RESEARCH PROTOCOL - Use of the eFisioTrack system for monitoring prescribed therapeutic exercises in patients with shoulder orthopedic injuries in a hospital setting: A pilot feasibility study

18/07/2023

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PROJECT SUMMARY

Rationale

To assess the effects of the eFisioTrack monitoring system on clinical variables in patients with prescribed physiotherapy for shoulder injuries.

Objectives

The main aim of the study was to evaluate the effect on clinical variables of monitoring exercises prescribed for shoulder injury rehabilitation with the eFisioTrack platform in patients of the Rehabilitation Service at University Hospital of Elche.

Methods

A pilot feasibility study, single bling with two groups (experimental and control group). Clinical outcome measures will be shoulder function and pain (Constant Murley Score and Disabilities of the Arm, Shoulder, and Hand or DASH score). Each variable will be measured by a blinded physiotherapist at baseline and at one month follow-up. Patients performed the prescribed exercises either supervised by the physiotherapist (control group) or in a separate room without therapist supervision (experimental group).

Population

The study will be carried out in the buildings of the Rehabilitation Service at University Hospital of Elche, starting in July 2023 and finishing in December 2023.

Expected outcomes.

This study aims to contribute to the advancement of the knowledge about the shoulder treatment. The system shows promising results as a work item in shoulder home-based rehabilitation. In fact, real-time telerehabilitation is a strategy for interventions in other musculoskeletal conditions, to provide continuity to healthcare services and mitigate distance and displacements. Confirmation of these preliminary results could reduce the workload of physiotherapy services, contributing to resource efficiency.

GENERAL INFORMATION

Protocol title. Use of the eFisioTrack system for monitoring prescribed therapeutic exercises in patients with shoulder orthopedic injuries in a hospital setting: A pilot feasibility study.

Protocol identifying number. The study protocol was approved by the Ethics and Research Committee of General University Hospital of Elche (CEIC HGUE-Shs2011).

Registration date. 21/07/2014

Name and address of the sponsor/funder. This research received no external funding.

Investigator responsible

Research site.

Authors.

(Ensure the names of research participants are not included in an uploaded document).

Author Contributions:

(Ensure the names of research participants are not included in an uploaded document).

RATIONALE AND BACKGROUND INFORMATION

Shoulder pain is a common health problem, and its prevalence has been estimated at around 7%–26%. There are several conditions that can produce pain in the shoulder complex, such as fractures, frozen shoulder, rotator cuff tendinopathy, or subacromial syndrome. Physiotherapy management helps to reduce pain, improve range of movement and strength, and improve function. Combining active exercises with manual therapies is a common practice when treating musculoskeletal injuries of the shoulder.

Therapeutic exercise, in both the physical therapy setting and at home, is a fundamental component of shoulder rehabilitation plans whether treatment is performed with or without surgery, and there is evidence of its effectiveness in the management of shoulder conditions[5]. The primary goal of a shoulder exercise program is to relieve pain, increase strength, reduce muscle imbalances, and restore pain-free joint range of motion. Therefore, its correct execution is of great importance for the clinical course.

However, one of the main problems in orthopedic shoulder rehabilitation is poor adherence to home exercise prescriptions. Some strategies for their control, such as daily or video recording, have been described, but their use is limited by recall bias or the need for advanced technology.

There is a growing number of trials about the use of technology to monitor rehabilitation exercises. Its application in shoulder injuries could be potentially beneficial. Carbonaro et al. presented the development and preliminary testing of a wearable-technology platform for the remote rehabilitation of shoulder muscular-skeletal diseases. This system (Shoulphy) was designed to lead and assess the patient wearing a minimal set of inertial sensors and following personalized physical rehabilitation programs under the remote supervision of the physician/therapist. Pan et al. reported the use of accelerometer-based sensors built into a smartphone to capture the rehabilitation exercises as a self-home monitoring system. Wearable sensors, smartphones, and inertial measurement units have become a feasible option for monitoring joint movement. There is also research on the application of Nintendo® Wii-technology for monitoring therapeutic exercises on shoulder injuries[16]. This is based on accelerometers and gyroscopes located in the controls, making it a low-cost option. However, most of these focus on stroke, to improve arm function and balance in hemiparetic patients.

Ruiz-Fernandez et al. described a software platform based on Wii-controls technology that could be used to monitor patients' activity in the scheduled exercise sessions. However, there is no clinical study of the results obtained in the laboratory. Therefore, the aim of this pilot study was to evaluate the effect on clinical variables of monitoring exercises prescribed for shoulder injury rehabilitation with the eFisioTrack platform in patients of the Rehabilitation Service at University Hospital of Elche.

OBJECTIVES

The main aim of the study was to evaluate the effect on clinical variables of monitoring exercises prescribed for shoulder injury rehabilitation with the eFisioTrack platform in patients of the Rehabilitation Service at University Hospital of Elche.

STUDY DESIGN

A pilot feasibility study, single bling with two groups (experimental and control group). Clinical outcome measures will be shoulder function and pain (Constant Murley Score and Disabilities of the Arm, Shoulder, and Hand or DASH score). Each variable will be measured by a blinded physiotherapist at baseline and at one month follow-up. Patients performed the prescribed exercises either supervised by the physiotherapist (control group) or in a separate room without therapist supervision (experimental group).

Regarding the study population.

Patients who will be referred to the rehabilitation service of the University Hospital of Elche (Spain) for physiotherapy treatment (manual therapy, exercise, stretching, and electrotherapy) after suffering orthopedic injury or surgery in the shoulder joint complex, from July 2023 to December 2023 will be considered for enrollment in the study.

Inclusion criteria were established as follows:

(i) be at least 18 years old and be able to read and understand Spanish.
(ii) suffer a traumatic or degenerative shoulder injury, with or without surgical treatment.
(iii) have a prescription for rehabilitative physical therapy that includes active exercises.

The exclusion criteria adopted were:

Patients were excluded if they had a concomitant injury on an upper extremity or the cervical spine at the time of participation or sequelae of previous injuries in the area.

Regarding sample size

The main objective of this study is to know whether a clinical trial will be feasible and to have an estimate of standard deviation, which will be used in the sample size calculation for the large-scale trial; to estimate the rate (proportion) of eligible people who are willing to participate, of participants who drop out of the trial, or of participants who comply with the assigned intervention. That is why the sample size could be between 20 and 40 participants.

METHODOLOGY

Following baseline examination, patients will be randomly assigned to either physiotherapist-supervised exercise (control group) or monitoring by the eFisioTrack

system (experimental group). Patients will perform the prescribed exercises either supervised by the physiotherapist (control group) or in a separate room without therapist supervision (experimental group). A system of codes (four last numbers of the patient's ID number) was assigned to each participant using a computerized application (Research randomizer: www.randomizer.org). Clinical outcome measures were shoulder function and pain (Constant Murley Score and Disabilities of the Arm, Shoulder, and Hand or DASH score). Each variable was measured by a blinded physiotherapist at baseline and at one month follow-up.

The intervention consists of the use of the eFisioTrack platform in the experimental group to perform active exercises as part of their shoulder rehabilitation. These were performed independently by each patient in a hospital room, using the efisioTrack system without supervision by the physiotherapist. The design and use of eFisioTrack has been assessed for usability and was described as appropriate and technically feasible. The subjects will be previously instructed in the use of the system in two 20-minute sessions. The type of exercise and its parameters will be chosen and progressed considering the functional status of the patient and being similar to those executed under the physiotherapist's supervision.

OUTCOME MEASURES

The baseline measures will be collected before randomization and the outcome assessments will blind. All assessment measures, will be collected by the same clinician who was not involved in the treatment programs. In addition, at the physiotherapy service patients received a paper copy of the questionnaires to fill out on their own.

The following patient-reported outcome measures were used to assess participants' shoulder pain and function: the Disabilities of Arm, Shoulder and Hand (DASH) score and the Constant-Murley (CM) score.

- **Primary outcome measures**

The DASH was taken as a primary outcome measure. It is one of the most widely used self-reported questionnaires that measures symptoms and degree of function related to a disorder in the upper extremity. It has been validated in Spanish and comprises 30 items: 21 about physical function, 6 for symptoms, and 3 to assess social aspects. In addition, there are two optional modules, each with four items, which are used to assess symptoms and function in those whose functional demands are not included in the main part of the questionnaire.

This instrument has been used in previous studies involving physical therapy and exercise for shoulder injuries. It is scored in two components: first the symptom questions (30 items) and second the optional modules. The assigned values for all completed responses are summed and averaged, producing a score that is then transformed on a scale of 0 to 100 by subtracting one and multiplying by . A higher score indicates greater disability. Differences in scores are considered clinically relevant (minimum clinically important difference or MCID) when they are above 10 points.

- **Secondary outcome measures**

The CM score is a commonly used specific instrument for assessing the shoulder joint. The maximum score is 100 points, 90 to 100 being excellent, 80 to 89 good, 70 to 79

medium, and less than 70 poor, considering that the scores can vary with age. This tool includes a subjective assessment of the patient's pain and ability to perform daily activities (35 points) and an objective assessment of mobility and strength by physical examination (65 points). Its use has been specifically validated in shoulder arthroplasty, rotator cuff repair, adhesive capsulitis, and fractures of the proximal humerus, but not in shoulder instability.

SECURITY CONSIDERATION

The risks of the treatment techniques or manual therapy procedures as well as other means of physical treatment and their possible adverse effects that will be used in this study are uncommon and generally mild. Follow-up of cases with adverse effects will be maintained until the end of the study. This measure ensures safe conditions for the treatment of patients.

STATISTICAL ANALYSIS

Descriptive data will be presented as a mean and standard deviation for continuous variables. For statistical analyses, the normality of the data distribution will be assessed by the Shapiro-Wilk test. To compare differences between groups in the studied variables, the Student's t-test will be used for normally distributed data. For each group, a paired t-test will be used to compare baseline and follow-up scores, and the 95% confidence interval (CI) will be calculated for the mean differences.

The theoretical sample size based on a 10-point difference (10%) in the DASH between the two studied groups, assuming a 95% confidence interval, 80% statistical power and 20% sampling error, resulted in 36 patients in each group.

All analyses will be conducted using SPSS Statistical Package for Windows, version 25 (SPSS Inc., 2009, Chicago, Illinois, USA). The significance level was set at $P < 0.05$.

EXPECTED OUTCOMES OF THE STUDY

This study aims to contribute to the advancement of the knowledge about the treatment of acute grade II WL, showing the effectiveness of SAT technique compared to other frequently used treatment protocols. The lack of randomized clinical trials related to the application of spinal manipulation techniques in whiplash injury, compared to studies in which passive and active interventions are applied, increases the interest of this study.

PROJECT DURATION

The study will be carried out in the buildings of the Rehabilitation Service at University Hospital of Elche, starting in July 2023 and finishing in December 2023.

ETHICAL ASPECTS

The study protocol was approved by the Ethics and Research Committee of General University Hospital of Elche (CEIC HGUE-Shs2011). All participants will sign an informed consent form prior to voluntary participation in the study.
The ethical requirements relevant to patient safety, as set out in the Declaration of Helsinki and the Belmont Report on Respect for Persons will be followed during the study. Furthermore, the patient will sign the informed consent form to authorise his or her inclusion in the study, confirming beforehand that he or she understood the study correctly.

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INFORMED CONSENT FOR PARTICIPATION IN THE PROJECT OF MONITORING SHOULDER REHABILITATION EXERCISES WITH THE EFISIOTRACK SYSTEM

Mr./Mrs ....
..... as a patient, being ..... years old, residing at .....
.... ID card number: ……

I DECLARE THAT:

The physiotherapist....., has explained to me that:

1.- Identification, description and objectives of the procedure.

Bioinspired Health Engineering group of the University of Alicante, in collaboration with the Physiotherapy area of the Miguel Hernández University of Elche and the General University Hospital of Elche, intends to carry out a study on exercise monitoring for shoulder rehabilitation with inertial sensors located in a game console (Wii) controller. This controller is connected to a computer and allows you to record the exercises you perform, as well as their trajectory and speed. The physiotherapist who treats you, will be able to see in real time from another location, if you complete the prescriptions that have been made, as well as interact with you if necessary through videoconference.

The results obtained will serve to refine the system and generalize its application to the population that performs therapeutic exercise for shoulder injuries and needs follow-up on them.

The procedure that is proposed to me consists of placing a movement sensor attached to the extremities or the trunk (depending on the exercise) with a velcro so that it registers how the exercise is performed. Everything will be visible on a screen, which will provide information on the range of movement of the exercise, the repetitions and series that you have to do, as well as if you are executing them correctly.

2.- Benefits that are expected to be achieved

I will not receive any financial compensation or other benefits for being evaluated. In any case, if the research were successful, it could help to perfect the system and extend its use as an aid to carrying out home exercise programs (without specialist supervision).

3.- Reasonable alternatives

The decision to participate in the work or to complete the data on the evaluation ***is completely voluntary*** , and I may refuse to receive it and may even revoke my consent at any time, without having to give any explanation and without prejudice to my personal consideration.

4.- Foreseeable consequences of its performance and non-performance

If I freely and voluntarily decide to carry out the eccentric work protocol and be evaluated later, I will have the right to decide whether or not to be informed of the results of the investigation, if it is finally carried out.

5.- Frequent and infrequent risks
No harmful risks are expected since the system will record movement during therapeutic exercise and does not modify its characteristics or parameters at all.

6.- Risks and consequences depending on the personal clinical situation of the patient and their personal or professional circumstances .
None

7.- Protection of personal data and confidentiality.
The information about my personal and health data will be incorporated and processed in a computerized database, complying with the guarantees established la Leyfor the Protection of Personal Data and health legislation.

The assignment to other research centers will be carried out through a disassociation procedure through which an identification code will be generated that prevents me from being directly or indirectly identified.

Likewise, I have been informed that I have the possibility of exercising the *rights of access, rectification, cancellation and opposition to the processing of personal data* , in the terms provided in the applicable regulations.

If you decide to revoke the consent that I now give, the data obtained from the examination at that time will continue to be part of the research.

8.- Project manager
The person in charge of the research project is Dr. Antonio Soriano Payá, professor in the Department of Information Technology and Computing at the University of Alicante

Therefore, having read the above information, I understand that :

My participation in this study is **voluntary** , and **I can revoke my consent at any time, without explanation and without affecting my medical care** .

I give my consent for la Universidad MiguelHernández or other research centers to use my data, including my health information, for medical research, always maintaining my anonymity and the confidentiality of my data.
The information and this document have been provided to me sufficiently in advance to reflect calmly and make my decision freely and responsibly.

I have understood the explanations that have been provided to me in clear and simple language and the physiotherapist who has treated me has allowed me to make all the observations and has clarified all the doubts that I have raised.

confidentiality of these data *will be maintained in accordance with the provisions of Organic Law 15/1999 on the Protection of Personal Data. In addition, the confidentiality of clinical data will be maintained according to LAW 41/2002, of November 14, the basic regulation of patient autonomy and rights and obligations regarding clinical information and documentation.*

Observations you consider making:

Therefore, I state that I am satisfied with the information received and under such conditions I agree and **CONSENT to participate in the study on 'Monitoring for the performance of therapeutic rehabilitation exercises'**

In .....……..... . Date: (day)……/ (month)……/ (year)……

Signature of the patient Signature of a witness Signature of the Physiotherapist

Signed.: ..... Signed..... ..... Signed:..... .....

(Name and two surnames) (Name and two surnames) (Name and two surnames)

RESPONSIBLE FOR THE PROJECT
Dr. Antonio Soriano Payá

REVOCATION OF INFORMED CONSENT

Mr./Mrs. .... as a patient (or representative of the patient D..... ....), of ..... years of age, residing at .... ID. nº ..... I revoke the consent given on date..... ..... , which I end with this date and without having to give explanations.

In ..... of ..... of 20...

Signature of the patient Signature of a witness Signature of the Physiotherapist
ID:

Signed: ..... Signed:..... ..... Signed:..... ..
(Name and two surnames) (Name and two surnames) (Name and two surnames)