 weeks after initiation of rehabilitation, at the end of the 8-week program, and at 3- and 6-months follow-up evaluations.

Sample Size Estimation

Calculations were performed taking into consideration the primary outcome measure—TUG—and based on a minimal detectable change of 2.49 seconds, as reported by Kennedy et al [43] on a longitudinal study evaluating outcomes following total hip and knee arthroplasty. Considering an effect size of 0.65, a power of 80%, and a two-sided .05 significance level, 60 patients (30 in each group) would be necessary to detect a difference of 2.49 seconds between the two groups. Considering a dropout rate of 15%, the target recruitment was 70 patients.

Statistical Analysis

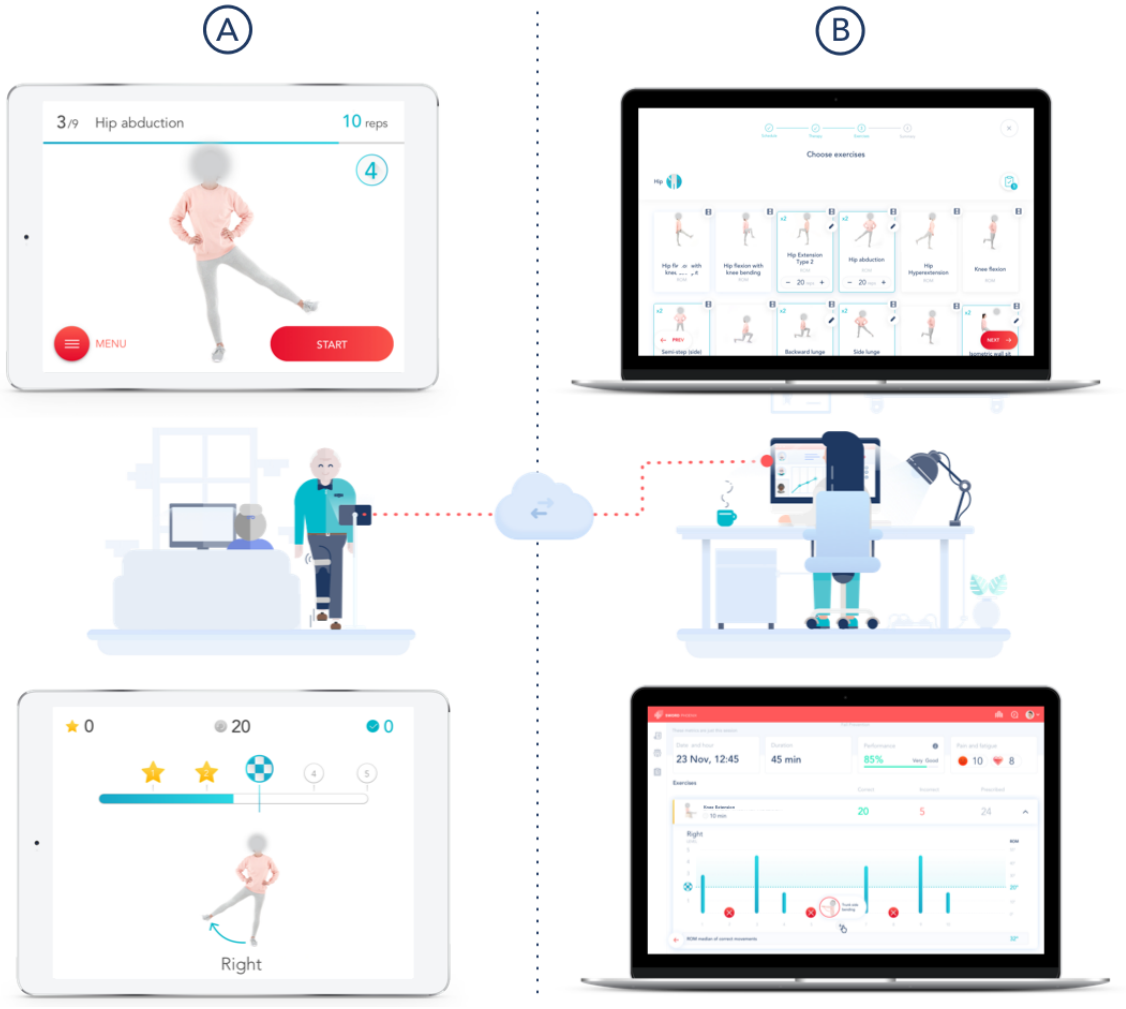
To assess differences in clinical and demographic variables of the patients allocated to the two study groups, independent samples *t* test or Mann-Whitney *U* test were used for quantitative variables. For categorical variables, chi-square test or Fisher exact test were used.

Outcome analysis was performed using both an intention-to-treat analysis and a per-protocol analysis. Differences between interventions were evaluated using independent samples *t* test or Mann-Whitney *U* test. For nonnormally distributed variables, the magnitude of the difference in the medians was assessed using Hodges-Lehman estimator. Additionally, a repeated measures ANOVA was also performed, with group as an independent factor and time as a within-subjects factor. When necessary, logarithm transformation was performed to obtain normally distributed variables. In all analysis, a significance level of .05 was considered. Statistical analysis was performed using IBM SPSS version 24.0.

System Technical Specifications

The system consisted of the elements described subsequently (Figure 1).

Figure 1. System components. (A) Mobile app. Preparation screen (top left): this screen displays video and audio instructions for each exercise. Execution screen (bottom left). (B) Web portal. Prescription screen (top right) displaying the exercise list and session layout. Results screen (bottom right) presenting (1) date, time, and session duration; (2) pain and fatigue scores; and (3) information on each repetition-range of motion and movement errors.



Inertial Motion Trackers

Each tracker consisted of a gyroscope, an accelerometer, and a magnetometer, which enabled precise movement quantification. The trackers were placed on body segments using Velcro straps in three specific positions: (1) over the sternal manubrium (red tracker), (2) on the anterior surface of the hip (green tracker), and (3) over the anterior tibial crest (blue tracker).

Mobile App

The app guided the patient through the session, providing video and audio instructions before each exercise, as well as real-time audio and video biofeedback during the exercise. If the patient performed a movement error or assumed an incorrect posture, an error message was displayed, allowing the patient to correct the movement in the following attempts.

Web-Based Portal

The portal enabled remote result monitoring and exercise prescription/edition by the clinical teams.

Ethics Approval of Research

The study was approved by the National Data Protection Commission (authorization number 1476/2017) and by the local ethics committee at Hospital da Prelada (Chair: Dr Juiz Conselheiro Almeida Lopes). The methods were conducted in accordance with the approved guidelines. All patients and caregivers were provided with information about the purpose and procedures of the study and provided written informed consent before inclusion. All patient data were anonymized and linked to the patient by a unique study number that did not contain any personal identifiers.

Data Availability

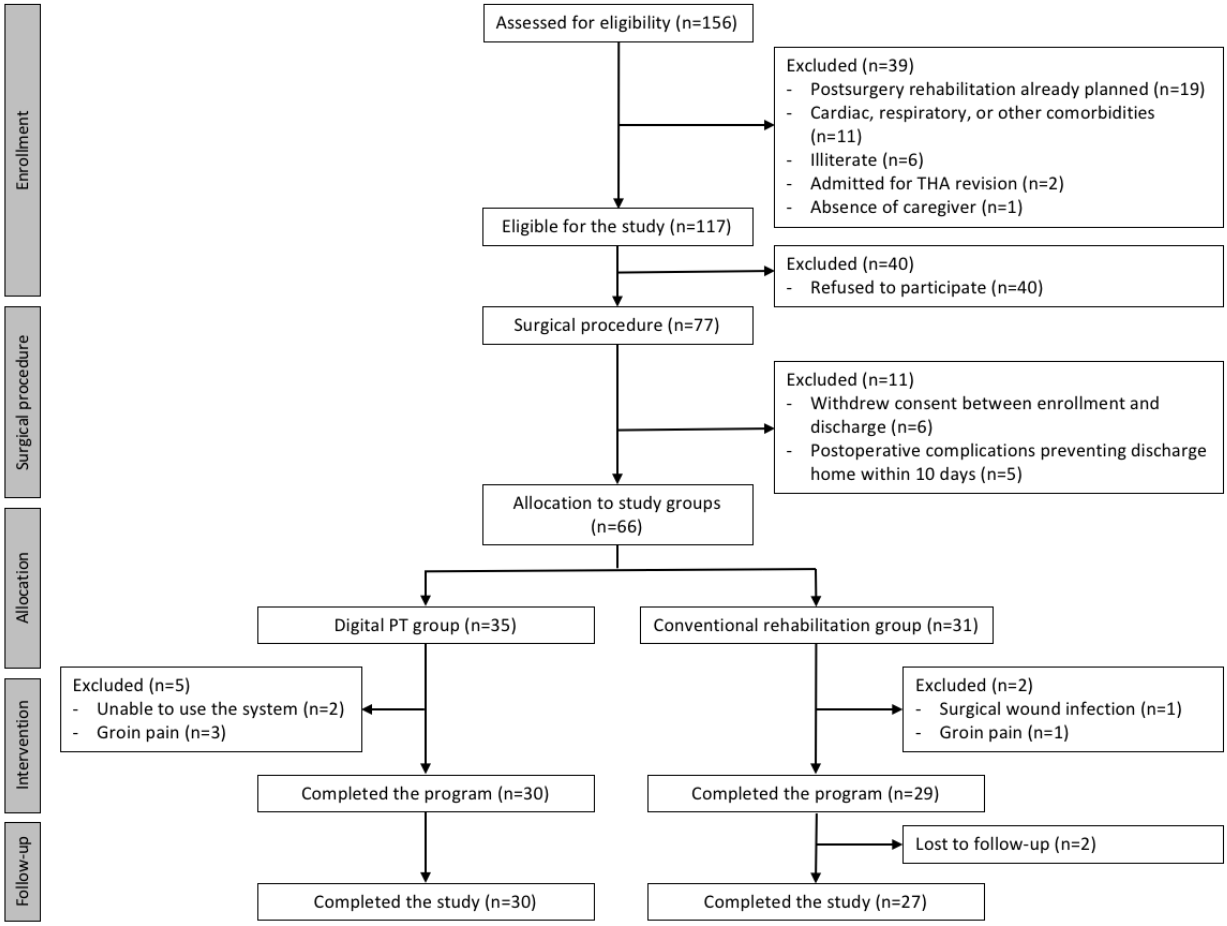
Individual participant data that underlie the results reported in this article will be shared after deidentification as supplementary information (Multimedia Appendix 2) of this paper. Other documents, namely the study protocol, Consolidated Standards of Reporting Trials (CONSORT) details, will also be made permanently available immediately following publication, either through the online version of this paper or at ClinicalTrials.gov (UI: NCT03045549).

Results

Overview

A total of 156 patients were assessed for eligibility between December 19, 2016 and January 16, 2018. Figure 2 shows the CONSORT diagram for the study (see also Multimedia Appendix 3). The study inclusion rate was of 42% (66/156). Between initial assessment and patient allocation, 90 patients refused to participate or withdrew consent, corresponding to 58% of all screening failures.

Figure 2. CONSORT (Consolidated Standards of Reporting Trials) diagram. PT: physiotherapy; THA: total hip arthroplasty.



Overall, 66 patients were included (35 in the digital PT group versus 31 in conventional rehabilitation). The dropout rate in the digital PT group was 14% (5/35): two patients did not adapt to the system and withdrew consent in the first week and three were excluded due to groin pain. The dropout rate in the conventional rehabilitation group was 6% (2/31): two patients were excluded, one due to a surgical wound infection requiring readmission and another due to groin pain. In total, 59 patients completed the study (30 versus 29) and 57 completed the follow-up assessments—two patients in the conventional rehabilitation group were lost to follow-up between the 3- and 6-month assessments.

Study Population Characteristics

Baseline characteristics of study participants regarding demographics, comorbidities, and risk factors for adverse events, as well as data on hospitalization and surgery are summarized in Table 1 (divided by allocation group). There were no differences at baseline between the two study groups regarding any population characteristics.

Independence of Use

In the digital PT group, 13 of 35 patients (37%) required the assistance of a caregiver for tracker or strap placement or navigation. Patients requiring assistance were older (mean age 68.0, SD 7.6 years versus mean 57.7, SD 6.6; *P*=.001).

Table 1. Baseline characteristics of study participants (N=66).

Population characteristics	Digital physiotherapy group (n=35)	Conventional rehabilitation (n=31)	*P* value
Demographics			
Age (years), mean (SD)	62.4 (8)	66.6 (10)	.07[a]
Gender (female), n (%)	15 (43)	16 (2)	.64
Operated hip side (right), n (%)	16 (46)	12 (39)	.74
Comorbidities and known risk factors for adverse events			
Body mass index, mean (SD)	28.3 (3)	27.4 (4)	.31[a]
Smoking, n (%)	2 (6)	7 (23)	.07[b]
Hypertension, n (%)	14 (40)	12 (39)	>.99
Diabetes, n (%)	11 (31)	7 (23)	.59
Pulmonary disease, n (%)	1 (3)	1 (3)	>.99
Cardiac disease, n (%)	3 (9)	5 (16)	.46[b]
Stroke, n (%)	1 (3)	0.0	—[c]
Renal disease, n (%)	0.0	0.0	—
Bleeding disorders, n (%)	0.0	2 (6)	—
ASA[d] (class 3 or 4), n (%)	8 (23)	10 (32)	.56
Steroids for chronic condition, n (%)	0	0	—
Previous contralateral hip replacement, n (%)	7 (20)	5 (16)	.93
Previous knee replacement, n (%)	1 (3)	0	—
Hospital admission and surgical procedure			
Time between admission and surgery (hours)	<24	<24	—
Operative time (min), mean (SD)	63.7 (19)	59.9 (9)	.10[a]
Noncemented prosthesis, n (%)	2 (6)	2 (6)	>.99
Minor adverse events before discharge, n (%)	0.0	0.0	—
Length of stay (days), median (IQR[e])	6.0 (2)	6.0 (1)	.43[f]

[a]Independent sample *t* test.

[b]Fisher exact test.

[c]Not applicable.

[d]American Society of Anesthesiology physical status classification system.

[e]IQR: interquartile range.

[f]Mann-Whitney *U* test.

Adherence to the Intervention

Only five patients (17%) did not comply with the recommended session frequency of five times per week.

Patient Satisfaction

Patients in the digital PT group were asked to report their satisfaction level by answering the question: "On a scale from 0-10 ('0' meaning that you would not recommend and '10' that you would highly recommend), how much would you recommend the system to one of your friends or neighbors?" Of the 35 patients in this group, 32 (91%) rated the system as 10, two patients rated the system as 9, and one did not answer.

Therapist-Patient Interaction

Patients in the conventional rehabilitation group had 24 in-person sessions, whereas patients in the digital PT group had 3 face-to-face contacts with the therapist and, on average, 0.6 (range 0-2) extra contacts for technical assistance. Regarding telephone calls, in addition to the two scheduled calls per protocol, each patient received a median of four extra calls (range 0-7), the vast majority due to difficulties in interacting with the system.

Treatment Intensity

Total active treatment time was similar in both groups in both intention-to-treat (ITT) and per-protocol analysis (ITT: P=.11; per protocol: P=.24). In the ITT analysis, treatment intensity in the digital PT group was 20 hours (interquartile range [IQR] 11.0, range 1.0-59.0) and in the per-protocol analysis was 21 hours (IQR 10.3, range 8.0-59) versus 24 hours in the conventional PT group.

Outcomes Assessment

Total Therapist Time

Total therapist time was lower in the digital intervention group (mean 6.5, IQR 1.2 hours versus mean 32.1, IQR 5.2 hours; P<.001).

Safety and Adverse Events

For all patients enrolled in the study (66 patients), there was no significant difference between groups for safety and adverse events (P>.99).

In the digital PT group, the adverse event rate was 14% (5/35). Three patients were excluded due to significant pain during hip abduction, without inflammatory or other warning signs. All three patients recovered spontaneously within 2 weeks. One patient reported inflammatory signs over the surgical wound and another suffered a fall (not during system use), with no need for hospital assistance.

In the conventional rehabilitation group, the adverse event rate was 23% (7/31). One patient required hospital readmission and a revision procedure due to a surgical wound infection, one was excluded due to groin pain, two patients reported inflammatory signs over the surgical wound, one patient had a thrombophlebitis, one reported a unilateral lower limb edema (with spontaneous recovery), and one patient suffered a fall, with no need for hospital assistance.

Primary and Secondary Outcomes

Baseline

There were no differences between the two groups regarding outcome measures, except for the HOOS QoL subscale (P=.03; see Tables 2-4). The median difference between the TUG scores in the two groups was of 2.34 seconds (95% CI −0.69 to 5.17) in favor of the conventional rehabilitation group. Taking into consideration the 2.49 seconds reported as minimal detectable change for this test [43], this difference is neither statistically nor clinically significant.

Table 2. Primary outcome assessment of Timed Up and Go (TUG) test: intention-to-treat analysis (N=66).

Time point	TUG time (seconds), median (IQR[a])		P value[b]	Estimate difference between groups (95% CI)
	Digital PT[c] group (n=35)	Control group (n=31)		
Baseline	17.50 (6.33)	14.89 (9.42)	.12	2.34 (−0.69, 5.17)
Short term				
8 weeks	7.26 (2.15)	11.03 (6.84)	<.001	−3.34 (−5.14, −1.70)
Change baseline-8 weeks	−10.50 (7.45)	−2.90 (7.10)	<.001	−6.33 (−8.79, −3.42)
Medium term				
6 months	6.38 (2.30)	8.20 (4.22)	<.001	−1.87 (−3.02, −0.62)
Change baseline-6 months	−10.50 (7.39)	−5.10 (6.94)	.005	−4.79 (−7.24, −1.71)

[a]IQR: interquartile range.

[b]Mann-Whitney U test.

[c]PT: physiotherapy.

Table 3. Secondary outcome of patient-reported Hip dysfunction and Osteoarthritis Outcome Scale (HOOS): intention-to-treat analysis (N=66).

Time point and variable	Score, median (IQR[a])		*P* value[b]	Estimate difference between groups (95% CI)
	Digital PT[c] group (n=35)	Control group (n=31)		
Baseline				
Symptoms	35.0 (20.0)	40.0 (30.0)	.12	−10.0 (−20.0, 0.0)
Pain	33.0 (13.0)	33.0 (35.0)	.50	−3.0 (−13.0, 5.0)
Activities of daily living	29.0 (15.0)	28.0 (28.0)	.75	1.0 (−6.0, 7.0)
Sports	0.0 (6.0)	0.0 (19.0)	.34	0.0 (0.0, 0.0)
Quality of life	13.0 (13.0)	19.0 (25.0)	.03	−6.0 (−13.0, 0.0)
8 weeks				
Symptoms	100.0 (5.0)	95.0 (20.0)	.01	5.00 (0.0, 10.0)
Pain	100.0 (7.0)	98.0 (12.0)	.24	0.0 (0.0, 5.0)
Activities of daily living	93.0 (11.0)	82.0 (14.0)	<.001	9.0 (4.0, 13.0)
Sports	50.0 (18.0)	38.0 (19.0)	.004	12.0 (6.0, 19.0)
Quality of life	81.0 (19.0)	69.0 (31.0)	.08	6.0 (0.0, 18.0)
Change baseline-8 weeks				
Symptoms	60.0 (30.0)	45.0 (30.0)	.06	10.0 (0.0, 20.0)
Pain	60.0 (22.0)	60.0 (32.0)	.75	2.0 (−10.0, 10.0)
Activities of daily living	56.0 (23.0)	57.0 (27.0)	.63	−2.0 (−10.0, 6.0)
Sports	44.0 (25.0)	38.0 (25.0)	.26	6.0 (−6.0, 13.0)
Quality of life	63.0 (31.0)	50.0 (25.0)	.46	6.0 (−6.0, 13.0)
6 months				
Symptoms	100.0 (5.0)	95.0 (10.0)	.20	0.0 (0.0, 5.0)
Pain	100.0 (5.0)	100.0 (7.0)	.75	0.0 (0.0, 0.0)
Activities of daily living	96.0 (11.0)	88.0 (19.0)	.02	4.0 (0.0, 10.0)
Sports	75.0 (32.0)	50.0 (32.0)	.01	19.0 (6.0, 37.0)
Quality of life	94.0 (12.0)	81.0 (19.0)	.02	7.0 (0.0, 19.0)
Change baseline-6 months				
Symptoms	60.0 (25.0)	45.0 (30.0)	.06	10.0 (0.0, 20.0)
Pain	65.0 (18.0)	53.0 (30.0)	.21	7.0 (−5.0, 17.0)
Activities of daily living	63.0 (22.0)	56.0 (25.0)	.10	7.0 (−1.0, 15.0)
Sports	69.0 (31.0)	38.0 (38.0)	.004	25.0 (7.0, 37.0)
Quality of life	75.0 (32.0)	56.0 (31.0)	.01	19.0 (6.0, 25.0)

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]PT: physiotherapy.

Table 4. Secondary outcome of hip range of motion assessment: intention-to-treat analysis (N=66).

Time point and variable	Median (IQR[a])		*P* value[b]	Estimate difference between groups (95% CI)
	Digital PT[c] group (n=35)	Control group (n=31)		
Baseline				
Lying flexion	28.2 (19.1)	37.1 (20.0)	.07	−8.9 (−18.53, 0.67)
Lying abduction	12.2 (5.4)	15.9 (9.1)	.05	−3.7 (−7.48, 0.02)
Standing flexion	45.1 (15.9)	49.6 (16.7)	.27	−4.5 (−12.52, 3.53)
Standing hyperextension	−11.9 (7.0)	−15.4 (8.8)	.31	3.4 (−0.44, 7.33)
Standing abduction	23.5 (6.8)	25.8 (10.7)	.08	−2.2 (−6.78, 2.26)
8 weeks				
Lying flexion	84.0 (23.5)	66.6 (19.6)	.002	17.5 (6.78, 28.18)
Lying abduction	50.5 (17.5)	39.2 (15.2)	.01	11.4 (3.27:19.50)
Standing flexion	87.6 (21.2)	80.0 (19.8)	.14	7.5 (−2.58, 17.66)
Standing hyperextension	−36.7 (14.3)	−30.1 (8.2)	.03	−6.6 (−12.28, −0.96)
Standing abduction	52.2 (13.8)	40.3 (11.3)	<.001	11.9 (5.62, 18.13)
Change baseline-8 weeks				
Lying flexion	55.8 (27.4)	29.4 (25.6)	<.001	26.4 (13.32, 39.50)
Lying abduction	38.4 (17.3)	23.3 (15.7)	<.001	15.1 (6.91, 23.25)
Standing flexion	42.5 (21.3)	30.4 (20.3)	.02	12.0 (1.81, 22.33)
Standing hyperextension	−24.7 (12.7)	−14.7 (10.1)	.001	−10.1 (−15.75, −4.38)
Standing abduction	28.7 (13.4)	14.6 (13.5)	<.001	14.1 (7.51, 20.76)
6 months				
Lying flexion	80.7 (24.4)	70.0 (19.3)	.06	10.7 (−0.27, 21.6)
Lying abduction	49.8 (18.2)	41.6 (14.3)	.048	8.2 (0.06, 16.31)
Standing flexion	90.2 (23. 1)	84.8 (19.8)	.32	5.4 (−5.25, 16.03)
Standing hyperextension	−34.1 (15.1)	−28.8 (9.2)	.10	−5.3 (−11.36, 0.81)
Standing abduction	51.7 (15.1)	43.8 (11.8)	.02	8.0 (1.24, 14.69)
Change baseline-6 months				
Lying flexion	52.5 (26.6)	32.8 (25.6)	.003	19.6 (6.73, 32.50)
Lying abduction	37.6 (18.2)	25.7 (15.2)	.01	11.9 (3.57, 20.20)
Standing flexion	45.1 (22.6)	35.2 (20.6)	.07	9.9 (−0.79, 20.57)
Standing hyperextension	−22.2 (13.3)	−13.5 (11.1)	.01	−8.7 (−14.72, −2.59)
Standing abduction	28.2 (14.3)	18.0 (12.1)	.003	10.2 (3.64, 16.74)

[a]IQR: interquartile range.

[b]Mann-Whitney *U* test.

[c]PT: physiotherapy.

Short-Term Outcomes Assessment

4-Week Assessment

Differences between groups were found for TUG between the digital PT and the conventional group: mean 9.9 (SD 5.4) seconds versus mean 15.0 (SD 8.2) seconds, respectively (*P*<.001), (see Multimedia Appendix 4) and for all hip ROM exercises, except standing flexion (*P*=.05; see Multimedia Appendix 4). There were no differences between groups in terms of patient-reported outcomes (see Multimedia Appendix 4).

8-Week Assessment

The TUG scores were again lower in the digital PT group (*P*<.001; see Table 2). The median difference between the TUG scores in the two groups was 3.34 seconds (95% CI −5.14 to −1.70).

Regarding HOOS, the median scores in the digital PT group were superior to the conventional rehabilitation group for all subscales, except for pain and QoL (see Table 3). Importantly, in the symptoms and pain subscales, the median scores at the 8-week assessment were either the maximum score that can be attained (100) or close to that value in both groups, revealing a ceiling effect, which persisted over time (see Table 3).

Hip ROM was also higher in the digital PT group for all exercises, except for standing flexion (see Table 3).

Change Between Baseline and the 8-Week Assessment

The median difference between the changes in the two groups regarding the TUG score was 6.33 seconds (95% CI −8.79 to −3.42). The minimal detectable change was 2.49 seconds, which reveals a clinically significant difference (see Table 2).

No significant differences were detected in the median changes from baseline and week 8 for HOOS scores (see Table 3).

For hip ROM, significant improvements from baseline were noted in both groups, again with the digital PT group showing greater results (see Table 4).

In the per-protocol analysis, the change between baseline and week 8 was superior in the digital PT group for all outcome measures (see Multimedia Appendix 5).

Medium-Term Outcomes Assessment

3-Months Assessment

The TUG score remained significantly different between groups (P<.001), with patients from the SWORD group experiencing better results (see Multimedia Appendix 4).

For the HOOS, the median scores in the digital PT group were superior for all subscales except for pain (P=.10) and symptoms (P=.08; see Multimedia Appendix 4).

Hip ROM was also higher in the digital PT group for all measured exercises (P<.001), except for standing flexion (P=.41; see Multimedia Appendix 4).

6-Months Assessment

The median difference between the TUG scores in the two groups was 1.87 seconds (95% CI −3.02 to −0.62) in favor of the digital PT group (P=.002; see Table 2).

For HOOS, the median scores in the digital PT group were significantly superior to the conventional rehabilitation group for the ADL (P=.02), sports (P=.01), and QoL (P=.02) subscales (see Table 3). Importantly, the majority of patients from both groups reported the highest possible scores in the symptoms and pain subscales, and the ADL and QoL scores from the digital PT group nearly reached this same plateau (see Table 3).

Hip ROM was higher in the digital PT group for lying abduction (P=.048) and standing abduction (P=.02; see Table 4).

Change Between Baseline and the 6-Months Assessment

The ITT analysis revealed the superiority of the digital PT group in the TUG test, HOOS sports and QoL subscales, and all hip ROM exercises, except for standing flexion.

The median difference between the changes in the two groups for TUG was 4.79 seconds (95% CI −7.24 to −1.70) in favor of the digital PT group (see Table 2).

For HOOS, the difference between median score changes was both statistically and clinically significant in the sports (25.0 points, 95% CI 7.0-37.0) and the QoL (19.0 points, 95% CI 6.0-25.0) subscales (see Table 3).

For hip ROM, significant differences between the mean changes in the two groups were detected in all ROM exercises, except the standing flexion hip ROM (P=.07; see Table 4).

In the per-protocol analysis, the superiority of the digital PT group was verified for all outcome measures (see Multimedia Appendix 5).

Repeated Measures Analysis

A repeated measures ANOVA was performed only for variables with normal distribution—TUG (after log transformation) and hip ROM—and results are summarized in Table 4. Although both groups presented an improvement in every dimension evaluated, this analysis revealed a main effect of time, a main effect of group (here with the exception of the standing hip flexion ROM), and an interaction between time and group for all outcome measures in favor of the digital PT group (see Table 5 and Figure 3).

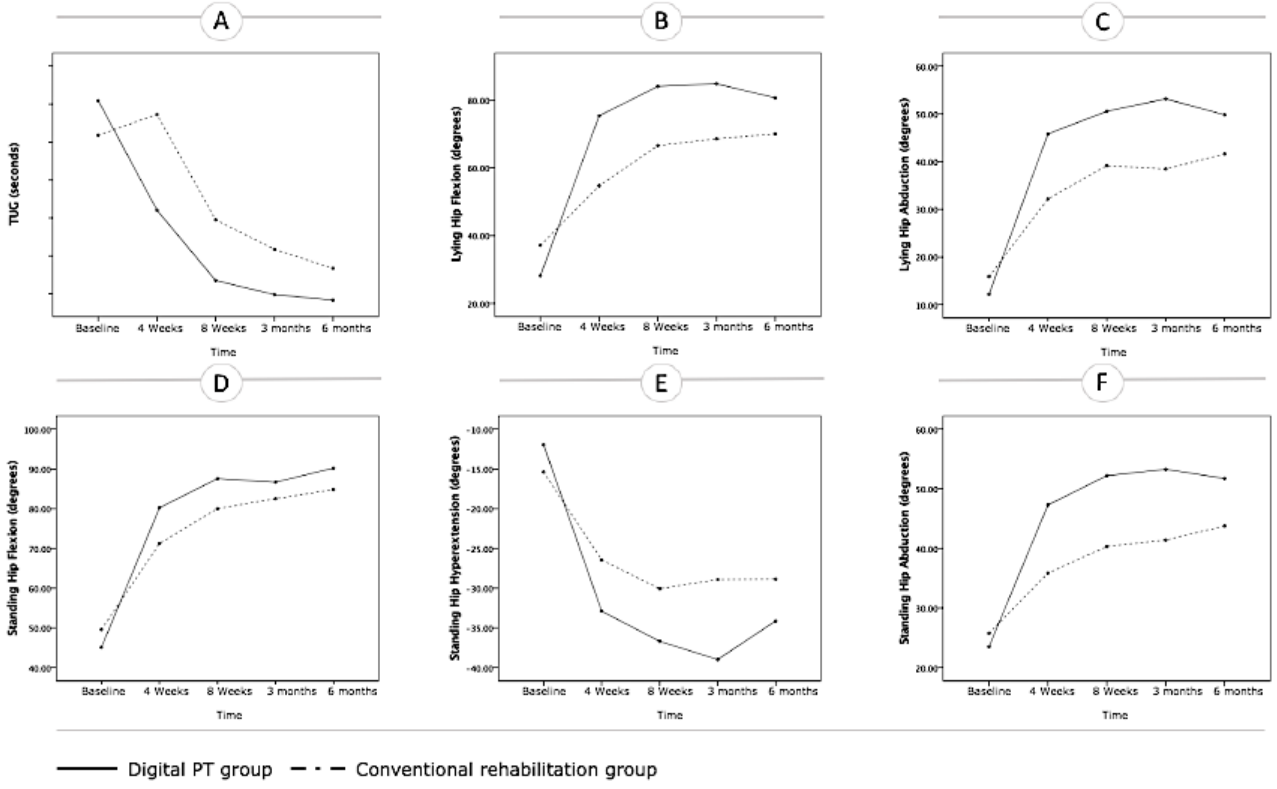
Table 5. Outcomes assessment: repeated measures analysis.

Outcome variable	Time		Group		Time*Group	
	F (df1,df2)	*P* value	*F* (df1,df2)	*P* value	*F* (df1,df2)	*P* value
Patient performance						
Timed Up and Go[a,b]	128.6 (2.5,159.6)	<.001	12.3 (1,64)	.01	14.9 (3.2,159.6)	<.001
Hip range of motion[b]						
Lying hip flexion	119.4 (1.9,121.6)	<.001	6.5 (1,64)	.01	12.0 (1.9,121.6)	<.001
Lying hip abduction	139.0 (2.9,188.1)	<.001	9.4 (1,64)	.03	10.4 (2.9,121.6)	<.001
Standing hip flexion	154.9 (1.9,123.1)	<.001	1.06 (1,64)	.31	4.0 (1.9,123.1)	.02
Standing hip hyperextension	91.1 (3.3,211.2)	<.001	4.6 (1,64)	.04	8.2 (3.3,211.2)	<.001
Standing hip abduction	125.5 (2.1,137.3)	<.001	10.0 (1,64)	.002	12.1 (2.1,137.3)	<.001

[a]ln transformation.

[b]Greenhouse-Geisser correction.

Figure 3. Evolution of the outcomes over time in both groups based on the repeated measures analysis (estimated marginal means are presented). (A) Timed Up and Go (TUG) score, (B) lying hip flexion, (C) lying hip abduction, (D) standing hip flexion, (E) standing hip hyperextension, (F) standing hip abduction. PT: physiotherapy.



Discussion

Patient refusal and consent withdrawal were the main reasons for screening failures in this study (57.7%, 90/156). The explanation for this high refusal rate resides in patient skepticism on the patient side, especially in an older population with little technological literacy. This same difficulty was reported by other authors in studies with similar devices [44] and is one of the challenges that these technologies need to overcome. The oldest patients in this study were also afraid of hidden costs, even though it was clear and thoroughly explained that participation in the study did not imply any cost.

There were two dropouts in the digital PT group, and a high percentage of patients needed assistance from a caregiver to interact with the system (37%, 13/35) or required assistance calls. This likely represents the challenges felt by an older population when dealing with technology and some issues with the user interface that need to be overcome. In particular, each physical interaction (ie, the need to calibrate sensors and the multiple touches needed to start a session) represent huge hurdles for elderly patients. This has been another challenge faced by similar technologies and is an aspect where there is still much room for improvement.

The patient satisfaction score was very high, with all but two patients rating the system with a 10/10. This is particularly interesting considering the high percentage of patients who needed assistance in using the system. When they were asked to elaborate on the reasons, almost all referred to the possibility of performing sessions at home, at their convenience. Still, it must be considered that patients who agreed to enter the study were more prone to use new technologies, and thus more likely to give high scores.

Regarding clinical outcomes, considering the reference values for the TUG [43], HOOS [45], and hip ROM [46], both groups attained clinically relevant improvements in all outcome measures in the short- and medium-term assessments. This is in line with the findings of other authors who reported the effectiveness of early exercise interventions post-THA [8,10,47-49].

Greater benefits were observed in the digital PT group, which was particularly evident in the per-protocol analysis, for all outcome measures. Furthermore, for TUG and hip ROM, these were confirmed in the repeated measures analysis. This is a major achievement for remotely assisted PT programs, considering no evidence exists yet on the superiority of a specific exercise intervention post-THA [13,50-52]. Indeed, this approach could be a game-changer on how rehabilitation programs are delivered following hip replacement. By offering a scalable solution that does not rely entirely on human resources and maximizes the reach of existing resources, while minimizing patient discomfort and the need for traveling back and forth, access to effective rehabilitation could be democratized.

A synergy of factors might explain the results obtained in this study. These have already been discussed in a previous paper [34] and can be summarized as follows: (1) beneficial impact of biofeedback and gamification on patient engagement and performance, namely on achieving a higher ROM and on a more effective correction of movement errors; (2) greater patient empowerment, coupled with the effect of monitoring on patient effort; and (3) program changes based on objective data.

In the absence of studies using technologies similar to this one, it was nearly impossible to establish interstudy comparisons. In fact, we found five reports on biofeedback systems designed to complement physical therapists' intervention following hip arthroplasty [17,32,33,53,54], of which only two were based on inertial motion tracking [53,54]. However, the aims of these studies were distinct from ours and did not propose any rehabilitation program. Furthermore, reports on PT interventions for THA recipients revealed high methodological variability regarding timing, duration and intensity, outcome measures, and timelines for assessment [5,6,51,55]. Thus, only broad comparisons can be made between this study and previous ones.

Despite being one of the most often used and recommended performance-based outcome measures [13], the TUG test was only found in four studies [24,25,30,56]. From these, one compared the change between baseline and 9 to 12 months postsurgery [30], and the others presented data on 4- [56], 8- [24], 12- and 26-week [25] assessments or on the change between baseline and 9 to 12 months [30]. All studies but one [56] reported similar significant improvements on the TUG test with time in both intervention groups. Overall, reported changes in TUG scores varied between 0.36 seconds [56] and −5.8 seconds [25]. The results in the conventional PT group from this study fall broadly within these values, whereas the results of the digital PT group were higher, even surpassing the scores previously reported for healthy, community-living older adults (mean 8 seconds) [57,58]. Additionally, although the pattern of recovery from the conventional group followed a similar trend to the ones found in other studies using conventional PT [59,60], patients from the digital PT group improved faster (38% at 4 weeks after surgery) and to a greater extent in the medium term (60% at 24 weeks). Indeed, in the study from Naylor et al [59], an Australian cohort of 44 THA recipients (mean age 65 years) with TUG baseline values similar to ours (18 seconds), patient recovery at 4 weeks was approximately 6% and plateaued at 36% 24 weeks after surgery. Additionally, Kennedy et al [60] reported a very slow recovery in a Canadian cohort of 68 patients (mean age 68 years), with a 78% TUG aggravation within the first 4 weeks following surgery (18 seconds) and a 21% improvement from baseline after 24 weeks. However, in this latter case, baseline values were oddly low (10.14 seconds), masking an actual 73% recovery after 24 weeks when the postoperative TUG (30 seconds) was set as the reference value.

Regarding HOOS, all subscales from both groups presented higher scores than those reported on a French (N=30; 37.5-55.3 points) [45] or Swedish HOOS validation study (N=90; 56.3-82.3 points) [42] 3 and 6 months after THA, respectively. In another randomized controlled trial (RCT; N=68) on the effect of a walking skill training program in THA patients, significant improvements were detected between 3 and 5 months. However, changes were much smaller than those we observed. Also, in terms of changes from baseline, both the digital PT and the control group improved significantly from baseline to 4 weeks postoperatively, which was sooner than what was reported by Mikkelsen et al (RCT; N=73) [8] and Heiberg et al (RCT; N=68) [61]. Importantly, a ceiling effect was observed on the HOOS symptoms and pain subscales, with patients from both intervention groups reporting the best possible score from 8 weeks onward. Ceiling effects have also been reported on all subscales in the Swedish HOOS validation study, 6 months after THR [42], and in the Dutch RCT by Mikkelsen et al [8]. Considering some sensitivity is lost using this scale, a revision and adaptation to the context of digital interventions, such as the one we presented, would be very useful in the future.

Regarding hip ROM, all reports use goniometry as a means to measure hip ROM, whereas we applied high-precision sensor-based technology to assess active hip ROM, enabling continuous remote monitoring [34,62], while eliminating operator errors [63]. In a retrospective study by Davis et al (N=1383) [64], a logistic regression model yielded three levels of postsurgery hip ROM: high (115° of flexion, 25° of abduction), average (90°-114° of flexion, 16°-24° of abduction), or low (<90° of flexion, ≤15° of abduction) motion. Considering these ranges, scores from our study revealed very high abduction amplitudes in both groups at month 6 postsurgery, particularly in the digital PT group. Indeed, we found no other reports showing superior abduction results than those reported in this study [31,56,61,65,66].

On the other hand, flexion ROM values fell in the lower range reported, revealing some room for improvement. Notwithstanding, our results from the digital PT group at month 6 (median 80.7°, IQR 24.4) were comparable to the ones reported on another prospective study (N=15) [66] on THA outcomes 12 months postsurgery (flexion mean 93.3°, SD 18.7°).

Another study by Umpierres et al (RCT, N=106) [65] also reported on the improvement of hip flexion and extension ROM following THR, with an early 2-week inpatient supervised versus unsupervised intervention. Although closer to the values reported at the 4-week assessment in this study, results from the digital PT group in our study were superior to the ones reported in this RCT. Other studies were found in which flexion and extension ROMs were higher than those we reported [31,56,61]. However, even considering possible differences related to measurement methods, high baseline angles revealed that the population in these studies was not as disabled as the one in this study.

Although the improvements achieved in hip ROM are substantial, the values are still far from those reported for healthy individuals [67].

This study has several limitations that need to be acknowledged. This was a quasi-randomized study, in which patient allocation was performed according to geographical location. This implies that even if no differences were found in demographics, comorbidities, and risk factors for adverse and clinical characteristics (except for the HOOS QoL subscale), a number of factors (eg, socioeconomic) might have influenced the results. Still, almost all the patients resided in urban areas; therefore, the authors speculate that the impact of these aspects is small, but nonetheless needs to be controlled in ensuing studies.

There was a potential selection bias toward more technologically prone recipients, given the low inclusion rate. To address this, greater involvement of the clinical teams (doctors and nursing staff) in the wards is required to overcome natural patient skepticism.

The limited context of the clinical setting, which was a low-volume orthopedic hospital, may not reflect the reality of other settings. Thus, generalization of the results needs to be confirmed in larger hospitals and multicentric trials.

The study protocol depicts slight differences between the digital PT group and conventional rehabilitation group that could be confounders. First, the total active treatment time was similar between groups. However, the intensity in the digital PT group was highly variable, and unsupervised sessions in the conventional group were not taken into consideration. These aspects also need to be homogenized and controlled in future studies. Second, the exercise program was similar in both groups, with the exception of additional exercises that were possible only with a face-to-face intervention. In this sense, although the authors agree that these may be confounding factors, they benefit the conventional group and not the digital intervention group and therefore do not bias results toward the latter.

There was a notable absence of minor adverse events, in particular after 8 weeks, most likely due to underreporting. In future studies, in addition to direct telephone contacts at predetermined time stamps and specific questioning of adverse events in assessment appointments, event logs should be delivered to the patients for them to fill in.

In conclusion, this study demonstrates that home-based rehabilitation with this novel digital biofeedback system is feasible and safe following THA as previously demonstrated for TKA, and is associated with high patient satisfaction, albeit with room for improvement in terms of usability by elderly patients. Plus, to our knowledge, it is the first study demonstrating that a digital rehabilitation solution can reduce the dependence on human resources while ensuring better clinical outcomes than conventional rehabilitation in the short and medium term following THA. These promising results justify further investigation and prove the feasibility of larger RCTs to confirm these findings.

Acknowledgments

This work was supported by the European Commission through the Project H2020 SME Instrument Phase 2-Grant Agreement number 672814. The study sponsor, SWORD Health, was involved in study design, data collection, and interpretation and writing of the manuscript. All patients included in this study were referred to post-THA rehabilitation by JP and RS, who also served as independent controllers of the study. The decision to submit the manuscript for publication was made by these two independent authors.

Authors' Contributions

Study concept and design: FDC, AN, VB, JP, RS, and LT. Data acquisition: IM, JG, MM, and IB. Direct supervision of rehabilitation program: IM, JG, MM, and IB. Independent supervision of rehabilitation program: JP and RS. Outcomes assessment: JP. Analysis and interpretation of data: FDC, LT, AN, and MM. Critical revision of the manuscript for important intellectual content: all authors. Obtained funding: FDC and VB. Administrative, technical, and material support: IM, JG, MM, and IB. Study supervision: FDC, VB, JP, RS, and AN.

Conflicts of Interest

FDC and VB have a shareholder position at SWORD Health, a company that develops and commercializes SWORD-related products. AN, IM, JG, MM, and IB are employees of SWORD Health but do not have shareholder positions. LT and JL receive honoraria from SWORD Health. JP and RS have no conflicts of interest to report.

Multimedia Appendix 1

Rehabilitation protocol.

[DOCX File, 17KB - rehab_v6i1e14523_app1.docx]

Multimedia Appendix 2

Raw data.

[XLSX File (Microsoft Excel File), 260KB - rehab_v6i1e14523_app2.xlsx]

Multimedia Appendix 3

CONSORT-EHEALTH checklist (V 1.6.1).

[PDF File (Adobe PDF File), 2MB - rehab_v6i1e14523_app3.pdf]

Multimedia Appendix 4

Intent-to-treat analysis.

[DOCX File, 43KB - rehab_v6i1e14523_app4.docx]

Multimedia Appendix 5

Per protocol analysis.

[DOCX File, 186KB - rehab_v6i1e14523_app5.docx]

References

1. Singh JA. Epidemiology of knee and hip arthroplasty: a systematic review. Open Orthop J 2011 Mar 16;5:80-85 [FREE Full text] [doi: 10.2174/1874325001105010080] [Medline: 21584277]
2. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 2007 Apr;89(4):780-785. [doi: 10.2106/JBJS.F.00222] [Medline: 17403800]
3. Ethgen O, Bruyère O, Richy F, Dardennes C, Reginster J. Health-related quality of life in total hip and total knee arthroplasty. A qualitative and systematic review of the literature. J Bone Joint Surg Am 2004 May;86(5):963-974. [doi: 10.2106/00004623-200405000-00012] [Medline: 15118039]
4. Kennedy DM, Hanna SE, Stratford PW, Wessel J, Gollish JD. Preoperative function and gender predict pattern of functional recovery after hip and knee arthroplasty. J Arthroplasty 2006 Jun;21(4):559-566. [doi: 10.1016/j.arth.2005.07.010] [Medline: 16781410]
5. Vissers MM, Bussmann JB, Verhaar JA, Arends LR, Furlan AD, Reijman M. Recovery of physical functioning after total hip arthroplasty: systematic review and meta-analysis of the literature. Phys Ther 2011 May;91(5):615-629. [doi: 10.2522/ptj.20100201] [Medline: 21393418]
6. Coulter CL, Scarvell JM, Neeman TM, Smith PN. Physiotherapist-directed rehabilitation exercises in the outpatient or home setting improve strength, gait speed and cadence after elective total hip replacement: a systematic review. J Physiother 2013 Dec;59(4):219-226 [FREE Full text] [doi: 10.1016/S1836-9553(13)70198-X] [Medline: 24287215]
7. Okoro T, Lemmey AB, Maddison P, Andrew JG. An appraisal of rehabilitation regimes used for improving functional outcome after total hip replacement surgery. Sports Med Arthrosc Rehabil Ther Technol 2012 Feb 07;4(1):5 [FREE Full text] [doi: 10.1186/1758-2555-4-5] [Medline: 22313723]
8. Mikkelsen LR, Mechlenburg I, Søballe K, Jørgensen LB, Mikkelsen S, Bandholm T, et al. Effect of early supervised progressive resistance training compared to unsupervised home-based exercise after fast-track total hip replacement applied to patients with preoperative functional limitations. A single-blinded randomised controlled trial. Osteoarthritis Cartilage 2014 Dec;22(12):2051-2058 [FREE Full text] [doi: 10.1016/j.joca.2014.09.025] [Medline: 25305374]
9. Trudelle-Jackson E, Smith SS. Effects of a late-phase exercise program after total hip arthroplasty: a randomized controlled trial. Arch Phys Med Rehabil 2004 Jul;85(7):1056-1062. [Medline: 15241750]
10. Mikkelsen LR, Mikkelsen SS, Christensen FB. Early, intensified home-based exercise after total hip replacement-a pilot study. Physiother Res Int 2012 Dec;17(4):214-226. [doi: 10.1002/pri.1523] [Medline: 22451440]

11. Haas R, Sarkies M, Bowles K, O'Brien L, Haines T. Early commencement of physical therapy in the acute phase following elective lower limb arthroplasty produces favorable outcomes: a systematic review and meta-analysis examining allied health service models. Osteoarthritis Cartilage 2016 Dec;24(10):1667-1681 [FREE Full text] [doi: 10.1016/j.joca.2016.05.005] [Medline: 27224276]
12. Chiung-Jui Su D, Yuan K, Weng S, Hong R, Wu M, Wu H, et al. Can early rehabilitation after total hip arthroplasty reduce its major complications and medical expenses? Report from a nationally representative cohort. Biomed Res Int 2015;2015:641958 [FREE Full text] [doi: 10.1155/2015/641958] [Medline: 26146625]
13. Westby MD, Brittain A, Backman CL. Expert consensus on best practices for post-acute rehabilitation after total hip and knee arthroplasty: a Canada and United States Delphi study. Arthritis Care Res (Hoboken) 2014 Mar;66(3):411-423 [FREE Full text] [doi: 10.1002/acr.22164] [Medline: 24023047]
14. Bashshur R, Shannon G, Krupinski E, Grigsby J. The taxonomy of telemedicine. Telemed J E Health 2011;17(6):484-494. [doi: 10.1089/tmj.2011.0103] [Medline: 21718114]
15. Dinesen B, Nonnecke B, Lindeman D, Toft E, Kidholm K, Jethwani K, et al. Personalized telehealth in the future: a global research agenda. J Med Internet Res 2016 Mar 01;18(3):e53 [FREE Full text] [doi: 10.2196/jmir.5257] [Medline: 26932229]
16. Dahlberg LE, Grahn D, Dahlberg JE, Thorstensson CA. A web-based platform for patients with osteoarthritis of the hip and knee: a pilot study. JMIR Res Protoc 2016 Jun 03;5(2):e115 [FREE Full text] [doi: 10.2196/resprot.5665] [Medline: 27261271]
17. Antón D, Nelson M, Russell T, Goñi A, Illarramendi A. Validation of a Kinect-based telerehabilitation system with total hip replacement patients. J Telemed Telecare 2016 Apr;22(3):192-197. [doi: 10.1177/1357633X15590019] [Medline: 26130735]
18. Tousignant M, Boissy P, Corriveau H, Moffet H. In home telerehabilitation for older adults after discharge from an acute hospital or rehabilitation unit: A proof-of-concept study and costs estimation. Disabil Rehabil Assist Technol 2006 Sep;1(4):209-216. [Medline: 19260168]
19. McCue M, Fairman A, Pramuka M. Enhancing quality of life through telerehabilitation. Phys Med Rehabil Clin N Am 2010 Feb;21(1):195-205. [doi: 10.1016/j.pmr.2009.07.005] [Medline: 19951786]
20. Granja C, Janssen W, Johansen MA. Factors determining the success and failure of eHealth interventions: systematic review of the literature. J Med Internet Res 2018 Dec 01;20(5):e10235 [FREE Full text] [doi: 10.2196/10235] [Medline: 29716883]
21. Mahomed NN, Davis AM, Hawker G, Badley E, Davey JR, Syed KA, et al. Inpatient compared with home-based rehabilitation following primary unilateral total hip or knee replacement: a randomized controlled trial. J Bone Joint Surg Am 2008 Aug;90(8):1673-1680. [doi: 10.2106/JBJS.G.01108] [Medline: 18676897]
22. Cottrell MA, Galea OA, O'Leary SP, Hill AJ, Russell TG. Real-time telerehabilitation for the treatment of musculoskeletal conditions is effective and comparable to standard practice: a systematic review and meta-analysis. Clin Rehabil 2017 May;31(5):625-638. [doi: 10.1177/0269215516645148] [Medline: 27141087]
23. Pastora-Bernal JM, Martín-Valero R, Barón-López FJ, Estebanez-Pérez MJ. Evidence of benefit of telerehabitation after orthopedic surgery: a systematic review. J Med Internet Res 2017 Dec 28;19(4):e142 [FREE Full text] [doi: 10.2196/jmir.6836] [Medline: 28455277]
24. Galea MP, Levinger P, Lythgo N, Cimoli C, Weller R, Tully E, et al. A targeted home- and center-based exercise program for people after total hip replacement: a randomized clinical trial. Arch Phys Med Rehabil 2008 Aug;89(8):1442-1447. [doi: 10.1016/j.apmr.2007.11.058] [Medline: 18586222]
25. Coulter C, Perriman DM, Neeman TM, Smith PN, Scarvell JM. Supervised or unsupervised rehabilitation after total hip replacement provides similar improvements for patients: a randomized controlled trial. Arch Phys Med Rehabil 2017 Dec;98(11):2253-2264. [doi: 10.1016/j.apmr.2017.03.032] [Medline: 28506775]
26. Unlu E, Eksioglu E, Aydog E, Aydog ST, Atay G. The effect of exercise on hip muscle strength, gait speed and cadence in patients with total hip arthroplasty: a randomized controlled study. Clin Rehabil 2007 Aug;21(8):706-711. [doi: 10.1177/0269215507077302] [Medline: 17846070]
27. Jan M, Hung J, Lin JC, Wang S, Liu T, Tang P. Effects of a home program on strength, walking speed, and function after total hip replacement. Arch Phys Med Rehabil 2004 Dec;85(12):1943-1951. [Medline: 15605331]
28. Picha KJ, Howell DM. A model to increase rehabilitation adherence to home exercise programmes in patients with varying levels of self-efficacy. Musculoskeletal Care 2018 Dec;16(1):233-237. [doi: 10.1002/msc.1194] [Medline: 28401666]
29. Pisters MF, Veenhof C, Schellevis FG, Twisk JW, Dekker J, De Bakker DH. Exercise adherence improving long-term patient outcome in patients with osteoarthritis of the hip and/or knee. Arthritis Care Res (Hoboken) 2010 Aug;62(8):1087-1094 [FREE Full text] [doi: 10.1002/acr.20182] [Medline: 20235201]
30. Okoro T, Whitaker R, Gardner A, Maddison P, Andrew JG, Lemmey A. Does an early home-based progressive resistance training program improve function following total hip replacement? Results of a randomized controlled study. BMC Musculoskelet Disord 2016 Apr 21;17:173 [FREE Full text] [doi: 10.1186/s12891-016-1023-x] [Medline: 27097833]
31. Sashika H, Matsuba Y, Watanabe Y. Home program of physical therapy: effect on disabilities of patients with total hip arthroplasty. Arch Phys Med Rehabil 1996 Mar;77(3):273-277. [Medline: 8600871]

32. Pataky Z, De León Rodriguez D, Golay A, Assal M, Assal J, Hauert C. Biofeedback training for partial weight bearing in patients after total hip arthroplasty. Arch Phys Med Rehabil 2009 Aug;90(8):1435-1438. [doi: 10.1016/j.apmr.2009.02.011] [Medline: 19651281]
33. Raaben M, Vogely HC, Blokhuis TJ. Real-time visual biofeedback to improve therapy compliance after total hip arthroplasty: a pilot randomized controlled trial. Gait Posture 2018 Mar;61:306-310. [doi: 10.1016/j.gaitpost.2018.01.038] [Medline: 29413802]
34. Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, et al. Home-based rehabilitation with a novel digital biofeedback system versus conventional in-person rehabilitation after total knee replacement: a feasibility study. Sci Rep 2018 Jul 26;8(1):11299 [FREE Full text] [doi: 10.1038/s41598-018-29668-0] [Medline: 30050087]
35. Ribinik P, Le Moine F, de Korvin G, Coudeyre E, Genty M, Rannou F, et al. Physical and rehabilitation medicine (PRM) care pathways: "patients after total knee arthroplasty". Ann Phys Rehabil Med 2012 Nov;55(8):533-539 [FREE Full text] [doi: 10.1016/j.rehab.2012.02.001] [Medline: 22455993]
36. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. J Am Geriatr Soc 1991 Feb;39(2):142-148. [Medline: 1991946]
37. Poitras S, Wood KS, Savard J, Dervin GF, Beaule PE. Predicting early clinical function after hip or knee arthroplasty. Bone Joint Res 2015 Sep;4(9):145-151 [FREE Full text] [doi: 10.1302/2046-3758.49.2000417] [Medline: 26336897]
38. Nankaku M, Tsuboyama T, Akiyama H, Kakinoki R, Fujita Y, Nishimura J, et al. Preoperative prediction of ambulatory status at 6 months after total hip arthroplasty. Phys Ther 2013 Jan;93(1):88-93. [doi: 10.2522/ptj.20120016] [Medline: 23001525]
39. Doll H, Gentile B, Bush EN, Ballinger R. Evaluation of the measurement properties of four performance outcome measures in patients with elective hip replacements, elective knee replacements, or hip fractures. Value Health 2018 Dec;21(9):1104-1114 [FREE Full text] [doi: 10.1016/j.jval.2018.02.006] [Medline: 30224116]
40. Stratford PW, Kennedy DM, Riddle DL. New study design evaluated the validity of measures to assess change after hip or knee arthroplasty. J Clin Epidemiol 2009 Mar;62(3):347-352. [doi: 10.1016/j.jclinepi.2008.06.008] [Medline: 18834709]
41. Klässbo M, Larsson E, Mannevik E. Hip disability and osteoarthritis outcome score. An extension of the Western Ontario and McMaster Universities Osteoarthritis Index. Scand J Rheumatol 2003;32(1):46-51. [Medline: 12635946]
42. Nilsdotter AK, Lohmander LS, Klässbo M, Roos EM. Hip disability and osteoarthritis outcome score (HOOS)--validity and responsiveness in total hip replacement. BMC Musculoskelet Disord 2003 May 30;4:10 [FREE Full text] [doi: 10.1186/1471-2474-4-10] [Medline: 12777182]
43. Kennedy DM, Stratford PW, Wessel J, Gollish JD, Penney D. Assessing stability and change of four performance measures: a longitudinal study evaluating outcome following total hip and knee arthroplasty. BMC Musculoskelet Disord 2005 Jan 28;6:3 [FREE Full text] [doi: 10.1186/1471-2474-6-3] [Medline: 15679884]
44. Piqueras M, Marco E, Coll M, Escalada F, Ballester A, Cinca C, et al. Effectiveness of an interactive virtual telerehabilitation system in patients after total knee arthoplasty: a randomized controlled trial. J Rehabil Med 2013 Apr;45(4):392-396 [FREE Full text] [doi: 10.2340/16501977-1119] [Medline: 23474735]
45. Ornetti P, Parratte S, Gossec L, Tavernier C, Argenson J, Roos EM, et al. Cross-cultural adaptation and validation of the French version of the Hip disability and Osteoarthritis Outcome Score (HOOS) in hip osteoarthritis patients. Osteoarthritis Cartilage 2010 Apr;18(4):522-529 [FREE Full text] [doi: 10.1016/j.joca.2009.12.007] [Medline: 20060086]
46. Foucher KC. Identifying clinically meaningful benchmarks for gait improvement after total hip arthroplasty. J Orthop Res 2016 Jan;34(1):88-96 [FREE Full text] [doi: 10.1002/jor.22996] [Medline: 26218738]
47. Hesse S, Werner C, Seibel H, von FS, Kappel E, Kirker S, et al. Treadmill training with partial body-weight support after total hip arthroplasty: a randomized controlled trial. Arch Phys Med Rehabil 2003 Dec;84(12):1767-1773. [Medline: 14669181]
48. Suetta C, Magnusson SP, Rosted A, Aagaard P, Jakobsen AK, Larsen LH, et al. Resistance training in the early postoperative phase reduces hospitalization and leads to muscle hypertrophy in elderly hip surgery patients--a controlled, randomized study. J Am Geriatr Soc 2004 Dec;52(12):2016-2022. [doi: 10.1111/j.1532-5415.2004.52557.x] [Medline: 15571536]
49. Rahmann AE, Brauer SG, Nitz JC. A specific inpatient aquatic physiotherapy program improves strength after total hip or knee replacement surgery: a randomized controlled trial. Arch Phys Med Rehabil 2009 May;90(5):745-755. [doi: 10.1016/j.apmr.2008.12.011] [Medline: 19406293]
50. Di Monaco M, Vallero F, Tappero R, Cavanna A. Rehabilitation after total hip arthroplasty: a systematic review of controlled trials on physical exercise programs. Eur J Phys Rehabil Med 2009 Sep;45(3):303-317 [FREE Full text] [Medline: 19238130]
51. Wijnen A, Bouma SE, Seeber GH, van der Woude LH, Bulstra SK, Lazovic D, et al. The therapeutic validity and effectiveness of physiotherapeutic exercise following total hip arthroplasty for osteoarthritis: A systematic review. PLoS One 2018;13(3):e0194517 [FREE Full text] [doi: 10.1371/journal.pone.0194517] [Medline: 29547670]
52. Artz N, Elvers KT, Lowe CM, Sackley C, Jepson P, Beswick AD. Effectiveness of physiotherapy exercise following total knee replacement: systematic review and meta-analysis. BMC Musculoskelet Disord 2015 Feb 07;16:15 [FREE Full text] [doi: 10.1186/s12891-015-0469-6] [Medline: 25886975]

53. Jeldi AJ, Grant M, Allen DJ, Deakin AH, McDonald DA, Stansfield BW. Upright time and sit-to-stand transition progression after total hip arthroplasty: an inhospital longitudinal study. J Arthroplasty 2016 Mar;31(3):735-739. [doi: 10.1016/j.arth.2015.09.024] [Medline: 26603439]
54. Lin JF, Kulić D. Human pose recovery using wireless inertial measurement units. Physiol Meas 2012 Dec;33(12):2099-2115. [doi: 10.1088/0967-3334/33/12/2099] [Medline: 23174667]
55. Lowe CJ, Davies L, Sackley CM, Barker KL. Effectiveness of land-based physiotherapy exercise following hospital discharge following hip arthroplasty for osteoarthritis: an updated systematic review. Physiotherapy 2015 Sep;101(3):252-265. [doi: 10.1016/j.physio.2014.12.003] [Medline: 25724323]
56. Nankaku M, Ikeguchi R, Goto K, So K, Kuroda Y, Matsuda S. Hip external rotator exercise contributes to improving physical functions in the early stage after total hip arthroplasty using an anterolateral approach: a randomized controlled trial. Disabil Rehabil 2016 Dec;38(22):2178-2183. [doi: 10.3109/09638288.2015.1129453] [Medline: 26750398]
57. Steffen TM, Hacker TA, Mollinger L. Age- and gender-related test performance in community-dwelling elderly people: Six-Minute Walk Test, Berg Balance Scale, Timed Up & Go Test, and gait speeds. Phys Ther 2002 Feb;82(2):128-137. [Medline: 11856064]
58. Lusardi M, Pellecchia G, Schulman M. Functional performance in community living older adults. J Geriatr Phys Ther 2003 Dec 01;26(3):e1.
59. Naylor JM, Harmer AR, Heard RC, Harris IA. Patterns of recovery following knee and hip replacement in an Australian cohort. Aust Health Review 2009;33(1):124. [doi: 10.1071/AH090124]
60. Kennedy DM, Stratford PW, Hanna SE, Wessel J, Gollish JD. Modeling early recovery of physical function following hip and knee arthroplasty. BMC Musculoskelet Disord 2006 Dec 11;7:100 [FREE Full text] [doi: 10.1186/1471-2474-7-100] [Medline: 17156487]
61. Heiberg KE, Bruun-Olsen V, Ekeland A, Mengshoel AM. Effect of a walking skill training program in patients who have undergone total hip arthroplasty: Followup one year after surgery. Arthritis Care Res (Hoboken) 2012 Mar;64(3):415-423 [FREE Full text] [doi: 10.1002/acr.20681] [Medline: 22170790]
62. Bahadori S, Immins T, Wainwright TW. A review of wearable motion tracking systems used in rehabilitation following hip and knee replacement. J Rehabil Assist Techn Eng 2018 Jun 18;5. [doi: 10.1177/2055668318771816]
63. Charbonnier C, Chagué S, Schmid J, Kolo FC, Bernardoni M, Christofilopoulos P. Analysis of hip range of motion in everyday life: a pilot study. Hip Int 2015;25(1):82-90. [doi: 10.5301/hipint.5000192] [Medline: 25385049]
64. Davis KE, Ritter MA, Berend ME, Meding JB. The importance of range of motion after total hip arthroplasty. Clin Orthop Relat Res 2007 Dec;465:180-184. [doi: 10.1097/BLO.0b013e31815c5a64] [Medline: 18090472]
65. Umpierres CS, Ribeiro TA, Marchisio Â, Galvão L, Borges Í, Macedo CADS, et al. Rehabilitation following total hip arthroplasty evaluation over short follow-up time: randomized clinical trial. J Rehabil Res Dev 2014;51(10):1567-1578 [FREE Full text] [doi: 10.1682/JRRD.2014.05.0132] [Medline: 25856757]
66. Trudelle-Jackson E, Emerson R, Smith S. Outcomes of total hip arthroplasty: a study of patients one year postsurgery. J Orthop Sports Phys Ther 2002 Jun;32(6):260-267. [doi: 10.2519/jospt.2002.32.6.260] [Medline: 12061707]
67. Tannast M, Kubiak-Langer M, Langlotz F, Puls M, Murphy SB, Siebenrock KA. Noninvasive three-dimensional assessment of femoroacetabular impingement. J Orthop Res 2007 Jan;25(1):122-131 [FREE Full text] [doi: 10.1002/jor.20309] [Medline: 17054112]

Abbreviations

ADL: activities of daily living
CONSORT: Consolidated Standards of Reporting Trials
HOOS: Hip dysfunction and Osteoarthritis Outcome Scale
IQR: interquartile range
ITT: intention-to-treat
PT: physiotherapy
QoL: quality of life
RCT: randomized controlled trial
ROM: range of motion
THA: total hip arthroplasty
TKA: total knee arthroplasty
TUG: Timed Up and Go

Edited by G Eysenbach; submitted 29.04.19; peer-reviewed by RR Pai, P Boissy; comments to author 26.05.19; revised version received 31.05.19; accepted 31.05.19; published 23.06.19.

Please cite as:
Dias Correia F, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Molinos M, Teixeira L, Pires J, Seabra R, Lains J, Bento V
Digital Versus Conventional Rehabilitation After Total Hip Arthroplasty: A Single-Center, Parallel-Group Pilot Study
JMIR Rehabil Assist Technol 2019;6(1):e14523
URL: http://rehab.jmir.org/2019/1/e14523/
doi:10.2196/14523
PMID:

Annex IV

E-POSTER CERTIFICATE

2th International Society of Physical and Rehabilitation Medicine World Congress, Paris, 8-12 July 2018

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V.

Home-based rehabilitation with SWORD Phoenix versus standard of care after total knee replacement: a randomized controlled study.

E-POSTER CERTIFICATE

This is to certify that

Fernando Correia

Presented an e-poster entitled

HOME-BASED REHABILITATION WITH SWORD PHOENIX VERSUS STANDARD OF CARE AFTER TOTAL KNEE REPLACEMENT: A PILOT STUDY

F. Correia [1], ***A. Nogueira*** [1], ***I. Magalhaes*** [1], ***J. Guimaraes*** [1], ***M. Moreira*** [1], ***I. Barradas*** [1], ***L. Teixeira*** [2], ***J. Tulha*** [3], ***J. Seabra*** [3], ***V. Bento*** [4]

[1]SWORD Health, Clinical Department, Porto, Portugal;[2]Abel Salazar Institute of Biomedical Sciences, Department of Population Studies, Porto, Portugal;[3]Hospital da Prelada, Orthopaedics Department, Porto, Portugal;[4]University Institute of Maia, Electronics Department, Porto, Portugal.

At the **12th International Society of Physical and Rehabilitation Medicine (ISPRM) World Congress**
Paris, France | July 8-12, 2018

Isabelle Laffont
ISPRM 2018
Congress
Scientific Chair

André Thevenon
Co-President ISPRM
2018 Congress

Alain Yelnik
Co-President ISPRM
2018 Congress

ISPRM Secretariat
Kenes International
7, rue François-Versonnex, C.P.
6053, 1211 Geneva 6 Switzerland
Tel:+ 41 22 908 0488
Fax:+ 41 22 906 9140

www.isprm2018.com

SOCIETE ROYALE BELGE DE MEDECINE PHYSIQUE ET DE READAPTATION a.s.b.l.
KONINKLIJKE BELGISCHE VERENIGING VOOR FYSISCHE GENEESKUNDE EN REVALIDATIE v.z.w.

SOFMER

Annex V

SCIENTIFIC PROGRAM AND CERTIFICATES

13th International Society of Physical and Rehabilitation Medicine World Congress, Kobe, 9-12 June 2019

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Tulha J, Seabra R, Lains J, Bento V

Medium-term outcomes after Total Knee Replacement: follow up results of a feasibility study comparing digital versus conventional home-based rehabilitation.

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Pires J, Seabra R, Lains J, Bento V

Digital Biofeedback System versus Conventional Home-based In-person Rehabilitation for Total Hip Arthroplasty: a feasibility study.

Correia FD, Nogueira A, Magalhães I, Guimarães J, Moreira M, Barradas I, Teixeira L, Pires J, Seabra R, Lains J, Bento V

Medium-term outcomes of a feasibility study comparing digital versus conventional home-based rehabilitation after Total Hip Replacement.

O21-4 17:00
Factors Affecting Discharge to Home after Surgery for Spinal Metastasis: Analysis Using a National Inpatient Database
Ryoko Sawada *[Japan]*, Hayato Yamana, Yusuke Shinoda, Takahiro Ohki, Hideo Yasunaga, Nobuhiko Haga

O21-5 17:10
Relationship between Physical Frailty and Activities of Daily Living in Persons with Respiratory Disease
Shigenori Hiraoka *[Japan]*, Yoichiro Aoyagi, Yuji Kono, Michiko Taya, Kanan Yatsuya, Eriko Mizokoshi, Chen Hui, Hitoshi Kagaya, Eiichi Saitoh

O21-6 17:20
Longitudinal Study on Activity Monitoring for Over 24 Hours among Patients in a Rehabilitation Ward
Hirotaka Matsuura *[Japan]*, Masahiko Mukaino, Yasushi Aoshima, Ayaka Inukai, Emi Hattori, Yurie Yamada, Masaki Kato, Yuki Okochi, Takayuki Ogasawara, Eiichi Saitoh

O21-7 17:30
Prediction of Life-Space Mobility in Patients with Stroke 2 Months after Discharge from Rehabilitation: A Retrospective Cohort Study
Mari Nakao *[Japan]*, Shinichi Izumi, Yuki Yokoshima, Yoshiko Matsuba, Yutaka Maeno

O21-8 17:40
Do Family Members' Hospital Visits Influence Clinical Outcome of the Patients Admitted to a Convalescent Rehabilitation Ward?
Wataru Kakuda *[Japan]*, Sawako Kagamizono, Ayaka Iwato, Kazumi Cho, Mitsuhiro Sano, Takeki Ishida, Ayaka Takahashi

O21-9 17:50
Do Outpatient Rehabilitation Services Save Inpatient Bed Days? Mapping the Relationship between Outpatient Services and Inpatient Rehabilitation Length of Stay in NSW/ACT Hospitals
Steven Faux *[Australia]*, Angela Vrasistas-Curto, Chrisitine Shiner, Ian Harris, Michael Pollak, Francis Simmons, Linda Klien

16:30–18:00 **Room 10**

Special Session 25: Current Status of Telerehabilitation

Chairs: **Kazuko Shem** *[United States]*
Sonoko Nozaki *[Japan]*

SS25-1 16:30
Telemedicine in Spain Cord Injury in the United States: Implementation, Outcomes and Future
Kazuko Shem *[United States]*

SS25-2 16:50
Digital Biofeedback System versus Conventional Home-based In-person Rehabilitation for Total Hip Arthroplasty: a Feasibility Study
Fernando D Correia *[Portugal]*, Andre Nogueira, Ivo Magalhaes, Joana Guimaraes, Maria Moreira, Isabel Barradas, Maria Molinos, Laetitia Teixeira, Joaquim Pires, Rosmaninho Seabra, Jorge Lains, Virgilio Bento

SS25-3 17:00
Medium-term Outcomes a Feasibility Study Comparing Digital versus Conventional Home-based Rehabilitation after Total Hip Replacement
Fernando D Correia *[Portugal]*, Andre Nogueira, Ivo Magalhaes, Joana Guimaraes, Maria Moreira, Isabel Barradas, Laetitia Teixeira, Maria Molinos, Joaquim Pires, Rosmaninho Seabra, Jorge Lains, Virgilio Bento

SS25-4 17:10	**Medium-term Outcomes after Total Knee Replacement: Follow Up Results of a Feasibility Study Comparing Digital versus Conventional Home-based Rehabilitation** Fernando D Correia *[Portugal]*, Andre Nogueira, Ivo Magalhaes, Joana Guimaraes, Maria Moreira, Isabel Barradas, Maria Molinos, Laetitia Teixeira, Jose Tulha, Rosmaninho Seabra, Jorge Lains, Virgilio Bento
SS25-5 17:20	**Artificial Intelligence and Telerehabilitation of Patients with Injuries of the Lower Extremities** Andriy J Hospodarskyy *[Ukraine]*, Andriy I Tsvyakh, Roman S Drevnitskyy, Roman O Lutsyshyn
SS25-6 17:30	**Rehabilitation of Patients with Injuries of the Elbow Joint of the Upper Extremities by Telemedicine and Artificial Intelligence Technology** Andriy I Tsvyakh *[Ukraine]*, Andriy J Hospodarskyy, Roman S Drevnitskyy, Roman O Lutsyshyn
SS25-7 17:40	**Telerehabilitation for Patients with Dysphagia and Dysarthria: Usefulness and Satisfaction** Sonoko Nozaki *[Japan]*, Maiko Nishiguchi, Kyoko Okuno, Takako Tanimura, Mika Takeichi, Kentarou Akagi, Yoko Nakano, Mitsuru Furuta, Shiro Yorifuji
SS25-8 17:50	**Continued Home Rehabilitation with the Personal Video-physiotherapist** Polina V. Tkachenko *[Russia]*, Oleg E. Karpov, Vadim D. Daminov

16:30–18:00 **Room 11**

Special Session 26: Phenol Neurolysis for Spasticity Management: an Update

Chair: **Gerard E Francisco** *[United States]*

SS26-1 16:30	**A Retrospective Review on Phenol Neurolysis for Spasticity Management in the Distal Upper Extremity** Sheng Li *[United States]*, Kay Jarri, Bei Zhang
SS26-2 17:15	**Phenol Neurolysis for Spasticity Management: An Update** Rochelle Dy *[United States]*

ISPRM 2019

KOBE, JAPAN | JUNE 9 - 13

Certificate of Appreciation

presented to

Fernando D Correia

In recognition of your distinguished lecture in

13th International Society of
Physical and Rehabilitation Medicine
World Congress (ISPRM 2019)

Kobe, Japan
June 9-13, 2019

Eiichi Saitoh, MD, DMSc
President
13th International Society of
Physical and Rehabilitation Medicine World Congress

Kazuhisa Domen, MD, PhD
Chair of the Scientific Committee
13th International Society of
Physical and Rehabilitation Medicine World Congress

Annex VI

BEST INNOVATION AWARD

ISPRM 2018

ISPRM Innovation Contest

SWORD Phoenix:

an AI-powered Digital Therapist for Physical Rehabilitation

ISPRM 2018
12th International Society of Physical and Rehabilitation Medicine World Congress
Paris, France | July 8 – 12, 2018

Annex VII

Hip Osteoarthritis Outcome Score

Portuguese version

Measuring quality of life related to health in patients with osteoarthritis of the hip and hip replacement surgery: Adaptation and validation of the Hip disability and Osteoarthritis Outcome Score LK 2.0 (HOOS 2.0) to the Portuguese culture

In memory of Prof.º Dr.º João Gil

Sandra Nunes, Jan Cabri, João Gil

Abstract

Introduction: The existence of few health status measurements in Portugal for the hip osteoarthritis specific condition justifies the adaptation and validation of the Hip disability and Osteoarthritis Outcome Score (HOOS-LK2.0).
Objective: Validate and adapt the HOOS LK2.0 to the Portuguese population in individuals suffering from osteoarthritis (OA) and from hip replacement (HR)
Methods: The Portuguese version was developed through the translation into Portuguese/back to the original, analysis of the quality of the translation done by doctors and subsequent cognitive panel involving 11 patients some of whom suffering from hip OA and others had undergone hip replacement surgery. Another sample of patients was selected to test the validity and obtain the Portuguese version.
Results: For reliability The *Cronbach alfa* values of the HOOS LK2.0 were between 0.7 and 0.9 (internal consistency) and intra-class correlation coefficient values were between 0.786 and 0.954 (reproducibility). The direction of the relations between the HOOS and pain intensity, degree of discomfort and degree of disability (r between -0.245 and -0.541) as well as the MOS SF-36 (r between 0.221 and 0.824) agree with the expected outcome and were almost always significant. Following the caring process, the effect size values varied between 0.39 (pain) and 0.72 (everyday activities) in the bulk sample and between 0.56 (pain) and 1.05 (everyday activities) in the hip replacement sub-sample.
Conclusions: The Portuguese HOOS-LK2.0 version is a valid, reliable and responsive measurement whose use is recommended in clinical practice and research.

Keywords: Hip osteoarthritis, hip replacement surgery, measurement, disability, health status.

Additional information about the Portuguese version of the HOOS LK 2.0 can be requested from:

Sandra Nunes
Fisioterapeuta
Rua Ferreira Borges n.º102- 1º andar
1350-135 Lisboa, Portugal
Tel. +351 21 3830644
Mob. +351 936964937
E-mail: Sandranunesnunes@sapo.pt

Faculty of Human Kinetics
Center for Research in Physiotherapy
Technical University of Lisbon
Estrada da Costa 1499-002 Cruz Quebrada
Dafundo-Portugal
Tel. +351 21 4149100
Fax. +351 21 4151248
E-mail: servicosacademicos@fmh.utl.pt

Jan Cabri, PhD
Professor and Head
Department Physical Performance
Norwegian School of Sport Sciences
Postbooks 4014 Ullevål Stadion0806 Oslo, Norway
Tel. +47 23 26 22 47
Mob +47 93 44 33 31
E-mail: Jan.Cabri@nih.no

CEISUC- Centro de Estudos e Investigação em Saúde da Universidade de Coimbra
Faculdade de Economia da Universidade de Coimbra
Avenida Dias da Silva, 165, 3004-512 Coimbra, Portugal
Tel. +351 239 790 507
Fax: +351 239 790 514
E-mail: ceisuc@fe.uc.pt
Site: http://www.uc.pt/org/Ceisuc/RIMAS/Lista/Instrumentos/HOOS

QUESTIONÁRIO HOOS SOBRE A ANCA

Data: _____/_____/_____ Data de nascimento: _____/_____/_____

Nome: _____

INSTRUÇÕES: Este questionário pretende saber como vê a sua anca. Esta informação dar-nos-á dados sobre como se sente em relação à anca e até que ponto é que é capaz de desempenhar as suas actividades habituais.
Responda a cada uma das perguntas marcando o quadrado adequado, apenas um quadrado para cada pergunta. **Se não tiver a certeza** sobre a resposta a escolher, por favor **escolha a que achar melhor.**

Sintomas

Estas perguntas devem ser respondidas tendo em conta as dificuldades e os sintomas na sua anca durante a **última semana**.

S1. Tem sentido a anca a ranger ou ouve um estalido ou qualquer outro tipo de barulho?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
❒	❒	❒	❒	❒

S2. Dificuldades em afastar as pernas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

S3. Dificuldades em andar com passadas largas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

Rigidez

As perguntas que se seguem dizem respeito ao grau de rigidez na anca que sentiu na **última semana**. Rigidez é a sensação de dificuldade ou lentidão a mexer a sua anca.

S4. Até que ponto sente rigidez na anca logo após acordar de manhã?

Nada	Pouco	Moderadamente	Muito	Muitíssimo
❒	❒	❒	❒	❒

S5. Até que ponto sente rigidez na anca depois de se sentar, deitar ou descansar **ao fim do dia**?

Nada	Pouco	Moderadamente	Muito	Muitíssimo
❒	❒	❒	❒	❒

Dor

P1. Com que frequência tem dores na anca?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Sempre
❒	❒	❒	❒	❒

Que intensidade de dor na anca é que sentiu durante a **última semana** nas seguintes actividades?

P2. Esticar a anca completamente

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P3. Dobrar a anca completamente

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P4. Andar sobre uma superfície plana

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P5. Subir ou descer escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P6. À noite, na cama

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P7. Estar sentado/a ou deitado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P8. Estar de pé

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P9. Andar numa superfície dura (asfalto, cimento, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

P10. Andar numa superfície irregular

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

Actividades da vida diária

As perguntas que se seguem dizem respeito à sua função física. Por função física referimo-nos à sua capacidade de se deslocar e de cuidar de si. Para cada uma das actividades seguintes, indique o grau de dificuldade que sentiu na **última semana** por causa da sua anca.

A1. Descer escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A2. Subir escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

Para cada uma das seguintes actividades indique, por favor, o grau de dificuldade que teve na **última semana** devido à sua anca.

A3. Levantar-se partindo da posição de sentado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A4. Manter-se de pé

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A5. Dobrar-se para apanhar um objecto do chão

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A6. Andar numa superfície plana

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A7. Entrar ou sair do carro

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A8. Ir às compras

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A9. Calçar meias/collants

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A10. Levantar-se da cama

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A11. Tirar meias/collants

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A12. Estar deitado/a na cama (virar-se, manter a posição da anca)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A13. Entrar/sair da banheira

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A14. Estar sentado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A15. Sentar-se ou levantar-se da sanita

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

Para cada uma das actividades seguintes, indique o grau de dificuldade que sentiu na **última semana** por causa da sua anca.

A16. Tarefas domésticas pesadas (ex.: pegar em caixas pesadas, esfregar o chão, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

A17. Tarefas domésticas leves (ex.: cozinhar, limpar o pó, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

Actividades desportivas e de lazer

As perguntas que se seguem dizem respeito à sua função física, estando activo/a a um nível mais elevado. As perguntas devem ser respondidas tendo em conta o grau de dificuldade que teve durante a **última semana** por causa da sua anca.

SP1. Pôr-se de cócoras

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

SP2. Correr

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

SP3. Rodar/virar-se/torcer sobre a perna em carga

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

SP4. Andar numa superfície irregular

Nenhuma	Pouca	Moderada	Muita	Muitíssima
❒	❒	❒	❒	❒

Qualidade de Vida

Q1. Com que frequência é que tem consciência do problema que tem na anca?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Constantemente
❒	❒	❒	❒	❒

Q2. Modificou o seu estilo de vida para evitar actividades que poderiam afectar a anca?

De modo algum	Um pouco	Moderadamente	Muito	Completamente
❒	❒	❒	❒	❒

Q3. Até que ponto é que a falta de confiança na anca o/a incomoda?

Nada	Um pouco	Moderadamente	Muito	Muitíssimo
❒	❒	❒	❒	❒

Q4. Em geral, a anca causa-lhe muitos problemas?

Nenhuns	Poucos	Alguns	Muitos	Muitíssimos
❒	❒	❒	❒	❒

Obrigado por ter respondido a todas as perguntas deste questionário

Annex VIII

Knee Osteoarthritis Outcome Score

Portuguese version

Additional information about the Portuguese version of the KOOS can be requested from:

Rui Soles Gonçalves, PT, MSc

Prof. Adjunto do Curso de Fisioterapia

Escola Superior de Tecnologia da Saúde de Coimbra

Rua 5 de Outubro - S. Martinho do Bispo - Apartado 7006 - 3040-162 Coimbra

PORTUGAL

Tel.: +351 239 802 430

E-mail: ruigoncalves@estescoimbra.pt

QUESTIONÁRIO KOOS SOBRE O JOELHO

Data: _____/_____/_____ Data de nascimento: _____/_____/_____

Nome: _____

INSTRUÇÕES: Este questionário pretende saber como vê o seu joelho. Esta informação dar-nos-á dados sobre como se sente em relação ao joelho e até que ponto é que é capaz de desempenhar as suas actividades normais.
Responda a cada uma das perguntas marcando o quadrado adequado, apenas um quadrado para cada pergunta. Se não tiver a certeza sobre a resposta a escolher, por favor escolha a que achar melhor.

Sintomas

Estas perguntas devem ser respondidas tendo em conta os sintomas no seu joelho durante a **última semana**.

S1. Tem tido o joelho inchado?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S2. Tem sentido ranger, ouvido um estalo ou qualquer outro som quando mexe o joelho?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S3. Tem sentido o joelho preso ou bloqueado quando se mexe?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S4. Tem conseguido esticar o joelho completamente?

Sempre	Frequentemente	Às vezes	Raramente	Nunca
☐	☐	☐	☐	☐

S5. Tem conseguido dobrar o joelho completamente?

Sempre	Frequentemente	Às vezes	Raramente	Nunca
☐	☐	☐	☐	☐

Rigidez

As perguntas que se seguem dizem respeito ao grau de rigidez no joelho que teve na **última semana**. Rigidez é uma sensação de dificuldade ou lentidão a mexer o seu joelho.

S6. Até que ponto sente rigidez no joelho logo após acordar de manhã?

Nada	Pouco	Moderadamente	Muito	Muitíssimo
☐	☐	☐	☐	☐

S7. Até que ponto sente rigidez no joelho depois de se sentar, deitar ou descansar **ao fim do dia**?

Nada	Pouco	Moderadamente	Muito	Muitíssimo
☐	☐	☐	☐	☐

Dor

P1. Com que frequência tem dores no joelho?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Sempre
☐	☐	☐	☐	☐

Que intensidade de dor no joelho é que teve durante a **última semana** nas seguintes actividades?

P2. Rodar/virar-se/torcer sobre o joelho

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P3. Esticar o joelho completamente

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P4. Dobrar o joelho completamente

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P5. Andar sobre uma superfície plana

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P6. Subir ou descer escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P7. À noite, na cama

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P8. Estar sentado/a ou deitado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P9. Estar de pé

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Actividades da vida diária

As perguntas que se seguem dizem respeito à sua função física. Por função física referimo-nos à sua capacidade de se deslocar e de cuidar de si. Para cada uma das actividades seguintes, indique o grau de dificuldade que sentiu na **última semana** por causa do seu joelho.

A1. Descer escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A2. Subir escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Para cada uma das seguintes actividades indique, por favor, o grau de dificuldade que teve na **última semana** devido ao seu joelho.

A3. Levantar-se a partir da posição de sentado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A4. Manter-se de pé

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A5. Dobrar-se para baixo/apanhar um objecto

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A6. Andar numa superfície plana

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A7. Entrar ou sair do carro

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A8. Ir às compras

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A9. Calçar meias/collants

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A10. Levantar-se da cama

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A11. Descalçar meias/collants

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A12. Estar deitado/a na cama (virar-se, manter a posição do joelho)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A13. Entrar/sair da banheira

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A14. Estar sentado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A15. Sentar-se ou levantar-se da sanita

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Para cada uma das actividades seguintes, indique o grau de dificuldade que sentiu na **última semana** por causa do seu joelho.

A16. Tarefas domésticas pesadas (ex.: pegar em caixas pesadas, esfregar o chão, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A17. Tarefas domésticas leves (ex.: cozinhar, limpar o pó, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Actividades desportivas e de lazer

As perguntas que se seguem dizem respeito à sua função física, estando activo/a a um nível mais elevado. As perguntas devem ser respondidas tendo em conta o grau de dificuldade que teve durante a **última semana** por causa do seu joelho.

SP1. Pôr-se de cócoras

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP2. Correr

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP3. Saltar

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP4. Rodar/virar-se/torcer sobre o joelho afectado

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP5. Ajoelhar

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Qualidade de Vida

Q1. Com que frequência é que tem consciência do problema que tem no joelho?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Constantemente
☐	☐	☐	☐	☐

Q2. Modificou o seu estilo de vida para evitar actividades que poderiam afectar o joelho?

De modo algum	Um pouco	Moderadamente	Muito	Completamente
☐	☐	☐	☐	☐

Q3. Até que ponto é que a falta de confiança no joelho o/a incomoda?

Nada	Um pouco	Moderadamente	Muito	Muitíssimo
☐	☐	☐	☐	☐

Q4. Em geral, o joelho causa-lhe muitos problemas?

Nenhuns	Poucos	Alguns	Muitos	Muitíssimos
☐	☐	☐	☐	☐

Obrigado por ter respondido a todas as perguntas do questionário.

Annex IX

PATIENT INFORMATION AND INFORMED CONSENT

Impacto Clínico do sistema SWORD Phoenix na reabilitação pós artroplastia total da anca ou joelho: um estudo piloto contra comparador ativo

Consentimento Informado, Livre e Esclarecido Para Participação Em Investigação

Por favor, leia com atenção a seguinte informação. Se achar que algo está incorreto ou que não está claro, não hesite em solicitar mais informações. Se concorda com a proposta que lhe foi feita, queira assinar este documento.

Título do estudo: Impacto Clínico do sistema SWORD Phoenix na reabilitação pós artroplastia total da anca ou joelho: um estudo piloto contra comparador ativo

Enquadramento:

As necessidades de realização de próteses de anca e de joelho estão a aumentar, em virtude do envelhecimento da população. Um programa eficaz de fisioterapia após a cirurgia permite maximizar os resultados clínicos obtidos. Contudo, o acesso a estes programas é dificultado pelo facto de estes dependerem da disponibilidade de recursos humanos, que são escassos, ou implicarem deslocamentos frequentes dos doentes às instituições que prestam estes cuidados. No atual contexto económico, é vital encontrar formas mais eficientes de entrega de cuidados de saúde.

Explicação do estudo

Este estudo tem como objetivo avaliar a evolução clínica do utente utilizador de um programa de reabilitação no domicílio recorrendo à tecnologia SWORD Phoenix®, em comparação com programas de reabilitação dita convencional, ministrados ao domicílio por parte de um fisioterapeuta. Este estudo está direcionado para doentes submetidos colocação de prótese de anca ou joelho. Este documento informativo foi-lhe entregue porque é um candidato a participar no estudo.

Se tiver indicação e aceitar participar, será feita uma avaliação clínica inicial (pré-operatória), onde serão recolhidas as seguintes informações: género, idade, lado afectado, doenças concomitantes e medicação habitual. Será, também, feita uma avaliação da severidade da sua condição clínica, recorrendo a testes e questionários específicos.

O internamento hospitalar decorrerá de acordo com os procedimentos internos do Hospital da Prelada. Aquando da alta hospitalar, será novamente avaliado, para recolha de informações relacionadas com a cirurgia e o internamento.

Será, depois, e encaminhado para o grupo de intervenção ou para o grupo de controlo, consoante a sua morada: se viver dentro da área metropolitana do Porto, será alocado ao grupo de fisioterapia convencional; se viver fora da área metropolitana do Porto, será alocado ao grupo de intervenção digital.

Se for alocado ao grupo de intervenção digital, a reabilitação será feita com recurso à utilização do sistema SWORD Phoenix®, de acordo com o protocolo do estudo. Este dispositivo usa pequenos sensores, que são colocados no tronco e membro inferior através de fitas de velcro, para digitalizar os movimentos, transmitindo a informação para uma aplicação móvel. Esta aplicação, que estará num tablet dedicado para o efeito, vai guiá-lo na realização das sessões de exercício, indicando-lhe se os está a realizar corretamente ou não, ajudando-o a corrigir eventuais erros. Toda a informação recolhida é transmitida para uma plataforma de internet onde a equipa clínica pode analisar remotamente as sessões, introduzindo alterações à medida do necessário. Assim, estará sempre a ser monitorizado

clinicamente, mesmo estando em casa. Será recomendada a realização de sessões diárias, com uma frequência de pelos menos 5 dias por semana, mas não será excluído do estudo se não cumprir esta periodicidade.

Se for alocado ao grupo de fisioterapia convencional, a sua reabilitação será feita através de visitas domiciliárias de um fisioterapeuta, três vezes por semana, de acordo com o protocolo do estudo e sob orientação do seu Ortopedista. Adicionalmente, ser-lhe-ão prescritas sessões de exercícios que deve realizar de forma autónoma, não supervisionada, pelo menos duas vezes por semana.

Em qualquer dos casos, será reavaliado em Consulta Externa pelo seu Ortopedista à 4a e 8a semanas após início da reabilitação, bem como aos 3 e 6 meses após cirurgia.

Condições e financiamento:

Este estudo será integralmente financiado pelo promotor do estudo, a empresa SWORD Health, S.A. que desenvolveu o SWORD Phoenix.

A participação neste estudo é inteiramente voluntária e não implica nenhum encargo financeiro para si. Em caso de necessidade de deslocações adicionais ao Hospital da Prelada, para reavaliações relacionadas com o estudo, os gastos com a viagem ser-lhe-ão devolvidos pelo Hospital.

Não receberá qualquer contrapartida financeira pela sua participação neste estudo.

Caso não queira participar, isso não acarretará qualquer consequência negativa, e continuará a usufruir do seguimento habitual junto do seu Ortopedista

Este estudo mereceu parecer favorável da Comissão de Ética do Hospital da Prelada.

Confidencialidade e anonimato:

Os dados referentes à sua identificação serão apenas do conhecimento dos investigadores do estudo e não serão tornados públicos em qualquer circunstância. Estes dados serão destruídos 5 anos após o fim do estudo.

Todos os dados recolhidos servirão única e exclusivamente para produção de artigos científicos relacionados com este estudo, sendo estes sempre anónimos e garantindo a privacidade e a proteção dos seus dados pessoais.

Em caso de persistência de dúvidas acerca do estudo, por favor contacte um dos investigadores, através dos seguintes contactos:

Dr. Rosmaninho Seabra: +351 918174900

Dr. Fernando Correia: +351 916557789

Os investigadores agradecem desde já a sua disponibilidade.

Título do estudo: Impacto Clínico do sistema SWORD Phoenix na reabilitação pós artroplastia total da anca ou joelho: um estudo piloto contra comparador ativo

Declaro ter lido e compreendido este documento, bem como as informações verbais que me foram fornecidas pela/s pessoa/s que acima assina/m.

Declaro que tive oportunidade para colocar as dúvidas que julguei necessárias, que me foram devidamente esclarecidas.

Foi-me garantida a possibilidade de, em qualquer altura, recusar participar neste estudo sem qualquer tipo de consequências.

Desta forma, aceito participar neste estudo e permito a utilização dos dados pessoais e clínicos que de forma voluntária forneço, confiando em que apenas serão utilizados para esta investigação e nas garantias de confidencialidade e anonimato que me são dadas pelo investigador.

Nome do Participante: … … … … … … … ….... … … … ….... … … … … … … … … … … … …

Assinatura: … … … … … … … ….... … … … … ... … … … … … … … … … … … … …

Data: …… /…… /……..

Nome do Investigador que recolheu o consentimento: … … … … … … … ….... … … … ….... … … … … … … … … … … … … …

Assinatura: … … … … … … … ….... … … … … ... … … … … … … … … … … … … …

Data: …… /…… /……..

Annex X

DATA PROTECTION AUTHORITY AUTHORIZATION

Autorização n.º 1476/ 2017

SWORD Health, SA , NIPC 510675565, notificou à Comissão Nacional de Protecção de Dados (CNPD) um tratamento de dados pessoais com a finalidade de realizar um Estudo Clínico com Intervenção, denominado Impacto Clínico do sistema SWORD Phoenix na reabilitação pós atroplastia total da anca ou joelho: um estudo piloto contra comparador activo.

O participante é identificado por um código especificamente criado para este estudo, constituído de modo a não permitir a imediata identificação do titular dos dados; designadamente, não são utilizados códigos que coincidam com os números de identificação, iniciais do nome, data de nascimento, número de telefone, ou resultem de uma composição simples desse tipo de dados. A chave da codificação só é conhecida do(s) investigador(es).

É recolhido o consentimento expresso do participante ou do seu representante legal.

A informação é recolhida diretamente do titular.

As eventuais transmissões de informação são efetuadas por referência ao código do participante, sendo, nessa medida, anónimas para o destinatário.

A CNPD já se pronunciou na Deliberação n.º 1704/2015 sobre o enquadramento legal, os fundamentos de legitimidade, os princípios aplicáveis para o correto cumprimento da Lei n.º 67/98, de 26 de outubro, alterada pela Lei n.º 103/2015, de 24 de agosto, doravante LPD, bem como sobre as condições e limites aplicáveis ao tratamento de dados efetuados para a finalidade de investigação clínica.

No caso em apreço, o tratamento objeto da notificação enquadra-se no âmbito daquela deliberação e o responsável declara expressamente que cumpre os limites e condições aplicáveis por força da LPD e da Lei n.º 21/2014, de 16 de abril, alterada pela Lei n.º 73/2015, de 27 de junho – Lei da Investigação Clínica –, explicitados na Deliberação n.º 1704/2015.

O fundamento de legitimidade é o consentimento do titular.

Annex XI

ETHICS COMMITTEE AUTHORIZATION

misericórdia do porto

Extrato da Ata Nº 26 da Comissão de Ética das Unidades Operacionais de Saúde da Santa Casa da Misericórdia do Porto, relativo à reunião de 29/11/2016

"Foi apresentado um projeto, enviado a este órgão pelo Hospital da Prelada, na área da Fisioterapia, designado Sword Health.

Assim, o documento trazido a esta comissão obteve parecer favorável com as seguintes ressalvas: verificar se possui certificação CE e se está registado no Portal do Infarmed ou em processo de registo; na informação ao utente deverá ser incluído o seguinte parágrafo, presente no projeto enviado a esta comissão: " Todos os dados recolhidos servirão única e exclusivamente para produção de artigos científicos, sendo estes sempre anónimos e garantindo privacidade e a proteção dos dados pessoais dos participantes".

Garantindo estas situações, não tem este comissão nada a opor à realização do presente projeto."

Presidente da Comissão de Ética

Sr. Dr. Juiz Conselheiro Almeida Lopes

A Secretária da Comissão de Ética

Anabela Monteiro

Rua das Flores, 5
Apartado 6018
4051-801 Porto
T. 222 074 710 F. 222 050 116
scmp@scmp.pt