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Efficacy of a physical rehabilitation program using virtual reality in patients with chronic tendinopathy: A randomized controlled trial protocol (VirTendon-Rehab)

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Abstract

Objectives: To analyze the efficacy of a virtual reality (VR)-based rehabilitation program in people with chronic tendinopathy (CT) on pain, muscle activation pattern, range of motion, muscle strength, kinesiophobia, physical function, quality of life, and user satisfaction compared to a control group. In addition, the relationship between these variables and the clinical profile of this population will be analyzed.

Design: A 12-week, single-blind, low-risk, randomized controlled trial.

Methods: Sixty patients diagnosed with CT will be enrolled and randomly assigned to two groups. The control group will receive a physical exercise program without VR support (45 min), whereas the experimental group will receive an additional 15-min intervention through a physical exercise program delivered by VR. Both groups will receive three sessions per week, and the outcomes will be collected at baseline, after 12 weeks, and at the 24-week follow-up. Stratified groups will be established according to tendinopathy location (shoulder rotator cuff, elbow, patella, and Achilles tendon). Statistical analyses using SPSS v.24 will include descriptive analysis, stratified analysis by tendinopathy location, normality checks, intragroup and intergroup differences, effect sizes, and variable relationships.

Discussion: The results of this project may have a significant impact on the knowledge of using VR in tendinopathy management, understanding how the outcomes are related, and characterizing the clinical profiles of the population diagnosed with CT. If these results are confirmed, VR would be clinically useful for the treatment of these conditions.

Trial registration number: NCT06056440.

Keywords

Exercise, physical therapy, rehabilitation, tendinopathy, virtual reality

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Introduction

Background and rationale

Tendon overuse injuries (tendinopathy) cause pain, decreased exercise tolerance, and reduced tendon function in the upper and lower limbs.[1] The most common tendinopathies include shoulder rotator cuff tendinopathy, epicondylitis/epitrochleitis, trochanteritis, patellar tendinopathy, and Achilles tendinopathy.[2] Tendinopathies cause significant morbidity and disability that may persist for several months, despite adequate treatment.[3] Chronic tendinopathies (CT), with symptoms present for more than six weeks, have a significant impact on patients' ability to perform their work, exercise, and/or perform activities of daily living.[4] Although it is difficult to determine the incidence of this pathology, it is estimated that 30% of musculoskeletal injuries are related to tendinopathies and 30%–50% of tendinopathies occur in sports.[5] Chronic tendon-related problems account for approximately 30% of all running-related injuries, and the prevalence of lateral elbow tendinopathy may be as high as 40% in tennis players.[6]

Additionally, it has recently been reported that CT scans are associated with neurophysiological changes. For example, patients with patellar tendinopathy have greater cortical inhibition in the quadriceps than healthy people.[7] In addition to this cortical inhibition, there is also greater corticospinal excitability compared to people who do not have CT, which ultimately leads to changes in motor control.[8] Given the high recurrence rate of tendinopathies, it could be considered that in asymptomatic people with a history of pain or previous tendon pathology, the previously induced motor control changes may not have resolved, predisposing them to recurrence.[9] Furthermore, it has been suggested that hypervigilance, which refers to an excessive tendency to attend to pain or somatic sensations or an excessive willingness to select pain-related information over other information, leading to kinesiophobia, may contribute to the development of a harmful cycle of chronicity in tendinopathies.[10] Changes in the nervous system are hypothesized to play a role in the induction or maintenance of persistent pain in tendinopathy.[11] In this sense, the use of distractors as a pain management strategy has received considerable attention in both experimental pain and acute and chronic clinical pain.[12,13] Additionally, psychological factors have been found to be associated with tendinopathy and can influence the development and maintenance of pain and disability, indicating the need for individualized, holistic assessment of tendinopathy management.[14] Therefore, novel strategies are needed to manage CT adequately, avoiding motor control and pain disturbances and, therefore, relapses and their undesirable consequences.

In this sense, virtual reality (VR) is an intervention tool that can complement the rehabilitation process of CT, and is defined as a "*simulation of a real computer-generated environment in which the subject can interact with certain elements within a simulated space through a human-machine interface.*"[15] It has been used in various areas, such as pain management, assessment of neurocognitive impairment, training in medical techniques, and exercise-based physical rehabilitation.[16,17] Specifically, the use of VR-based physical activity programs has emerged in recent years as a public health promotion strategy and as a more attractive alternative or complement to traditional interventions that could improve motivation without causing physical discomfort or compromising the integrity of the user.[18]

VR can support motor control rehabilitation in several ways, as it is considered an effective strategy to improve motor performance by using visual, sensory, and auditory effects in virtual environments, promoting the participant's attention,[19] allowing individualization of exercises by controlling the number of repetitions needed, inducing neuroplasticity[20] and motor learning,[21] and increasing neural reorganization. Furthermore, VR has been shown to influence kinesiophobia, which is an important factor in the prognosis of CT,[14] in patients with chronic neck and lower back pain through gradual exposure.[22] Concerning pain distraction, a recent meta-analysis confirmed VR-induced analgesia for both acute and short-term chronic pain in adults and children.[23] VR exerts its hypoalgesic effects through a combination of attentional distraction, enhanced multisensory integration, neuroplastic changes, activation of endogenous analgesic systems, emotional and cognitive modulation, improved sensorimotor integration, and altered body representation.[24] These mechanisms work together to reduce pain perception and improve the overall pain experience in chronic pain patients.

Nonetheless, there is a lack of scientific evidence regarding the use of VR in CT management. A recent randomized controlled trial (RCT) analyzed the effects of a VR-mediated gamified exercise program in people with shoulder impingement syndrome cursing with rotator cuff CT. They found significant results on shoulder range of motion (ROM) and pain scores compared to a supervised home exercise program, highlighting the ability of VR-based exercise programs to increase patient engagement in treatment and exercise compliance.[25] Conversely, another RCT exploring the effects of VR exergaming in people with shoulder impingement syndrome obtained non-significant results on pain, ROM, function and acromion-humeral distance compared with conventional exercise. The authors attributed the lack of significant results to different limitations of the study, such as the application of different exercises in the study groups, the limited sample size, and the short follow-up period.[26] In addition, different case reports have been presented in a publication exploring the effects of VR-based interventions after hand tendon repair, obtaining benefits in prehension and motor function. In view of this background, there is still needed to evaluate the effectiveness of a physical rehabilitation program that uses VR in CT.[27]

Objectives

The main objective of this study is to analyze the effects of a 12-week VR-based intervention and at 3 weeks of

follow-up after completion of the intervention program on pain, ROM, strength, pattern of muscle activation, kinesiophobia, physical function, quality of life, and user satisfaction in people with CT.

The secondary objectives will be: i) to analyze and characterize the clinical profile (pain, ROM), strength, muscle activation, kinesiophobia, physical function, and quality of life) of the population diagnosed with CT; and ii) to identify the relationships between the outcomes that determine the results obtained. Therefore, we hypothesized that a VR-based intervention would reduce the level of pain and kinesiophobia, which could improve ROM, strength, and pattern of muscle activation, and consequently, physical function and quality of life in people with CT (Figure 1).

Trial design

This is a 12-week, single-blind, parallel-group RCT protocol. Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT 2013 Statements)[28] were followed to report the trial protocol.

Methods

Participants and the study setting

Study participants diagnosed with CT will be recruited in the following private care physiotherapy clinics: Physiotherapy and Rehabilitation Center "Modofisio" (Cádiz, Spain), and the Physiotherapy Center "En Buenas Manos" (Cádiz, Spain).

Inclusion criteria

The following inclusion criteria will be used: (i) men and women over 18 years of age; (ii) with a previous diagnosis of CT (shoulder rotator cuff, elbow, patella, and Achilles) documented by a medical professional; and (iii) symptoms lasting longer than 6 weeks.

Clinical professionals responsible for private care physiotherapy clinics will verify whether the inclusion criteria are met.

Exclusion criteria

The following exclusion criteria will be considered: (i) inability to engage in physical exercise due to a pathological condition, (ii) people who have undergone tendon repair surgery, (iii) patients who have received exercise therapy in the last 3 months, and (iv) patients who have received corticosteroid injection in the last 3 months.

Interventions

The participants with CT will be divided into two groups. The control group will undergo a physical exercise program (45 min) with a frequency of 3 sessions/week for

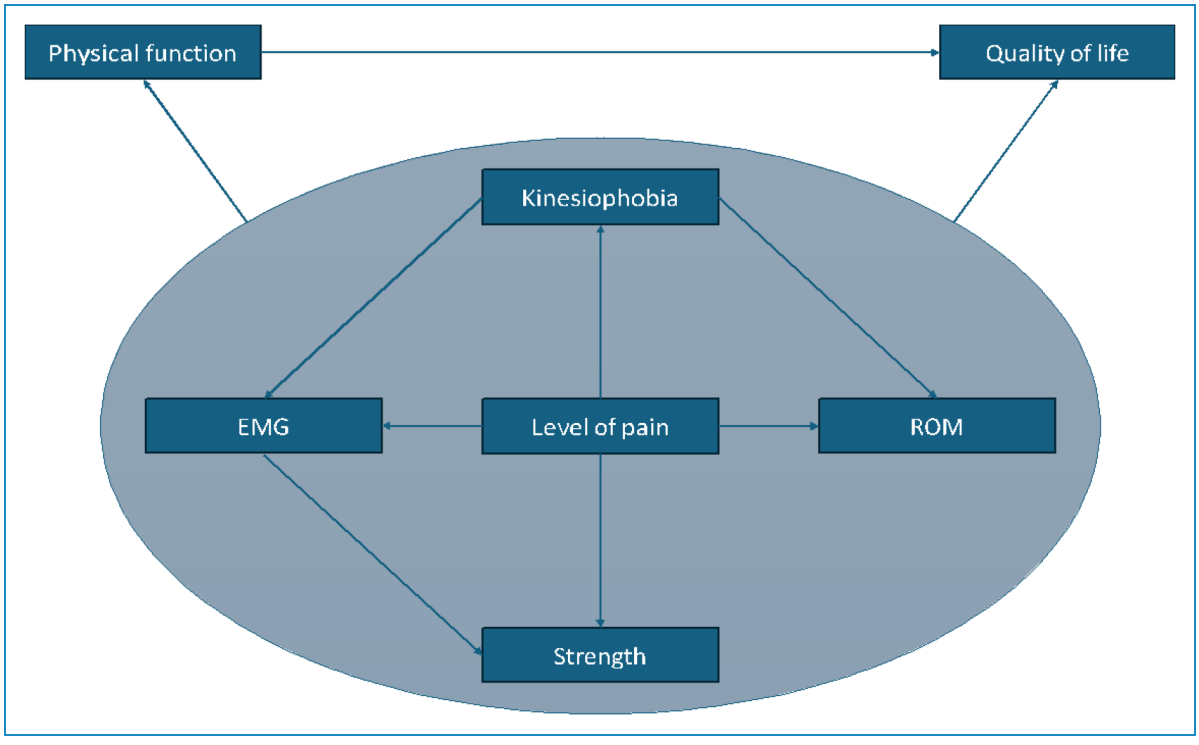

Figure 1. Diagram of effect relationships between outcomes.
EMG: electromyography; ROM: range of motion.

a total duration of 12 weeks. The experimental group will receive the same intervention (45 min, 3 sessions/week, 12 weeks) with an additional VR-based program (15 min) intrasession. The sessions will be conducted by a physiotherapist.

Control group. The control group will undergo an individualized program based on strengthening (isotonic, isometric, and eccentric), energy storage loading, and release exercises.[2] This involves progression from strengthening exercises to functional strength, speed, and jumping or throwing exercises. The exercise program will be supervised and guided by a physiotherapist.

Virtual reality program. The experimental group will perform the intervention provided to the control group with an additional 15 min of specific VR intervention. The Meta Quest 2 device (Meta Platforms Inc.), a headset that immerses the user in a fully simulated environment, will be used. To create this immersive experience, VR systems utilize technology that engages the senses. This head-mounted VR headset includes high-resolution screens and motion tracking to visually envelop the user from a first-person perspective. Users can explore the virtual environment, navigate through it, and interact with virtual objects or characters through a small display positioned directly in front of their eyes, by integrating audio and video feedback. In addition, the user interacts with the virtual environment by moving their upper limbs using controllers.[29] A software specifically designed for the physical rehabilitation of the upper and lower limbs: Dynamics VR (https://www.dynamics-vr.com/) will be used. It is a functional rehabilitation program that includes easy-to-perform exercises with a playful component that encourages the patient's continuous attention to the task performed, acting as a distracting phenomenon in the face of restricting factors of movement such as fear of pain. This software offers the possibility of adjusting the number of repetitions and characteristics of the exercises, thus allowing physical rehabilitation to be adapted to individual conditions. Specifically, virtual therapeutic exercises will be based on games that focus on pain distraction and gradual exposure to movement. In relation to the upper- and lower-limb conditions, the user interacts with various virtual objects. These games will include activities that require the patient to perform oriented tasks involving (1) frontal and lateral shoulder elevations, (2) internal and external rotations, (3) throws, (4) elbow flexion and extension, (5) pronation of the upper limbs, (6) bending and lifting, (7) heel lifts, (8) low-impact jumps, and (9) changes in direction for the lower limbs.

To ensure that the VR intervention is accessible and comfortable for all participants, we will implement a training session with a gradual introduction where participants familiarize themselves with the VR headset and software. A physiotherapist will guide participants through the setup and provide support throughout the trial. This approach is particularly important for older participants and those who may not be familiar with the VR technology.

Outcomes

Sociodemographic and clinical outcomes will be collected at baseline, as well as the rest of the outcomes that will also be measured at the end of the intervention (12 weeks) and at the follow-up of 24 weeks (12 weeks after ending the intervention): pain, physical function, ROM, strength, pattern of muscle activation, kinesiophobia, quality of life, and satisfaction with the use of the system.

Sociodemographic and clinical data. A structured questionnaire will be used to collect sociodemographic and clinical data that will include the following variables: date of tendinopathy diagnosis, duration of symptoms since symptom onset, presence of other pathologies, previous surgical interventions, and previous exercise. The questionnaire used can be found in the Supplemental material (File S1).

Pain. The Numeric Pain Rating Scale (NPRS) measures pain levels. It is a subjective pain measure in which the patient chooses a number between 0 and 10 (11-point numeric scale), showing the intensity of pain that they believe they are experiencing. A score of 0 corresponds to no pain, and a score of 10 corresponds to the worst imaginable pain.[30] Regarding the NPRS, it cannot be evaluated for structural validity or internal consistency, since it is a single-item measure. In addition, no research was found to examine its cross-cultural validity.[31] However, its construct validity showed a high correlation (0.86 to 0.95) with the visual analogue scale in patients with chronic pain conditions (pain > 6 months).[32]

Physical function. The Spanish versions of the Shoulder Pain and Disability Index (SPADI),[33] Victorian Institute of Sport Assessment - Patellar Tendon (VISA-P),[34] and Victorian Institute of Sport Assessment - Achilles Tendon (VISA-A)[35] will be used to measure physical function. The SPADI questionnaire evaluates disability and pain provoked by shoulder dysfunction and comprises 13 items related to the ability to perform activities of daily living. Higher scores indicate greater disability and pain.[33] It was validated for the Spanish population with musculoskeletal shoulder pain, confirming a bidimensional structure (pain and disability subscales), and a correlation of Spearman rho = 0.752 and Cronbach's $\alpha = 0.90$ with the quick-DASH scale.[36] The VISA-P and VISA-A questionnaires evaluate the health-related impact of tendinopathies based on symptoms, function, and the ability to perform sports. Higher scores indicate better conditions, with global scores ranging from 0 to 100. The VISA-P questionnaire demonstrated strong validity, evidenced by its high reliability (ICC = 0.994, Cronbach $\alpha = 0.885$), significant

correlations with established knee scales (Kujala score: Spearman rho = 0.897; Cincinnati scale: Spearman rho = 0.782), and sensitivity to clinical changes, making it a valid and reliable tool for assessing patellar tendinopathy in Spanish-speaking populations.[37] The VISA-A questionnaire demonstrated robust validity with high reliability (Cronbach's $\alpha > 0.8$, ICC = 0.993) and strong correlation with the SF-36 physical components (Spearman rho > 0.5). These psychometric properties suggest that VISA-A is a valid and reliable instrument for assessing Achilles tendinopathy in Spanish-speaking populations.[38]

Range of movement. The pain-free active ROM of shoulder abduction and external/internal rotation, wrist extension/flexion, knee extension/flexion, and ankle plantarflexion/dorsiflexion, will be measured using a goniometer.[39]

Muscle strength and muscle activation pattern. The maximum voluntary contraction and muscle activation pattern of shoulder abduction and external/internal rotation, wrist extension/flexion, knee extension/flexion, and ankle plantarflexion/dorsiflexion will be analyzed using a dynamometer[40] and electromyography (EMG),[41] respectively.

Kinesiophobia. The Spanish version of the Tampa Scale for Kinesiofobia (TSK-11) will be used. This 11-item questionnaire evaluates the fear of movement and can predict pain-related disability. Higher scores indicate higher levels of kinesiophobia, with global scores ranging from 0 to 52.[42] The Spanish version of the Tampa Scale demonstrated good reliability and validity (convergent and predictive). It showed strong correlations with the measures of catastrophizing, depression, anxiety, and functional status. These psychometric properties suggest that it is a valid and reliable instrument for assessing pain-related fear in Spanish-speaking patients.[43]

Quality of life. The Spanish version of the12-item Short-Form Health Survey version 2 (SF-12v2) will be used to evaluate the quality of life. It was validated for the Spanish population showing strong correlations with measures of temporal and spectral parameters of heart rate variability (Spearman rho > 0.5). The feasibility of its use for the diagnosis of stress states (overtraining, burnout, fatigue, exhaustion, anxiety) is suggested.[44] This tool includes 12 elements constituting its eight-dimensional profile: physical functioning, physical role, bodily pain, general health, vitality, social functioning, emotional role, and mental health. Higher scores indicate better conditions, with global scores ranging from 0 to 100.[45]

User satisfaction. The Spanish version of the Consumer Report Effectiveness Scale (CRES-4) will be used to evaluate user satisfaction. It consists of four items related to the level of problem resolution, emotional level before and after treatment, and satisfaction with the treatment. Higher scores indicate high levels of user satisfaction, with global scores ranging from 0 to 300.[46]

Sample size

The sample size was calculated to identify the differences between the groups in the measurement scales to be administered. The calculation of the sample size was carried out using the GRANMO calculator (Institut Municipal d'Investigació Mèdica, Barcelona, Spain). Based on Heron et al.,[47] 45 people in the experimental group and 45 people in the control group were required to detect a difference equal to or greater than 10 units, with a common standard deviation of 15 in the SPADI questionnaire. According to Gual et al.,[48] 55 people in each group were required to detect a difference equal to or greater than six units in the VISA-P questionnaire, with a common standard deviation of 10. Finally, considering the study carried out by De Vos et al.,[49] 31 people in each group will be required to detect a difference equal to or greater than 12 units in the VISA-A questionnaire, assuming a common standard deviation of 15. In all calculations, an alpha risk of 0.05 and a beta risk of 0.2 were accepted in a two-sided contrast, as well as a follow-up loss rate of 20%. Based on the above, a minimum of 120 participants (60 in each study group) will be recruited for the study. Consecutive sampling will be carried out with patients who attend to health entities and meet the criteria described above.

Assignment of interventions

Regarding the randomization process, the Epidat 3.1 program will be used to determine which group each patient will be assigned to. Through its module for assigning subjects to treatments with groups of equal size, two lists of 60 random numbers between 1 and 120 will be obtained without repetition, which will be used to determine the group to which each patient belongs according to their order of arrival. If this sample size is exceeded, the randomization process will continue to make use of the "balanced groups" strategy, in which the probability of inclusion in each group will be inversely proportional to the number of people already in that group, so that, by probability, both groups will grow in a balanced way.

Blinding

This is a single-blind study. Measurements of the variables in both study groups will be performed by an additional researcher who is blinded to the participant allocation. To minimize the potential transfer of clinician attitudes or inclinations for or against an intervention to the participants, which can lead to a bias of results, clinicians will be trained to always interact with both study groups in the same way. In this sense, clinicians will avoid using

language in their instructions or advice that might suggest to participants whether they are in the experimental or control group, and which group is expected to respond better to the intervention.[50,51]

Data collection

Participants who meet the inclusion criteria will be scheduled and asked to provide informed consent. Once participation is accepted, all patients will receive an information session in which the VR-based intervention will be explained. Different tests and questionnaires will be used to measure the study variables. Measurements of variables will be performed at baseline (T0) and data will be collected on baseline sociodemographic variables at the end of the intervention (T1) and 12 weeks after the end of the intervention program (T2).

A clinical professional at the healthcare center will be responsible for performing measurements during the study.

To minimize participant dropout, we will implement several retention strategies. In this way, regular communication and flexible scheduling options to accommodate participants' personal and professional commitments will be ensured. Close contact and rapport building by the study staff will further help reduce attrition, as developing trust has been shown to improve retention in long-term clinical trials.[52]

The data collection procedure is described in detail in Table 1.

Table 1. Timeline of data collection.

	Study Period				
	Selection	Allocation	Post-allocation		
Temporary Points	T-1	0	T0	T1	T2
Recruitment					
Eligibility criteria	X				
Informed consent	X				
Assignment of study groups		X			
Interventions					
Experimental group (VR)			⟺		
Control group			⟺	⟺	⟺
Assessments					
Baseline sociodemographic variables			X		
Functionality			X	X	X
Pain			X	X	X
Rom			X	X	X
Muscle strength			X	X	X
Pattern of muscle activation			X	X	X
Kinesiophobia			X	X	X
Quality of life			X	X	X
User satisfaction				X	X

T0: Baseline; T1: End of program intervention (12 weeks); T2: Follow-up after 12 weeks of ending intervention.

Statistical methods

Statistical analysis will be performed using the SPSS v.24 statistical software. First, a descriptive analysis of the data will be carried out using absolute and relative frequencies and measures of centralization and dispersion. Stratified analysis will be performed according to the location of tendinopathy. The Kolmogorov-Smirnov test will be used to check whether the dataset has a normal distribution.

On the other hand, the Student's *t*-test for paired samples (in case of normality) or the Wilcoxon test (in case of non-normality) will be used to measure the differences between the initial and post-intervention scores, and the *t*-test for independent samples or the U Mann-Whitney test will be used to check the differences between each group (experimental and control). A 95% confidence interval will be established. Cohen's *d* will be used to determine effect size. The effect size of 0.20 is considered a small effect, 0.5 is considered a medium effect, and more than 0.80 will be considered a large effect.[53] The results will be presented as the standard deviation (SD) and mean (min-max).

Finally, to analyze the relationships between physical function, quality of life, kinesiophobia, EMG, pain, ROM, and strength, multivariate structural equation models with latent variables will be used, both at baseline and during follow-up.[54] These models are powerful tools increasingly used in health practice, particularly for longitudinal data analysis. They allow the examination of relationships between constructs and their effects over time, enabling a joint study of the directional effects of some variables on others and the evolution of the variables themselves. In this sense, the total program duration will be included as a covariate to control for its potential influence on study outcomes. An additional sensitivity analysis will be performed, including and excluding the total treatment duration as a covariate.

In the case of missing data, we will use intention-to-treat analysis, where all participants will be analyzed in the groups to which they were originally randomized, regardless of adherence to the intervention or follow-up, thus preserving the benefit of randomization and minimizing bias from non-compliance or dropouts. Multiple imputation

techniques will be used to predict missing values based on the observed data, generating multiple data sets with different imputed values that will be combined to reduce bias and increase the validity of the results. Sensitivity analyses will be conducted to compare results between the complete-case and imputed datasets to ensure that any impact of missing data on the results is identified. In addition, attrition analyses will be conducted to identify patterns or differences between participants who drop out and those who complete the study, helping us to determine whether dropout is random or related to specific participant characteristics and allowing us to adjust models accordingly.

Ethics

This clinical trial has been approved by the Ethical Committee of the Province of Cádiz (Cádiz, Spain) (Register number: 31.23). All procedures shall be performed in accordance with the recommendations and ethical principles of the World Medical Association's Helsinki Declaration of Ethical Principles for Medical Research on Human Subjects and Ethical Principles for Medical Research on Human Subjects, the version of which was reformed at the 64th General Assembly in Fortaleza, Brazil, in October 2013. In addition, this clinical trial was recorded in the database delivered by the U.S. National Library of Medicine, ClinicalTrials.gov, with identifier code NCT06056440.

The Consolidated Standards of Reporting Trials (CONSORT)[55] will be followed to publish the study's findings in international peer-reviewed journals and present them at conferences worldwide. Additionally, as part of our knowledge translation strategy, we will disseminate the findings on institutional websites and social media, contact news organizations, and identify partner institutions that are interested in the findings.

Confidentiality

All participants will be informed verbally and in writing about the procedure that is going to be carried out, and will sign an informed consent document to participate before joining our study. This document states that they have read and understood the information given to them, that they have been able to ask questions about the study, that they understand that their participation is voluntary, and that they can withdraw from the study whenever they want without having to give explanations and without this having an impact on the attention given to them. On the other hand, they will give their consent for computer processing of the data obtained for scientific purposes, in accordance with legal regulations.

Discussion

The VirTendon-Rehab project aims to have a positive impact on the health of people diagnosed with CT, who often suffer from difficulties in the development of their work and domestic and sporting activities. As detailed in the Introduction, exercise is beneficial for patients with CT; therefore, it is expected that the use of the system based on VR exercises proposed in this study will cause a decrease in pain and kinesiophobia, an improvement in movement, and consequently, a positive impact on the quality of life. In addition to impacting the participants, the results obtained could be useful for the possible integration of VR systems into the daily clinical practice of public and private health systems.

These results build on previous research exploring the use of VR in therapies for chronic conditions, although evidence on CT is still needed. Current meta-analyses suggest that therapies involving VR can improve the level of pain and kinesiophobia, a clinical entity highly related to various types of tendinopathies,[14] in patients with various chronic pathologies. Brea-Gómez et al.[56] determined that VR intervention reduces the level of pain and kinesiophobia in patients with chronic low back pain in the short term and after six months of follow-up. Similar findings were reported by Li et al.,[57] concluding that VR-based training reduces the level of pain and kinesiophobia in the immediate term. In the context of other chronic pathologies, Guo et al.[58] stated that VR intervention for patients with neck pain reflected benefits in pain relief, based on moderate-quality evidence. Furthermore, current evidence indicates that VR is effective in reducing kinesiophobia, and is more effective when combined with physical exercise,[59] which supports the design of our study. Nevertheless, although the available meta-analyses are useful for establishing an overview of the effectiveness of VR, the heterogeneity among studies is high and further research is needed.

The management of pain and kinesiophobia using VR is suggested to be based on the mechanisms of distraction and embodiment; that is, the sensation that the virtual body is an extension of one's own physical body. Distraction diverts the person's attention away from pain by engaging the patient in a virtual immersive environment, reducing pain perception and kinesiophobia.[23] However, Baker et al.[60] stated that the most common mechanism is distraction, but in subjects with chronic pain, there is an important presence of the embodiment mechanism as a mechanism of pain reduction.

In view of this overview, it should be noted that to date, to the best of our knowledge, no study has been found in the literature that includes the use of VR in CT. Therefore, there have been no previous analyses of the neurophysiological effects of this type of intervention in patients in the chronic stages of this pathology. Given the etiopathogenic differences, as well as the neurophysiological and tissue differences between the pathologies previously discussed and CT, it cannot be stated with certainty that this intervention has the same effects in patients with CT.

Despite the limited evidence for the effectiveness of VR in the treatment of CT, the importance of task-oriented physical exercise for the recovery of various pathologies, including tendon injuries, has been highlighted in recent years. For example, a clinical guideline highlighted the importance of an active, task-oriented rehabilitation program to reduce pain and disability in adults with rotator cuff disorders.[61] This recommendation is encouraging and suggests that the support and known benefits of VR intervention, which are almost entirely goal-oriented, may be effective in improving the clinical practice of patients with CT. However, it should be noted that our theoretical basis was established using other chronic pathologies as references because of the lack of evidence specifically related to CT. This may lead to a potential bias in our intended study results, thus affecting the generalizability and applicability of our findings. It is important to use caution when extrapolating data from these conditions to CT, as they differ in their pathophysiology and treatment requirements. Although VR-based interventions have demonstrated efficacy in the treatment of other chronic pain conditions, the unique characteristics of CT, specifically the need for appropriate mechanical loading to promote tendon healing,[62] may result in different therapeutic outcomes.

It should be noted that the chronicity of tendinopathy not only affects the physiology of tendon tissue[63,64] but may also influence the psychological and social aspects of patients suffering from it.[65] This fact is fundamental when considering active interventions, where patient engagement in treatment and the level of patient satisfaction are variables of utmost importance. In this context, our study aimed to improve patient engagement and satisfaction in patients undergoing CT using a tool that, although increasingly used, is still novel for the general population, such as VR. In addition to addressing the clinical needs of patients, this study may open new lines of research exploring the implementation of VR in different areas of telerehabilitation and personalized treatment, where the role of the Artificial Intelligence (AI) will be crucial. AI could prevent injuries by examining biomechanical and physiological information to anticipate potential harm and track recovery progress. In this sense, predictive analytics will use historical and current data to assess human performance and support strategic clinical decision-making.[66]

Strengths and limitations of the study

This study has several strengths that highlight the potential impact of these findings on the treatment of patients with CT. One of the main strengths of this study is its technological innovation, which employs VR to create safe and controlled environments for patients. This approach not only facilitates physical rehabilitation, but also addresses psychological aspects, such as kinesiophobia, by offering a different experience from the conventional treatment model. This experience is immersive and motivating. VR interventions have the potential to adapt exercises to the individual needs of patients, thereby improving the treatment efficacy. Furthermore, the versatility of VR, coupled with the portability of the device, suggests that it could be a valuable tool for other fields of treatment, such as telerehabilitation. Moreover, a comprehensive assessment of the various clinical parameters included in the study, such as pain, physical function, ROM, strength, and quality of life, provides a complete understanding of the impact of the intervention. Furthermore, the playful and motivating nature of VR is expected to promote high patient satisfaction with treatment, which is crucial for its long-term success.

Nevertheless, it is important to acknowledge that this study has several limitations that should be considered when interpreting the results. One potential limitation of the study is the possibility of user discomfort or disorientation associated with VR, particularly in older adults or those unfamiliar with digital technology. To address this, we have designed a training session with gradual introduction to familiarize participants with the VR system and will provide ongoing technical support throughout the study. The flexibility of the VR software will also allow for customization of exercises, ensuring that the experience is tailored to the capabilities of each participant. A possible limitation of this study is related to the difference in total program duration between the two study groups. In addition to the program performed by the control group, the VR-based intervention program will be conducted for 15 min. This issue may give rise to a possible bias since the intervention group obtained superior results compared to the control group, which could be due to the increased therapy time received. However, an attempt has been made to mitigate this limitation, including the total program duration as a covariate and performing a sensitivity analysis. Another potential limitation is the loss of participants during the follow-up period, which could affect the validity and generalizability of the results. In addition, the recruitment of participants in private clinics may result in selection bias, thereby limiting the applicability of the findings to other clinical settings. Despite calculating the optimal sample size to detect significant differences, a small sample size could limit the ability to detect minor effects and reduce the statistical power of the study. The nature of the intervention makes it impossible to perform complete blinding, which introduces the potential for expectation bias in self-reported patient outcomes in single-blind studies. Participant dropout during the follow-up period is a potential limitation of the study and could affect the validity and generalizability of the results. To address this, we have outlined several retention strategies, including personalized follow-up, flexible scheduling, and incentives to maintain participant engagement throughout

the trial. Furthermore, we will implement intention-to-treat analysis and multiple imputation techniques to handle missing data and reduce potential biases. Sensitivity analyses will also be conducted to examine the robustness of the findings, ensuring that the impact of dropout is minimized. Finally, although validity studies exist for the scales used, some have not been validated in our study population. Furthermore, although the CRES-4 scale has been used in previous studies involving Spanish-speaking populations,[67–69] there is a lack of validation specifically in patients with CT. The absence of validation could result in measurement bias, potentially under- or overestimating patient satisfaction with the intervention, affecting the generalizability of the results obtained. In this sense, we will interpret the results with caution to mitigate this issue. Therefore, it is essential to address these limitations in order to ensure the validity and generalizability of the results.

Conclusion

The VirTendon-Rehab study protocol is designed to research the effectiveness of a VR-based exercise program in people with CT. Based on the current scientific literature, this program may result in improvements in pain and kinesiophobia through hypoalgesic mechanisms, pain distraction, task repetition, focused attention on the task, and gradual exposure to movement. Consequently, improvements in pain and kinesiophobia could have a positive impact on the outcomes of this study. If such results are obtained, inclusion of this intervention program in the clinical practice of healthcare centers should be considered.

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