



Clinical Study Protocol

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Efficacy of a Digital Biofeedback System for Home-based Rehabilitation After Total Joint Replacement

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1. Introduction

The effects of total hip (THA) and knee (TKA) arthroplasty are well documented, with the majority of patients showing significant pain relief and relevant functional improvement ¹⁻³. It is also proven that rehabilitation after THA or TKA maximizes results ⁴⁻⁶. As such, rehabilitation is widely prescribed upon surgery.

There are no universally accepted guidelines for rehabilitation after THA or TKA ⁷⁻¹⁰. Moreover, clinical evidence on this matter is limited, with variable quality and sometimes inconsistent ¹⁰.

Importantly, the exact composition and duration of physical therapy is not standardized ^{11,12}. This fact is particularly relevant considering that the rehabilitation program may influence both short- and long-term results ¹³⁻¹⁸. There are no defined optimal doses of physical exercise, nor ideal progression curves for therapist's guidance ¹⁰. Notwithstanding, studies suggest that intensive and progressive rehabilitation translates into better results ⁴, also maximizing patient's adhesion to therapy and overall satisfaction ⁸.

According to an expert consensus on best practices for post-acute rehabilitation after THA and TKA, rehabilitation should start within 3 weeks of discharge ¹⁰. Despite the absence of criteria on specific dose parameters of duration, frequency, and number of treatment sessions, the recommendations support 4 to 12 weeks of supervised rehabilitation, 2 to 3 times per week ¹⁰. There is also evidence stating that therapeutic exercise should be a primary component of post-operative care, and that the exercise programs should be supervised and progressed as the patients meet clinical and strength milestones ^{9,13}.

Regarding the rehabilitation setting, home-based and clinic-based rehabilitation protocols have generated similar improvements ^{7,19-24}. Also, tele-rehabilitation has demonstrated similar outcomes in comparison to standard rehabilitation ^{21,22,25}.

These findings are in line with recent trends in healthcare delivery, away from inpatient care and towards home-based care, towards cost-effectiveness improvement. Optimizing uptake and adherence is of paramount importance ²⁶, and this can be maximized by home-based care ²⁷.

In this sense, digital health solutions that empower patients, maximize engagement and allow home-based rehabilitation, without the need for constant therapist supervision, could improve effectiveness and lower the cost of rehabilitation.

Hence, we created SWORD Phoenix, a novel digital biofeedback system for home-based physical rehabilitation. SWORD Phoenix® is a class I medical device that, using inertial motion trackers, 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 efficacy of SWORD Phoenix has already been demonstrated in two previous feasibility studies conducted at Hospital da Prelada, Porto, Portugal, between December 2016 and March 2018 (Clinical trial IDs: NCT03047252 and NCT03045549). These were two parallel-group studies, comparing the clinical evolution of patients submitted to an 8-week rehabilitation program after THA or TKA, divided into two distinct groups: the experimental group, which performed a home-based rehabilitation program using SWORD Phoenix, and the control group, which was also engaged in a home-based rehabilitation program, but with conventional physiotherapy instead. Geographical location was used as the allocation criterion, with patients living within the city's administrative limits allocated to the conventional physiotherapy group and patients living outside the city's administrative limits allocated to the experimental group. Results from the experimental group were superior to those from the conventional physiotherapy group in all outcome measures, and adverse effects rates were similar in both groups. The main results of the TKA study were already published ²⁸, and the main results of the THA study are in publication route.

More recently, a new version of the system was developed, where the possibility to execute bilateral exercises was added, focusing not only on the rehabilitation of the affected limb, but also on muscular reinforcement of the contralateral limb. As such,

a new clinical study was designed, aiming at exploring the clinical impact of this update on the therapeutic program (bilateral).

The present study is a single-center, prospective, single-arm, historical control study, designed to evaluate the clinical outcomes of a bilateral home-based rehabilitation program using **SWORD Phoenix®**. The clinical outcomes will be compared to those of the above-mentioned feasibility studies. The investigation hypothesis is that the clinical outcomes of the bilateral exercise program will be superior to those of the unilateral exercise program.

2. Study Outcomes

The aim of the studies is to evaluate the clinical impact of a home-based bilateral rehabilitation program after THA or TKA, using **SWORD Phoenix®**.

a) Primary outcome

The primary outcome will be the change in patient performance compared to the baseline, measured through the TUG.

b) Secondary outcomes

- The change in patient reported outcomes, measured by HOOS and KOOS scales, as compared to baseline evaluation
- The change in the maximum amplitude of joints movements, as compared to baseline evaluation

3. Sample size estimate

Sample size estimation calculations were performed taking into consideration the primary outcome measure - Timed up and Go (TUG) test score. Calculations were based on the baseline TUG distribution of the participants in the two previous feasibility studies (total n=131; mean 18,00 seconds; sd=6,3) and on a Minimal Clinical Significant Change of 2.27 seconds as reported by Yuksel *et al.*²⁹.

Considering a power of 80%, a two-sided 0.05 significance level and an allocation rate of 2:1, 216 patients (144 in this study; 72 historical control) would be necessary to detect a 2.27 seconds difference against the historical control.

4. Inclusion criteria

- a) Patients over 18 years old
- b) Clinical and imaging evidence of hip/knee osteoarthritis
- c) Indication for total hip or knee replacement according to the patient's orthopedic surgeon
- d) Ability to walk unaided, with unilateral or bilateral support
- e) Availability of a caregiver to assist the patient after surgery

5. Exclusion criteria

- a) Patients admitted for revision of total hip/knee 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
- h) Patients residing outside a 30km radius from the investigation center

6. Methods for identifying and recruiting patients

All patients admitted for total hip or knee replacement during the study period will

be screened for inclusion and exclusion criteria.

When a potential candidate is identified, the local investigator will approach the candidate and explain the study in detail. The prospective candidate will be given the patient information document and sufficient time to consider whether he wishes to participate in the study.

Subsequently, the prospective candidate will be given opportunity to clarify any doubts, after which the informed consent form will be signed and dated in duplicate by the patient and the investigator. Only then will the randomization and baseline assessments be performed.

7. Informed consent

Informed consent will be delivered in paper format (see annex), informing individuals of their free will to drop out of the study, without any prejudice to their health assistance or medical attention. It includes information on collected data confidentiality and its publication potential in scientific journals, respecting all due ethical standards.

Finally, it assures the individual that he was correctly informed about the study, requiring the signature from both the patient and one of the study researchers.

8. Data anonymization

Numerical codes will be attributed to each study participant. As soon as possible, all the information from the questionnaires will be transferred to digital data bases and the documents kept in a specific location at SWORD Health, SA headquarters, with restricted access.

9. Scales and assessment tools

Several studies suggest that the outcomes should be measured not only in terms of range of motion, which is considered a poor marker of implant success and patient satisfaction^{9,30-32} but also using patient-reported outcomes and a performance test^{33,34}. As such, results will be evaluated according to three outcome measures: **a)** a performance test; **b)** patient-reported outcomes (using HOOS and KOOS scales); **c)**

range of motion of the hip or knee.

a) Performance test

Timed up and Go (TUG) test was selected as a performance test, which measures the time the patient takes to rise up from a chair, walk three meters, turn around, walk again towards the chair and sit. This test was chosen as it is simple and practical, quick and easy to administer, has high inter-rater reliability ³⁵ and has been demonstrated to predict both short- ³⁶ and long-term ^{37,38} function, following arthroplasty.

Instructions to perform the test:

- 1) Select a chair with armrests and a seating height of 44-47 cm
- 2) Measure 3 meters in a straight line from the chair and place a mark on the floor
- 3) Ask the patient to sit in a chair with his/her back against the chair back
- 4) Instruct the patient to rise from the chair on the command “go”, walk 3 meters at a comfortable and safe pace, turn, walk back to the chair and sit down
- 5) Begin timing at “go” and stop when the patient is seated
- 6) Register the time with two decimal digits in the patient file

b) Patient reported outcomes scales

b.1. Hip Osteoarthritis Outcome Scale (HOOS)

The HOOS scale was validated for patients submitted to THA by Nilsson and colleagues ³⁹. The HOOS 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) hip related Quality of life (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 (5 Likert boxes). A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) is calculated for each subscale.

A copy of the questionnaire can be found in each patient file. To administer the questionnaire sheet, the investigator must extract it from the study file and hand it over to the patient, so he can fill in the form. The patient cannot be assisted in performing the movement at any time. Once finished, the sheet must be signed and dated by the investigator, and archived in the patient file.

b.2. Knee Osteoarthritis Outcome Score (KOOS)

The KOOS scale ⁴⁰ was validated for patients submitted to TKA by Alviar and colleagues ⁴¹. 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 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.

A copy of the questionnaire can be found in each patient file. To administer the questionnaire sheet, the investigator must extract it from the study file and hand it over to the patient, so he can fill in the form. The patient cannot be assisted in performing the movement at any time. Once finished, the sheet must be signed and dated by the investigator, and archived in the patient file.

c) Range of motion of the hip and knee

Hip and knee range of motion will be assessed based in three distinct positions: lying, sitting and standing. The system used in the study is a validated medical device for joint angle measurement. Therefore, knee range of motion will be measured automatically by the system.

In this study, the active range of motion will be measured through the following movements:

| <u>Knee:</u> | <u>Hip:</u> |
|------------------------|-----------------------------|
| Lying knee flexion | Lying hip flexion |
| Sitting knee flexion | Lying hip abduction |
| Standing knee flexion | Standing hip flexion |
| Sitting knee extension | Standing hip abduction |
| | Standing hip hyperextension |

To assess range of motion, the investigator will need to:

- 1) Create a patient profile in the Portal
- 2) Prescribe one set of each exercise, with 5 repetitions
- 3) Ask the patient to perform the session through the App, executing each repetition to the best of his ability
- 4) After the session, login to the Portal, go to the session's results and click on detailed results for each exercise. Record the flexion or extension angle of the best repetition for each exercise in the patient file.

10. Patient assessment

Patients will be assessed at baseline (pre-operatively) (A1), upon discharge (A2), at 4 weeks after rehabilitation program initiation (A3), and at the end of it (A4).

Assessments will be performed within a time window of 5-working-days, previous or ahead of the day the assessment was scheduled for.

Baseline assessment (A1)

Participant characterization will consist of:

- Demographics (gender, age at enrollment);
- Educational level (years at school);
- Diagnosis and affected side
- Date of surgery

- Height, weight, body Mass Index
- Comorbidities
 - Smoking
 - Diabetes
 - Cardiac disease
 - Respiratory disease
 - Hypertension
 - Stroke
 - Renal Disease
 - Bleeding disorders
 - Previous hip/knee replacement
 - American Society of Anesthesiologists physical status classification score of 3 or 4⁴²

b) HOOS/KOOS score

c) Timed Up and Go (TUG) test score

d) Hip and knee active range of motion

Assessment upon discharge (A2)

Patients will be reevaluated immediately upon hospital discharge, and the following parameters will be registered:

- Surgery date
- Operative time
- Type of prosthesis
- Adverse effects before discharge

Subsequent assessments (A3 e A4)

Patients will be reassessed at 4 and 8 weeks after rehabilitation program initiation, collecting the following data:

- TUG score
- HOOS / KOOS score
- Maximum range of motion of the affected joint

11. Intervention

Upon hospital discharge, all participants will have immediate access to home-based rehabilitation therapy.

The rehabilitation program will be carried out at home, using **SWORD Phoenix®**. Patients will be instructed to engage on their rehabilitation sessions daily, but will not be excluded from the study in case this periodicity is not respected.

The rehabilitation programs proposed are presented in **Tables 1 to 4**.

Table 1: Hip replacement rehabilitation protocol - Stage 1 (weeks 0-5)

| Stage 1 (weeks 0-4) | |
|--|--|
| Objectives | Precautions |
| Decrease pain and swelling | Avoid hip internal rotation and hip adduction beyond neutral |
| Restore range of motion | Avoid hip flexion above 90° |
| Strengthen hip flexors and abductors | Ice pack application after each session and throughout the day as needed |
| Restore full load capacity on both legs | |
| Intervention | |
| Open kinetic chain exercises without added resistance | |
| Lying: <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x20-24 reps) - Operated Limb Hip Flexion (1x12-14 reps) - Bilateral Hip Abduction (1x20-24 reps) - Operated Limb Hip abduction (1x20-24 reps) - Bilateral Knee flexion (1x20-24 reps) - Operated Limb Knee Flexion (1x12-14) | |
| Standing (initially with support) <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x20-24 reps) - Operated Limb Hip Flexion (1x12-14 reps) - Bilateral Hip Abduction (1x20-24 reps) - Operated Limb Hip abduction (1x12-14 reps) - Bilateral Knee flexion (1x20-24 reps) - Operated Limb Knee Flexion (1x12-14 reps) - Bilateral Hip Flexion with Knee Flexion (1x20-24) - Operated Limb Hip flexion with knee flexion (1x12-14 reps) - Bilateral Hip hyperextension (1x20-24 reps) - Operated Limb Hip Hyperextension (1x12-14 reps) | |
| Closed kinetic chain exercises | |
| <ul style="list-style-type: none"> - Bridge (2x12-14) - Squats (2x12-14 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: aim for at least 30 minutes in total

Note 3: recommend two daily sessions as soon as tolerated

Table 2: Hip replacement rehabilitation protocol - Stage 2 (weeks 6-8)

| Stage 2 (weeks 5-8) | |
|--|----------------------|
| Objectives | Precautions |
| <p>Strengthening of hip flexors and abductors</p> <p>Improve balance</p> <p>Independence on all activities of daily living</p> | Identical to stage 1 |
| Intervention | |
| <p>Open kinetic chain exercises in the lying, sitting and standing positions</p> <p>Lying:</p> <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x26-30 reps) - Operated Limb Hip Flexion (1x17-20 reps) - Bilateral Hip Abduction (1x26-30 reps) - Operated Limb Hip abduction (1x17-20 reps) - Bilateral Knee flexion (1x26-30 reps) - Operated Limb Knee Flexion (1x17-20 reps) - Bilateral Hip Flexion with Knee Flexion (1x26-30 reps) - Operated Limb Hip flexion with knee flexion (1x17-20 reps) <p>Standing</p> <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x26-30 reps) - Operated Limb Hip Flexion (1x17-20 reps) - Bilateral Hip Abduction (1x26-30 reps) - Operated Limb Hip abduction (1x17-20 reps) - Bilateral Knee flexion (1x26-30 reps) - Operated Limb Knee Flexion (1x17-20 reps) - Bilateral Hip Flexion with Knee Flexion (1x26-30 reps) - Operated Limb Hip flexion with knee flexion (1x17-20 reps) - Bilateral Hip hyperextension (1x26-30 reps) - Operated Limb Hip Hyperextension (1x17-20 reps) <p>Closed kinetic chain exercises</p> <ul style="list-style-type: none"> - Bridge (2x17-20 reps) - Squats (2x17-20 reps) - Bilateral Stand to Sit (2x12 reps) - Bilateral Wall Sit (2x15-30 secs) <p>Functional exercises</p> <ul style="list-style-type: none"> - Bilateral Forward Lunge (1x20-24 reps) - Operated Limb Forward Lunge (1x12-14 reps) | |

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- Bilateral Climb a Step (1x20-24reps)
- Operated Limb Climb a Step (1x12-14 reps)
- Bilateral Come down a Step (1x20-24reps)
- Operated Limb Come down a Step (1x12-14 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

Table 3: Knee replacement rehabilitation protocol - Stage 1 (weeks 0-4)

| Stage 1 (weeks 0-4) | |
|--|--|
| Objectives | Precautions |
| Decrease pain and swelling Gain range of motion | Beware with the tissues on the surgical wound |
| 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 | |
| Recommendations of good practices on the TKR procedure on the deploy day | |
| Open kinetic chain exercises without added resistance | |
| Lying | |
| <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x20-24 reps) - Operated Limb Hip Flexion (1x12-14 reps) - Bilateral Hip Abduction (1x20-24 reps) - Operated Limb Hip abduction (1x12-14 reps) - Bilateral Knee flexion (1x20-24 reps) - Operated Limb Knee Flexion (1x12-14 reps) - Lateral decubitus Hip Abduction (2x10-12 reps) - Clamshells (2x10-12 reps) - Bridge (2x10-12 reps) | |
| Sitting | |
| <ul style="list-style-type: none"> - Bilateral Knee Flexion (1x20-24 reps) - Operated Limb Knee flexion (1x12-14 reps) - Bilateral Knee Extension (1x20-24 reps) - Operated Limb Knee extension (1x12-14 reps) | |
| Standing (initially with support) | |
| <ul style="list-style-type: none"> - Hip abduction (2x10 reps) - Hip hyperextension (2x10 reps) - Knee flexion (2x10 reps) - Hip flexion with knee flexion (2x10 reps) | |
| Closed kinetic chain | |
| <ul style="list-style-type: none"> - Mini-squats (2x10 reps) - Bridge (2x10 reps) | |

Note 1: adjust sets, reps and total session duration according to patient tolerance based on the pain and fatigue attributed (aim for at least 30 minutes in total)

Note 2: recommend two daily sessions as soon as tolerated

Table 4: Knee replacement rehabilitation protocol - Stage 2 (weeks 5-8)

| 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 | Same as stage 1 |
| Intervention | |
| Open kinetic chain exercises in the lying, sitting and standing positions: | |
| Lying: <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x26-30 reps) - Operated Limb Hip Flexion (1x17-20 reps) - Bilateral Hip Abduction (1x26-30 reps) - Operated Limb Hip abduction (1x17-20 reps) - Bilateral Knee flexion (1x26-30 reps) - Operated Limb Knee Flexion (1x17-20 reps) - Lateral decubitus Hip Abduction (2x15-20 reps) - Clamshells (2x15-20 reps) | |
| Sitting <ul style="list-style-type: none"> - Bilateral Knee Flexion (1x26-30 reps) - Operated Limb Knee flexion (1x17-20 reps) - Bilateral Knee Extension (1x26-30 reps) - Operated Limb Knee extension (1x17-20 reps) | |
| Standing <ul style="list-style-type: none"> - Bilateral Hip Flexion (1x26-30 reps) - Operated Limb Hip Flexion (1x17-20 reps) - Bilateral Hip Abduction (1x26-30 reps) - Operated Limb Hip abduction (1x17-20 reps) - Bilateral Knee flexion (1x26-30 reps) - Operated Limb Knee Flexion (1x17-20 reps) - Bilateral Hip hyperextension (1x26-30 reps) - Operated Limb Hip Hyperextension (1x17-20 reps) | |
| Closed kinetic chain exercises | |
| <ul style="list-style-type: none"> - Bridge (2x17-20 reps) - Squats (2x17-20 reps) - Bilateral Stand to Sit (2x12 reps) - Bilateral Wall Sit (2x15-30 secs) | |

Functional exercises

- Bilateral Climb a Step (1x20-24reps)
- Operated Limb Climb a Step (1x12-14 reps)
- Bilateral Come down a Step (1x20-24reps)
- Operated Limb Come down a Step (1x12-14 reps)

Note 1: adjust sets, reps and total session duration according to patient tolerance based on the pain and fatigue attributed (aim for at least 45 minutes in total)

Note 2: maintain recommendation of two sessions/day

In any case, these protocols can be tailored to the patient's specific needs, according to the joint assessment between the orthopedic surgeon and the physical therapist.

The rehabilitation process will be remotely accompanied by SWORD Health clinical team, with phone calls and home visits to the patient whenever needed.

12. Home visits

Each of the participants will be assigned a physiotherapist, who will pay an initial visit to teach the patient how to operate the system, as well as to prescribe an exercise program based on the presented guidelines and adapted to the patient's specific needs. The therapist will perform an initial session with the patient, ensuring that the patient is able to perform each exercise and that he can operate the system, alone or with the help of a caregiver.

From here on, the patient will be followed remotely by the physiotherapist, with no home sessions. On the 4th week of therapy, each participant will receive an interim visit, in which the therapist will assess patient progress and adjust the rehabilitation program accordingly. This visit will not consist of a face-to-face session.

Additionally, a progress assessment phone call will be performed every two weeks (at weeks 2 and 6).

Extraordinary visits or phone call may be performed in case of necessity. Whenever it happens, these events will be recorded on patient's file (date, occurrence, duration)

13. Safety and adverse events

Patient safety will be ensured at all times during the sessions, and will be evaluated through pain and fatigue scores (graduated from 0 to 10) collected at the end of each session. These will be presented to the patient using the mobile App and will be available for remote monitoring by their physical therapist. In case of excessive pain or fatigue, patients will be contacted by their physical therapist to ascertain the cause and change prescription. Patients will also be asked to report any other adverse events to their physical therapist by telephone, and these will be registered on the patient's file (date of the event, date of resolution - if applicable, resolution

state, gravity).

14.Risks and Benefits to Participants

All participant will benefit from therapeutic rehabilitation immediately upon hospital discharge. Thus, the access to rehabilitation care is assured, which will likely translate into potential benefits for the patient. Patients will engage in a home-based rehabilitation program through **SWORD Phoenix®**, according to the latest treatment guidelines and following the clinician's recommendations. A physiotherapist will be allocated to each patient, guaranteeing a continuous follow up and home visits whenever necessary. Since the system will be used in line with its certified therapeutic indications, there will be no added risk or inconvenient to the user. In fact, the rate of adverse events reported on previous clinical trials was identical to that reported with conventional physiotherapy. Hence, participants are not exposed to any added risk, being able instead to directly benefit from a breakthrough technology, that allows a real and immediate measure of their performance, increasing their motivation and maximizing rehabilitation outcomes even further.

15.Results analysis

Per-protocol and intention-to-treat analysis will be applied to evaluate the study outcomes. Participants with an adhesion rate below 43% (corresponding to less than 3 sessions per week) will not be considered in the per-protocol analysis.

Intervention's impact on primary and secondary outcomes will be performed considering the variables evolution when comparing basal assessment and assessment at 8 weeks.

16.Confidentiality of Personal Data

Data collection for this study was authorized by the National Commission on Data Protection, with the authorization number 1476/2017.

Personal data will only be accessible to authorized individuals in this study. Personal data will not be entered into the database as part of this research. The clinical data

collected will only be linked to the patient by a unique study number and will contain no personal identifiers. Informed consent will be obtained from participants to collect and retain this data. The data that will be used for analysis and dissemination for research purposes will be completely anonymized.

17. Ethical issues

All participants will be provided with information about the purpose and procedures of the study and gave written informed consent before inclusion.

The study was approved by the local ethics committee (Chair: Dr. Juiz Conselheiro Almeida Lopes) and will be conducted in accordance with the relevant guidelines and regulations.

18. System technical specifications

SWORD Phoenix® system is composed of the following three interconnected components:

Motion trackers

The motion trackers are placed on body segments using Velcro® straps. Each motion tracker is placed in a specific position. To assist in the correct placement of the motion trackers, both the trackers and the matching straps are color-coded. In this study, the following setup will be used:

- **Red tracker:** over the sternal manubrium
- **Green trackers:** on the lateral surface of the leg, approximately midway between the trochanter and the lateral epicondyle
- **Blue trackers:** on the upper third of the antero-medial surface of the tibia

Mobile App

The mobile app guides the patient in each exercise session. Before each exercise, the patient is presented with a real-life video and audio explanation of that exercise. The execution interface is subsequently shown. This screen features: a) a progress bar; b) a repetition counter; c) a star counter and d) a timer displaying time left in the

exercise.

A correct repetition is defined as a movement starting at the baseline and reaching or surpassing the specified target, without violating movement or posture constraints. In case the patient violates a constraint, a message is prompted showing which movement error was performed, so that the patient can correct the movement in the following attempts.

For each correct repetition, the patient earns from 1 to 5 stars, depending on the range of motion of that specific movement in comparison to normative values for that movement.

At the end of each session, the patient is presented with a summary of the number of completed repetitions and stars, as well as with badges rewarding him for the progresses achieved in each exercise.

Web Portal

The portal is a web-based platform that allows the clinical team to create new patient profiles and create exercise sessions for each patient. To prescribe a session, the clinician needs to select the exercises, number of sets and number of repetitions. When a patient performs a session, the results are uploaded to the platform and available for review. Based on this information, the clinical team can edit the parameters of each exercise according to patient performance and progress.

19. References

1. Ethgen O, Bruyerè O, Richy F, Dardennes C, Reginster JY. Health-Related Quality of Life in Total Hip and Total Knee Arthroplasty: A Qualitative and Systematic Review of the Literature. *J Bone Jt Surg - Ser A*. 2004. doi:10.2106/00004623-200405000-00012
2. 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. doi:10.1016/j.arth.2005.07.010
3. Röder C, Staub LP, Eggli S, Dietrich D, Busato A, Müller U. Influence of preoperative functional status on outcome after total hip arthroplasty. *J Bone Joint Surg Am*. 2007. doi:10.2106/JBJS.E.00012
4. 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. doi:10.1016/j.apmr.2003.11.022
5. Okoro T, Lemmey AB, Maddison P, Andrew JG. An appraisal of rehabilitation regimes used for improving functional outcome after total hip replacement surgery. *Sport Med Arthrosc Rehabil Ther Technol*. 2012. doi:10.1186/1758-2555-4-5
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. doi:10.1016/S1836-9553(13)70198-X
7. Minns Lowe CJ, Barker KL, Dewey ME, Sackley CM. Effectiveness of physiotherapy exercise following hip arthroplasty for osteoarthritis: A systematic review of clinical trials. *BMC Musculoskelet Disord*. 2009. doi:10.1186/1471-2474-10-98
8. Mikkelsen LR, Mikkelsen SS, Christensen FB. Early, intensified home-based exercise after total hip replacement - A pilot study. *Physiother Res Int*. 2012. doi:10.1002/pri.1523
9. Pozzi F, Snyder-Mackler L, Zeni J. Physical exercise after knee arthroplasty: A systematic review of controlled trials. *Eur J Phys Rehabil Med*. 2013. doi:10.1016/j.biotechadv.2011.08.021.Secreted

10. 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.* 2014. doi:10.1002/acr.22164
11. Artz N, Dixon S, Wylde V, Beswick A, Blom A, Goberman-Hill R. 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.* 2013. doi:10.1002/msc.1027
12. Oatis CA, Wenjun L, DiRusso JM, et al. Variations in Delivery and Exercise Content of Physical Therapy Rehabilitation Following Total Knee Replacement Surgery: A Cross-Sectional Observation Study. *Int J Phys Med Rehabil.* 2014. doi:10.4172/2329-9096.S5-002
13. Petterson SC, Mizner RL, Stevens JE, 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
14. Bade MJ, Stevens-Lapsley JE. Early High-Intensity Rehabilitation Following Total Knee Arthroplasty Improves Outcomes. *J Orthop Sport Phys Ther.* 2011. doi:10.2519/jospt.2011.3734
15. 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
16. Vissers MM, Bussmann JB, Verhaar JAN, 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. doi:10.2522/ptj.20100201
17. Beswick AD, Wylde V, Goberman-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
18. Rossi MD, 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
19. 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. doi:10.1097/01.blo.0000063600.67412.11

20. Madsen M, Larsen K, Kirkegård Madsen I, Søe H, Hansen TB. Late group-based rehabilitation has no advantages compared with supervised home-exercises after total knee arthroplasty. *Dan Med J.* 2013. doi:A4607 [pii]
21. Tousignant M, Moffet H, Boissy P, Corriveau H, Cabana F, Marquis F. A randomized controlled trial of home telerehabilitation for post-knee arthroplasty. *J Telemed Telecare.* 2011. doi:10.1258/jtt.2010.100602
22. Piqueras M, Marco E, Coll M, et al. Effectiveness of an interactive virtual telerehabilitation system in patients after total knee arthroplasty: A randomized controlled trial. *J Rehabil Med.* 2013. doi:10.2340/16501977-1119
23. Mitchell C, Walker J, Walters S, Morgan AB, Binns T, Mathers N. Costs and effectiveness of pre- and post-operative home physiotherapy for total knee replacement: Randomized controlled trial. *J Eval Clin Pract.* 2005. doi:10.1111/j.1365-2753.2005.00535.x
24. Lowe CJM, Barker KL, Holder R, Sackley CM. Comparison of postdischarge physiotherapy versus usual care following primary total knee arthroplasty for osteoarthritis: An exploratory pilot randomized clinical trial. *Clin Rehabil.* 2012. doi:10.1177/0269215511427749
25. Russell TG, Buttrum P, Wootton R, Jull GA. 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
26. McLean SM, Burton M, Bradley L, Littlewood C. Interventions for enhancing adherence with physiotherapy: A systematic review. *Man Ther.* 2010. doi:10.1016/j.math.2010.05.012
27. 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. doi:10.1186/s12891-015-0469-6
28. Correia FD, Nogueira A, Magalhães 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.

doi:10.1038/s41598-018-29668-0

29. 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
30. Blom AW, Artz N, Beswick AD, et al. Improving patients' experience and outcome of total joint replacement: the RESTORE programme. *Program Grants Appl Res*. 2016. doi:10.3310/pgfar04120
31. 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. doi:10.1053/apmr.2002.27337
32. Lindemann U, Becker C, Unnewehr I, et al. Gait analysis and WOMAC are complementary in assessing functional outcome in total hip replacement. *Clin Rehabil*. 2006. doi:10.1191/0269215506cr958oa
33. 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 Jt Surg - Br Vol*. 2007. doi:10.1302/0301-620X.89B5.18117
34. Miner AL, Lingard EA, Wright EA, et al. Knee range of motion after total knee arthroplasty: How important is this as an outcome measure? *J Arthroplasty*. 2003. doi:10.1054/arth.2003.50046
35. Wright AA, Cook CE, Baxter GD, Dockerty JD, Abbott JH. 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*. 2011;41(5):319-327. doi:10.2519/jospt.2011.3515
36. Poitras S, Wood KS, Savard J, Dervin GF, Beaule PE. Predicting early clinical function after hip or knee arthroplasty. *Bone Joint Res*. 2015;4(9):145-151. doi:10.1302/2046-3758.49.2000417 [doi]
37. 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;93(7):579-585. doi:10.1097/PHM.0000000000000065
38. Nankaku M, Tsuboyama T, Akiyama H, et al. Preoperative Prediction of

Ambulatory Status at 6 Months After Total Hip Arthroplasty. *Phys Ther.* 2013;93(1):88-93. doi:10.2522/ptj.20120016

39. 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. doi:10.1186/1471-2474-4-10

40. 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 Sport Phys Ther.* 1998. doi:10.2519/jospt.1998.28.2.88

41. Alviar MJ, Olver J, Brand C, et al. Do patient-reported outcome measures in hip and knee arthroplasty rehabilitation have robust measurement attributes? A systematic review. *J Rehabil Med.* 2011. doi:10.2340/16501977-0828

42. ASA. ASA PHYSICAL STATUS CLASSIFICATION SYSTEM. <https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system>. Published 2014. Accessed June 13, 2018.

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