Clinical Investigation Plan for Medical Device Studies

Full title of investigation:	Digital care program for chronic shoulder tendinopathy versus conventional physical therapy: a prospective, randomized controlled study
Version and date of Clinical Investigation Plan (CIP):	Version 1.4, 8 October 2020
Sponsor:	SWORD Health
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REVISION HISTORY

Version	Date	Description	Author
1.0	07/13/2020	Original	FC and MM
1.1	08/05/2020	Content revision. Clarified procedures related to participant intake and assessment.	FC and MM
1.2	08/26/2020	Reviewed outcome measures and participant assessment procedures	FC
1.3	09/22/2020	Reviewed outcome measures, participant assessment procedures and clarified inclusion/Exclusion criteria	FC
1.4	10/08/20202	Reviewed exclusion criteria and conventional PT treatment protocol	FC and SP

SIGNATURES

The Principal Investigator (PI) and other personnel involved in the agree to perform the investigations and to abide by this CIP. The investigators agree to conduct the Investigation in compliance with all applicable laws and FDA Regulations Relating to Good Clinical Practice and Clinical Trials.

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1. BACKGROUND

Shoulder pain is highly prevalent, being the third main complaint in primary care settings.[1–3] There is a wide range of reported incidence and prevalence rates, with a median of 24.8% of adults reporting shoulder pain every month.[4] In developed countries, 1% of adults annually consult a primary care provider due to shoulder pain.[2,5]

Around 65 to 70% of shoulder pain complaints involve problems in the rotator cuff (RTC) tendons,[1,6] with incidence rising higher after the 4th decade of life.[1,7–9] Abundant data from across the world is available on the prevalence of RTC pathologies.[6,10–16]

RTC dysfunction represent a huge burden for healthcare systems, insurance companies and employers alike.[1,17] Shoulder problems account for 2.4% of all general practitioner consultations in the UK,[18] and 4.5 million visits to physicians annually in the USA.[19] One study in the UK[20] estimated that nearly £310 million is spent on medical appointments in the first 6 months of shoulder pain onset, and additional costs of surgical procedures are estimated at approximately £30 million/year, with up to 50% of these costs related to sick leave from paid employment. More than 300,000 surgical repairs for RTC pathologies are performed annually in the USA, and the annual financial burden of RTC management was also estimated at $3 billion.[21]

A myriad of international clinical practice guidelines have been put forth over the years, outlining the management of pain-causing shoulder disorders.[22–26] Most causes of mild-to-moderate and gradual onset shoulder pain are treated initially with conservative care. Indeed, many recent studies and systematic reviews, as well as the American Academy of Orthopaedic Surgeons guidelines, support that firstly the patient should be directed to a physical therapy (PT) program and not surgery. [26–30] For some specific conditions (e.g., symptomatic small to medium full-thickness RTC tears), strong evidence further supports that both PT and operative treatment attain significant improvements in patient-reported outcomes.[26] Of note, another systematic review on treatment options for shoulder pain suggests that passive modalities, such as manual therapy, electrotherapy and taping should be avoided as mono-therapy but that they could, in specific cases, provide

additional benefit when utilized in conjunction with therapeutic exercise programs.[31] This suggests that the exercise component of PT is fundamental in the treatment of painful shoulder disorders.

Regarding rehabilitation setting, some studies show that home-based therapy, based on exercise, could be as effective as conventional PT interventions.[32,33] This is in line with the recent trends in healthcare delivery, moving away from inpatient care and towards home-based care with the intent of improving cost-effectiveness. Furthermore, the need for home-based digital solutions is now felt more acutely than ever, in the face of the current pandemic.[34–36] In this context, solutions enabling home-based rehabilitation without requiring real-time human supervision can be key to improving effectiveness and lowering costs, while keeping all stakeholders safe. Indeed, there are studies demonstrating the potential[37–39] and cost-effectiveness[40] of shoulder postoperative care and rehabilitation through telehealth solutions.

However, while evidence is growing that digital therapeutics (DTx) can improve outcomes, personalize care and decrease costs,[41] there is still much ground to be explored in the field of digital therapy following RCR.[42,43] Several studies can be found on the validation/development of systems/algorithms for monitoring shoulder motion to assist clinicians on patient evaluation[44,45] but these do not meet the aforementioned needs and cannot be considered digital therapeutics.

There have been some advances on new technologies for shoulder rehabilitation, namely using wearable sensors[43] and augmented reality.[46] Of note, some of these studies focus on systems based on inertial motion trackers that can be used by the patient at home, under remote monitoring from the physical therapist. However, these are either in very preliminary stages of development or validation,[47–51] with no clinical validation studies performed, or are directed at rehabilitation after stroke.[43,46]

SWORD Health has developed a novel motion tracking-based digital biofeedback system for home-based physical rehabilitation - SWORD Phoenix®- which is an FDA-listed class II medical device. The company has previously conducted two pilot studies (NCT03047252; NCT03045549) comparing a digital therapy program using this device against conventional face-to-face physical therapy. These studies have proven the feasibility, safety and effectiveness of this digital therapeutic on rehabilitation after total knee and hip arthroplasty.[52–54]

This is a single-center, prospective, randomised, controlled study, with two parallel groups, designed to assess the clinical impact of a digital exercise program against conventional rehabilitation for shoulder tendonitis. The hypothesis is that all the clinical outcomes measured

will significantly improve after the program, and patients using this novel system will attain at least the same outcomes than the ones attained by the conventional PT group.

2. SWORD HEALTH DIGITAL CARE PROGRAMS

SWORD Health's Digital Care programs address the three pillars of musculoskeletal care: therapeutic exercise, patient education and cognitive behavioural therapy (CBT).

The exercise component is delivered through a digital feedback system - SWORD Phoenix®- which is an FDA-listed class II medical device. This device uses motion tracking technology to digitize motion and provide real-time biofeedback on performance during exercise execution (see more below). This allows individuals to perform independent exercise sessions at home without the need for constant face-to-face therapist supervision, while still being remotely monitored (asynchronously) through a cloud-based Portal.
The safety and effectiveness of digital exercise programs performed with this device, in a home-based scenario, have already been demonstrated for recovery after total knee and hip arthroplasty.[53–55] In these studies, where digital programs based on this device were compared with conventional PT, the clinical outcomes were superior in the digital group. These results were explained by (a) the positive impact of a kinematic biofeedback tool on patient performance, especially regarding error correction and stimulation of a greater range of motion; (b) patient empowerment regarding their rehabilitation process; (c) high patient engagement through the use of gamification strategies; (d) the positive effect of remote monitoring on patient effort and (e) the availability of objective data for clinical review, enabling data-driven decisions.

The education component is delivered through a smartphone app. Through this app, each individual is presented with educational content on their condition, in the form of small articles curated by SWORD's clinical team, focusing on subjects ranging from anatomy and physiology, pain, exercise and fear avoidant behaviours.

The CBT component takes the form of an 8-week program based on third-generation CBT techniques, particularly Mindfulness Based Stress Reduction, Acceptance and Commitment

Therapy and Compassion-based therapy. The program is presented to individuals through email, with links to short, pre-recorded, self-guided, meditation sessions, as well as written mindfulness exercises called “habit releasers”.

3. SYSTEM TECHNICAL SPECIFICATIONS

SWORD Phoenix® is a proprietary, 510(K) exempt, class I medical device, with CE mark, which is composed of the following three interconnected components:

- **Motion trackers**, 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. The motion trackers' setup varies according to each therapy.

- **Mobile App**, that comes pre-installed on a tablet, that 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-based Portal** that allows the clinical team to generate 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.

4. SECURITY AND DATA STORAGE

4.1 DATABASE

The networks where SWORD Health's infrastructure is hosted are maintained by Google and are included in Google Cloud Platform's SOC2 and HITRUST certifications. Security-related configurations are registered and verified periodically.

Collected data is stored in databases that are only accessible to SWORD's Application Programming Interface (API), and Personal Health Information (PHI) is individually encrypted inside this database. Separate databases are used for development, QA, and production environments.

4.2 WEB PORTAL

Data is secured in transit to SWORD's Application Programming Interface (APIs) due to enforced application of TLS 1.2 or above. Additionally, a web application firewall protects our servers from Cross-site Scripting (XSS) and SQL Injection attacks.

Access to SWORD's Web Portal is provided only to individuals who have a valid work contract with SWORD Health and have a role within the company that allows them to use the platform (i.e. PTs and IT support).

Access control mechanisms ensure that only authorized users have access to PHI and different functions are mapped to different roles within the platform (i.e. IT support personnel only have access to de-identified data).

4.3 WEBSITE

SWORD's Onboarding Website does not have a login function as it works only as a registry platform and user accounts are created in SWORD's Web Portal. Data is secured in transit to SWORD's Application Programming Interface (APIs) due to enforced application of TLS 1.2 or above. Additionally, a web application firewall protects our servers from Cross-site Scripting (XSS) and SQL Injection attacks.

4.4 MOBILE APP

For an individual to access the mobile app in the medical device, their profile must be created in SWORD's Web Portal. Upon profile creation, the individual is attributed a unique QR card that is shipped together with the medical device kit. Upon the first usage, the individual is required to set a personal pin code (two-factor authentication is employed, as the user must scan their QR code and input a confirmation code sent by text message. This is required for the first login, with subsequent logins being done by presenting the pin and the QR card. Each session expires within 24 hours, requiring the individual to present these again if >24 hours have passed since the last usage.

Transport Layer Security (TLS) protocols are applied on every connection to ensure secure data transmission between the mobile app and the Database. Additionally, data stored in the device is also encrypted.

5. STUDY OBJECTIVE

To assess the clinical outcomes of a digital program for chronic shoulder tendonitis versus conventional. PT.

6. STUDY HYPOTHESIS

The digital program will be associated with at least the same outcomes as conventional PT.

7. STUDY DESIGN

Prospective, single-center, parallel-group, randomised controlled study.

8. STUDY OUTCOMES

8.1 Primary Outcome

Impact on physical function and symptoms measured through the shortened Disabilities of the Arm, Shoulder and Hand questionnaire (QuickDASH) between baseline and 8 weeks.

8.2 Secondary Outcomes

The secondary outcomes will include the following:

a) Impact on shoulder range of motion

Shoulder range of motion will be measured in the following exercises: shoulder flexion; shoulder abduction and external shoulder rotation at 90 degrees of abduction.

b) Impact on Pain

Measured through the following question: "On a scale of 0 to 10, where 0 is no pain and 10 the worst pain imaginable, how would you rate your pain in the last 24 hours?"

c) Interest in undergoing surgery

Measured through the following question: "On a scale of 0 to 10, where 0 is not at all and 10 is extremely interested, how interested are you in undergoing shoulder surgery in the next 12 months"?

d) Medication consumption

Measured through the following questions:

- **i.** "Are you taking any medication for your shoulder pain?";
- **ii.** "If yes, on how many days in a week, on average, are you taking medication for your shoulder pain"

e) Impact on fear avoidance beliefs

Measured by: Patient-reported questionnaire (Fear Avoidance Beliefs Questionnaire- FABQ)

f) Impact on anxiety and depression

Measured by the General Anxiety Disorder-7 scale and Patient Health Questionnaire-9 scale

g) Impact on work productivity and activity impairment

Measured through Work Productivity and Activity Impairment Questionnaire: Specific Health Problem v2.0 (WPAI:SHP)

h) Satisfaction with social roles and discretional social activities

Measured through the Patient Reported Outcomes Measurement Information System Computerized Adaptive Test (PROMIS-CAT) scales: Ability to participate in social roles and activities (version 2.0) and satisfaction with social roles and activities (version 2.0).

i) Patient engagement

Measured through: g.1) adherence to exercise sessions; g.2) drop-out rates; g.3) treatment intensity (i.e. total number of exercise minutes)

j) Patient satisfaction

Measured through the Net Promoter Score, by asking participants the following question: "On a scale from 0 to 10, how likely are you to recommend this program to a friend or colleague?"

9. SAMPLE SIZE ESTIMATION

Sample size estimation calculations were performed taking into consideration the primary outcome measure – the QuickDASH. In a sample of 57 patients with shoulder tendon disorders treated with SWORD Health's medical device in the context of work-related conditions, the mean and standard deviation of the QuickDASH scale at baseline was of 59 and 19 points respectively. A Minimal Detectable Difference (MDD) of 11.2 points was considered, based on the psychometric properties of the scale.[56] Considering a power of 80%, a two-sided 0.05 significance level and a 10% dropout rate, 80 (40+40) patients would be necessary to detect a 11.2 points difference between the two groups.

10. INCLUSION/EXCLUSION CRITERIA

a. Inclusion Criteria

a) Subjects aged between 18 and 80 years of age at enrolment
b) Reporting intermittent or persistent shoulder pain for at least 6 weeks, and/or present at least 50% of the time in the past 6 months
c) Lack of visual/audio or cognitive impairment interfering with the ability to understand or comply with the program

b. Exclusion Criteria

a) Non-English speaking
b) Residing outside greater SF area
c) Known pregnancy
d) Submitted to spinal surgery less than 3 months ago
e) Symptoms and/or signs indicative of possible infectious disorder
f) Referred pain from spine and/or thoracic outlet syndrome
g) Active cancer diagnosis or undergoing treatment for cancer
h) Cardiac, respiratory or other known disorder incompatible with at least 20 minutes of light to moderate physical activity
i) Concomitant neurological disorder (e.g. stroke, multiple sclerosis, Parkinson's disease)
j) Dementia or psychiatric disorders precluding patient from complying with a home-based exercise program
k) Illiteracy and/or serious visual or auditory impairment interfering with communication or compliance

Additionally, any patient undergoing a PT program for shoulder pain will be required to stop ongoing programs to enroll in the study.

11. CANDIDATE IDENTIFICATION AND PROCEEDINGS

Patient recruitment will primarily be done through the use of UCSF electronic health record (EHR) recruitment services from the Clinical and Translational Service Institute (CTSI) to assist with targeting and identification of potentially eligible participants. As an "honest broker" of the EHR data, the service is designed to protect patient privacy and offer more efficient way to recruit eligible participants that meets the study's inclusion/exclusion criteria. The cohort of patients scheduled to receive physical therapy services will be identified and pre-screened by CTSI to ensure potential participants are eligible to meet the initial study's criteria. Once patients have been identified, they are flagged from their appointments for physical therapy services at the UCSF Outpatient Patient Faculty, and will be evaluated in-person as part of their regular initial scheduled visit (i.e. evaluation visit). At the time of this visit, potential participants will be assessed by one of the co-investigators to also ensure that participants meet the cognitive and mental capacity

requirements. Once the criteria are met, investigator will present the study and invite the patient to participate and provide consent. The participant's screening survey data will be collected and be randomized to one of the two arms, coordinated by the study coordinator. All study-related information will be stored by electronic data capturing (EDC) system.

To centralize all study-related information, a commercially available electronic data capturing (EDC) system will be used.

Following the identification of a potential candidate, the investigator will enter the EDC portal and fill the screening survey. If the patient is eligible (i.e. meets inclusion criteria and does not have any exclusion criteria) the investigator will present the study and invite the patient to participate and provide consent.

12. PROCESS OF CONSENT

The study will be presented verbally to potential participants by a study investigator, in a face-to-face meeting. Adequate time will be allowed for the candidate to clarify any doubts about the study, following which the eConsent form will be sent through the EDC platform to the participant and investigator, for signature. The study consent form (**Annex 1**) will then be signed by the participant and the investigator collecting consent, and stored in the EDC platform.

13. ALLOCATION & BLINDING

Patients will be randomly allocated to one of two groups, using random permuted blocks of 6. After eConsent collection, the investigator will enter the EDC portal and proceed with randomisation (also built into the EDC). Following randomisation, the investigator will contact the person responsible for the rehabilitation program in each group to allocate the participant to the respective study arm. Blinding of investigators and patients regarding allocation arm will not be possible, given the nature of the intervention. Analysis of study results will be performed by an independent statistician at UCSF.

14. INTERVENTION

a. Digital program

Patients in the digital intervention group will benefit from an 8-week program composed of therapeutic exercise, education and cognitive behavioural therapy (CBT) program provided by SWORD Health. These patients will be referred to SWORD Health by the investigator who identified the candidate. SWORD Health will then assign a physical therapist to each patient. The physical therapist will contact the patient for onboarding and will manage the case.

Patients in this group will performed home-based rehabilitation sessions using SWORD Phoenix®, under remote monitoring by a physical therapist. Participants will be provided with a tablet computer with a SWORD mobile app installed, along with two inertial motion trackers (each comprised of a gyroscope, an accelerometer and a magnetometer) to be placed on chest, upper arm and wrist, respectively. These trackers enable precise movement quantification, feeding the mobile app, which guides the patient through the session, providing video and audio instructions before each exercise, as well as real-time audio and video biofeedback during the exercise. On the other end, the clinical teams are allowed to remotely monitor results and prescribe/edit exercise sessions through a web-based portal.

The exercise component will follow the protocol outlined in **Annex 2**, which can however be adapted by the physical therapist to the specific needs of the participant. Participants will be asked to start with three 20 min sessions per week, building gradually to three 30 min sessions per week. Participants will not be excluded from the study in case of lower adherence, but will not be included in the per-protocol analysis if they perform less than 21 sessions over the course of 8 weeks.
Participants in this group will be considered as dropouts if they: a) choose to abandon the study; b) do not engage in any exercise session for at least fourteen consecutive days.

The educational component will be delivered automatically through a smartphone app (available for iOS and Android), and will take the form of small educational texts that will be released

periodically to the participant. This component is not mandatory per protocol, but metrics on user engagement will be measured.

The CBT program will take the form of a self-paced program consisting of written and pre-recorded audio materials. An email will be sent weekly by the physical therapist to the participant, during the 8 weeks of the program. Each email will contain an introductory text describing the objectives for that week, as well as a link to that week's audio session and a PDF attachment with self-guided exercises. The CBT component is not mandatory per protocol, but metrics on user engagement will be measured.

b. Conventional PT

Patients in this group will benefit from a 8-week program consisting of two 30 min face-to-face PT sessions per week in an outpatient clinic setting, for a total of 16 sessions. The program will follow the principles outlined in **Annex 3**, which includes commonly used interventions adapted by the physical therapist to the specific needs of the participant.

Participants in this group will be excluded from the per protocol analysis if they complete less than 14 sessions over 8 weeks. Participants in this group will be considered as dropouts if they: a) choose to abandon the study; b) miss four consecutive scheduled PT sessions.

In addition to the face-to-face sessions, PTs will also be communicating with participants in this group through a secure messaging system (Mychart) used at UCSF or, alternatively, through a telephone check-ins (10-15 min calls, up to twice per week).

15. PARTICIPANT ASSESSMENTS

Patients will be assessed at baseline, 4 and 8 weeks.

Baseline Assessment

This assessment will involve a face-to-face visit, where the following information will be collected:

a) date of birth
b) gender
c) height & weight
d) body mass index
e) formal education (years of schooling)
f) job type
g) previous shoulder surgery (> 3 months ago)
h) Working status
i) Geocodes/zip
j) Race/ethnicity
k) Age

The following outcomes will also be assessed in this visit: a) Shoulder Range of Motion; b) PROMIS CAT measures.

Shoulder Range of Motion will be measured in the following movements: 1) shoulder flexion; 2) shoulder abduction; 3) external rotations with shoulder abducted at 90 degrees. The participant will be asked to perform three non-painful repetitions of each movement, in a standing position. The investigator will measure the maximum joint angle attained by the participant, using a digital goniometer in each repetitions. The highest of the three values will be considered.

Regarding satisfaction with social role and ability to participate in social roles and activities, these will be collected through PROMIS CAT v2.0. These will be collected onsite, and the results will then be transferred by the investigator to the eCRF.

Assessment of primary outcome, as well as the remaining secondary outcomes will be performed through an electronic questionnaire to be filled by participants, through the EDC system. These will need to be filled within 5 consecutive days, counting from the date they are sent to the participant. To promote compliance with this schedule, whenever the deadline is approaching, automatic email reminders will be sent to participants. Participants will be excluded from the study

for protocol breach in case they don't fill in the assessment forms. Upon completion of the baseline form, participants in the study will receive a stipend of $25.

Additional measurements of upper limb function and tri-dimensional motion will also be performed at the onsite visit by the clinician, using a motion capture system. These will not be considered in the outcomes of this study, but will be made available for post-hoc analysis.

Interim assessment (4 weeks)

Participants will be required to complete a questionnaire similar to the baseline assessment, within a 5-day window beginning at the start of week 4. These assessments will include all the information pertaining to the primary and secondary outcomes, except for those that are collected through a face-to-face assessment. These (shoulder range of motion and PROMIS CAT measures) will not be collected on this assessment. Upon completion of this form, participants in the study will receive a stipend of $25.

Final assessment (8 weeks)

This assessment will involve a face-to-face visit, where the following outcomes will be assesed: a) shoulder Range of Motion; b) PROMIS CAT measures and c) Participant satisfaction (Net Promoter Score). Shoulder Range of Motion and PROMIS CAT measures will be assessed using a similar methodology to the one descried for the baseline assessment.

Participants will also be required to complete a questionnaire similar to the baseline and interim assessments, within a 5-day window beginning at the start of week 4. These assessments will include all the information pertaining to the primary and secondary outcomes, except for those that are collected in the face-to-face visit. Upon completion of this form, participants in the study will receive a stipend of $25.

Additional measurements of upper limb function and tri-dimensional motion will also be performed at the onsite visit by the clinician, using a motion capture system. These will not be considered in the outcomes of this study, but will be made available for post-hoc analysis.

Engagement assessment

For participants on the digital group, engagement and usage metrics of the educational and CBT components will also be collected automatically.

Additionally, the following activity log will be collected from patient's Electronic medical records and time stamps, as well as paper survey (or, in the case of the digital group, sent to the study coordinator via email, with the participant identified only by the study ID), to be entered into EDC portal by study coordinator:

1. Face-to-face visits registry (dates, times and duration)
2. Remote sessions registry (dates, times and duration)
3. Number and duration of contacts between PT and participant (emails, text messages, phone and videocalls)
4. Total time spent on remote monitoring of the patient (digital group only)

Adverse events

In any event during the course of the study if subjects experience adverse effects of both internal (on-site) and external (off-site) events, a prompt reporting to the UCSF Human Research Protection Program (HRPP)/institutional review board (IRB) and to the sponsor of the study will take place. This includes any unanticipated problems involving risk to subjects noted in the study. The safety plan in IRB will contain protocol to help with communication and procedures that are in place to monitor and report adverse events should they occur. The investigators will accurately document causality assessment to their best knowledge and follow-up of all definite, probable, or unrelated adverse events to the study and safety-related information.

Care continuity

To ensure that quality of care is not compromised throughout the study, all subjects from both

groups will be assessed at the final appointment to determine whether further care is warranted. If subjects require additional physical therapy services or follow-up back to the physician, the primary investigator will coordinate with UCSF physical therapist to ensure continuity of care or proper closure of their care are complete.

16. Statistical Analysis Plan

To assess differences in clinical and demographic variables of the patients allocated to the two study groups, independent samples t test or Mann–Whitney U test will be used for quantitative variables. For categorical variables, Chi-square test or Fisher's exact test will be used.
Outcome analysis will be performed using both an intention to treat analysis and a per-protocol analysis.
The overall impact of the intervention on the primary and secondary outcomes will be assessed considering both the results at the 8-week assessment as well as change from baseline.
Differences between interventions will be evaluated using independent samples t test or Mann-Whitney U test. For non-normally distributed variables, the magnitude of the difference in the medians will be assessed using Hodges-Lehman estimator. Additionally, a repeated measures ANOVA will also be performed, with group as an independent factor and time as a within-subjects factor. When necessary, logarithmic transformation will be performed to obtain normally distributed variables. In all analysis, a significant level of 0.05 will be considered.

17. Risks and Benefits

Participants in this clinical study will be allocated to one of two treatment groups. In any case, they will be receiving an evidence-based treatment program tailored to their condition, overseen by physicians and physical therapists. Participants in the digital care program will be performing the exercise component using a certified medical device for its intended purpose. Therefore, participants are not running additional risks by participating in this study.
Exercise programs can, however, be associated with temporary pain or discomfort as expected from the typical treatment. In the digital care group, pain and fatigue scores will be asked at the end of each session, and this information is relayed to the physical therapist assigned to the

participant, who will contact the patient in case of excessive pain or fatigue. In the conventional PT group, sessions will be performed under direct supervision from a physical therapist. In any case, both participants and physical therapists will be instructed to contact the study investigators in case of an adverse event.

As to the benefits, by participating in this study, participants may experience reduction in pain, improvement in function, mood and general well-being. However, the effects may vary from person to person, and therefore substantial improvements cannot be guaranteed.

18. CONFIDENTIALITY

PHI will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

Data used for dissemination of study results will be de-identified before publication.

19. REFERENCES

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ANNEX 1 - INFORMED CONSENT FORM

RESEARCH SUBJECT CONSENT FORM

Title:	Digital care program for chronic shoulder tendinopathy versus conventional physical therapy: a prospective, randomized controlled study
Protocol No.:	SH-SA-MSK-US-01
Sponsor:	SWORD Health Technologies, Inc.
Investigator:	Sang (Sam) Pak, PT, DPT Assistant Professor, UCSF
Study-Related Phone Number(s):	650-776-5514
Study-Related Email Contact:	sam.pak@ucsf.edu
Ethical Approval:	

DETAILED RESEARCH CONSENT

You were asked for your verbal consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

Your physician explained this research to you. This form sums up that explanation.

Taking part in this research is voluntary. Whether you take part is up to you. You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
This research study has been thoroughly reviewed by an independent group called an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. The protocol number given by the committee for this study is shown at the top of this information sheet.
If you don't understand, ask questions. Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study, which is looking to enroll about 144 subjects, is to assess the clinical impact of a digital program for chronic low back pain versus conventional physical therapy.

How long will I be in this research?

We expect that your taking part in this research will last 8 weeks. You will be asked to fill in a reassessment questionnaire once every four weeks.

What happens to me if I agree to take part in this research?

If you decide to take part in this research study, you will be assigned at random (i.e., as if tossing a coin) to one of two groups, which we have named digital or conventional.
If you are assigned to the digital group, you will be receiving a kit with a tablet and sensors in the next few days. A mobile app on the tablet, together with the sensors, will be guiding you through exercise sessions according to a protocol specific for your condition. You will be assigned a Physical Therapist that will be monitoring your performance and progress through an online portal, and adapting the program accordingly.
You will also have access to educational texts prepared by SWORD's clinical team, which are available through a smartphone app which you have to download.
You will also have access to a cognitive behavioural therapy program. This program was designed to help you relax and give you mental tools to deal better with your condition. This program will be delivered through a weekly email, which contains a description of the objectives for the week

and a link to a pre-recorded audio session. It may also have one additional file with mental exercises to complement the sessions.

If you are assigned to the conventional group, you will be receiving two 30-minute sessions for 8 weeks, face-to-face with a Physical Therapist. These sessions will take place at the Outpatient faculty practice at UCSF. **In addition, your** assigned PT will also be communicating with you through a secure messaging system (Mychart) used at UCSF or, alternatively, through telephone check-ins (10-15 min calls, up to twice per week).

Could being in this research hurt me?

Exercise programs can be associated with temporary pain and discomfort. If, at any point during the program, you unexpectedly experience any ill effects, contact the research team through the provided contacts: sam.pak@ucsf.edu or 650-776-5514.

Will it cost me money to take part in this research?

You will have access to this program at no cost to you.

Will being in this research benefit me?

You may experience a reduction in pain, improvement in function, mood and general well-being. However, the effects vary from person to person, and we cannot promise any definite benefits to you for taking part in this research.

We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the development of more effective evidence-based rehabilitation therapies for chronic musculoskeletal disorders.

What other choices do I have besides taking part in this research?

Your alternative is to not take part in the research, and discuss other alternatives with your physician.

What happens to the information collected for this research?

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor including the physical therapist
- Government agencies, such as the Food and Drug Administration
- The Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Data collected in this research might be deidentified and used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- The research is canceled by the FDA or the sponsor

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team through the following contact: sam.pak@ucsf.edu or 650-776-5514. This will not affect your access to medical care, impact your legal rights or lead to any penalty or loss of benefits to which you are otherwise entitled.

Will I be paid for taking part in this research?

You will be paid a financial incentive of 25$ for each electronic questionnaire you fill out and hand over to your physician.

Statement of Consent

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date
Signature of testimony in case subject is unable to sign	Date

ANNEX 2- DIGITAL THERAPEUTIC EXERCISE PROTOCOL

Shoulder Pain Exercise Protocol. Phase 1 (week 1)		
Goals		**Precautions**
Recovery of full range of motion (passive and active) Decrease pain and inflammatory signs Gradually increase muscular strength		Do not perform loaded exercises above 70º flexion / abduction
Intervention *Daily Digital Therapist Sessions* *Remote session – Assessment/Deploy*		
Digital Therapist Exercises	**Mobility**	**Strength 1 (External Load – RPE >8)**
Standing Position		
Shoulder Flexion	2 sets of 8 reps (alternating)	2 sets of 8 reps (2/5 lbs.) (alternating)
Shoulder Hyperextension	2 sets of 8 reps (alternating)	
Shoulder Abduction	2 sets of 8 reps (alternating)	2 sets of 8 reps (5/7 lbs.) (alternating)
Scapular Plane Elevation	2 sets of 8 reps (alternating)	2 sets of 8 reps (2/5 lbs.) (alternating)
Diagonal 1 Flexion		
Diagonal 2 Flexion	2 sets of 8 reps (alternating)	2 sets of 8 reps (2/5 lbs.) (alternating)
Shoulder External Rotation	2 sets of 8 reps (alternating)	2 sets of 8 reps – Theraband (alternating)
Shoulder Internal Rotation		
Hand to Back	2 sets of 8 reps (alternating)	
Shoulder Horizontal Abduction		2 sets of 8 reps (alternating)
Shoulder Horizontal Adduction		

Shoulder External Rotation in Abduction		3 sets of 8 reps (5/7 lbs.) (alternating)
Shoulder Internal Rotation in Abduction		
Scapulae Retraction with Shoulder Flexion	2 sets of 8 reps (alternating)	
Scapulae Protraction with Shoulder Flexion		
Arm Circles with Shoulder Flexion		
Arm Circles with Shoulder Abduction		2 sets of 8 reps (2/5 lbs.) (alternating)
Chair Press-Up		
Push-Up Against the Wall		
Pendulum		
Estimated Therapy Time	**20 min**	**20 min**

Shoulder Pain Exercise Protocol. Phase 1 (weeks 2 to 4)			
Goals			**Precautions**
Recovery of full range of motion (passive and active) Decrease pain and inflammatory signs Gradually increase muscular strength			Do not perform loaded exercises above 70º flexion / abduction
Intervention *Daily Digital Therapist Sessions* *4-Week Remote Assessment*			
Digital Therapist Exercises	**Mobility**	**Strength 1 (External Load – RPE >8)**	**Strength 2 (External Load – RPE >8)**
Standing Position			
Forearm Supination	2 sets of 10 reps (alternating)		
Elbow Flexion		2 sets of 10 reps (alternating)	
Shoulder Flexion	2 sets of 10 reps (alternating)	2 sets of 10 reps (2/5 lbs.) (alternating)	
Shoulder Hyperextension	2 sets of 10 reps (alternating)		2 sets of 10 reps – Theraband (alternating)
Shoulder Abduction	2 sets of 10 reps (alternating)	2 sets of 10 reps (5/7 lbs.) (alternating)	
Scapular Plane Elevation	2 sets of 10 reps (alternating)		2 sets of 10 reps (2/5 lbs.) (alternating)
Diagonal 1 Flexion		2 sets of 10 reps (2/5 lbs.) (alternating)	
Diagonal 2 Flexion	2 sets of 10 reps (alternating)		2 sets of 10 reps (2/5 lbs.) (alternating)
Shoulder External Rotation	2 sets of 10 reps (alternating)	2 sets of 10 reps – Theraband (alternating)	

Shoulder Internal Rotation	2 sets of 10 reps (alternating)		3 sets of 8 reps – Theraband (alternating)
Hand to Back	2 sets of 10 reps (alternating)		
Shoulder Horizontal Abduction		2 sets of 10 reps (alternating)	
Shoulder Horizontal Adduction			2 sets of 10 reps (alternating)
Shoulder External Rotation in Abduction		2 sets of 10 reps (5/7 lbs.) (alternating)	
Shoulder Internal Rotation in Abduction			2 sets of 10 reps (5/7 lbs.) (alternating)
Scapulae Retraction with Shoulder Flexion	2 sets of 10 reps (alternating)		
Arm Circles with Shoulder Flexion		2 sets of 10 reps (2/5 lbs.) (alternating)	
Arm Circles with Shoulder Abduction			2 sets of 10 reps (2/5 lbs.) (alternating)
Chair Press-Up			2 sets of 10 reps (alternating)
Push-Up Against the Wall			2 sets of 10 reps (alternating)
Pendulum			
Lying Position			
Shoulder Flexion		2 sets of 10 reps (2/5 lbs.) (alternating)	
Shoulder External Rotation			2 sets of 10 reps (2/5 lbs.) (alternating)
Shoulder Internal Rotation		2 sets of 10 reps (2/5 lbs.) (alternating)	
Estimated Training Time	**29 min**	**29 min**	**28 min**

Shoulder Pain Exercise Protocol. Phase 2 (Weeks 5 to 8)			
Goals		**Precautions**	
Range of motion conservation Global muscular strengthening in asymptomatic range of movement, focusing on: - Rotator cuff - Scapular stabilizers - Deltoids		Do not perform push-ups on the floor in case of complete rotator cuff tears (use inclined planes)	
Intervention *Daily Digital Therapist Sessions* *8 Week Remote Assessment*			
Digital Therapist Exercises	**Mobility**	**Strength 1 (External Load – RPE >8)**	**Strength 2 (External Load – RPE >8)**
Standing Position			
Shoulder Flexion	2 sets of 10 reps (alternating)	2 sets of 10 reps (5/7 lbs.) (alternating)	
Shoulder Hyperextension			2 sets of 10 reps (*Theraband*) (alternating)
Shoulder Abduction	2 sets of 10 reps (alternating)	2 sets of 10 reps (5/7 lbs.) (alternating)	
Scapular Plane Elevation	2 sets of 10 reps (alternating)		2 sets of 10 reps (5/7 lbs.) (alternating)
Diagonal 1 Flexion	2 sets of 10 reps (alternating)	2 sets of 10 reps (5/7 lbs.) (alternating)	
Diagonal 2 Flexion	2 sets of 10 reps (alternating)		2 sets of 10 reps (5/7 lbs.) (alternating)

Shoulder External Rotation	2 sets of 10 reps (alternating)	2 sets of 10 reps (*Theraband*) (alternating)	
Shoulder Internal Rotation			2 sets of 10 reps (*Theraband*) (alternating)
Hand to Back	2 sets of 10 reps (alternating)		
Shoulder Horizontal Abduction		2 sets of 10 reps (*Theraband*) (alternating)	
Shoulder Horizontal Adduction			2 sets of 10 reps (*Theraband*) (alternating)
Shoulder External Rotation in Abduction	2 sets of 10 reps (alternating)	2 sets of 10 reps (5/7 lbs.) (alternating)	
Shoulder Internal Rotation in Abduction	2 sets of 10 reps (alternating)		
Scapulae Retraction with Shoulder Flexion	2 sets of 10 reps (alternating)		
Scapulae Protraction with Shoulder Flexion			
Arm Circles with Shoulder Flexion		2 sets of 10 reps (5/7 lbs.) (alternating)	
Arm Circles with Shoulder Abduction			2 sets of 10 reps (5/7 lbs.) (alternating)
Chair Press-Up			2 sets of 10 reps (consecutive)
Push-Up Against the Wall			2 sets of 10 reps (alternating)
Pendulum			

Lying Position			
Shoulder Flexion		2 sets of 10 reps (5/7 lbs.) (alternating)	
Shoulder Abduction		2 sets of 10 reps (5/7 lbs.) (alternating)	
Shoulder External Rotation			
Shoulder Internal Rotation			
Shoulder Horizontal Abduction			2 sets of 10 reps (5/7 lbs.) (alternating)
Arm Circle with Shoulder Flexion		2 sets of 10 reps (5/7 lbs.) (alternating)	
Arm Circle with Shoulder Abduction			2 sets of 10 reps (5/7 lbs.) (alternating)
Estimated Training Time	**29 min**	**29 min**	**27 min**

ANNEX 3- CONVENTIONAL PT INTERVENTION PROTOCOL

The co-investigators are encouraged to use the McClure's staged based rehabilitation therapy (STAR) classification (see Table 1) as a ***guide*** but not necessarily as a prescriptive manner to select interventions. Instead, the co-investigators will reference their use interventions categorized based on commonly practiced in an outpatient physical therapy setting (see Table 2).

McClure's stage-based rehabilitation therapy (STAR) intervention approach is based on the Irritability of the patient's condition. Assessments of symptoms of Irritability are gathered from the patient's history and findings from the examination. Table 1 represents a guided approach to STAR for the chronic shoulder pain population and the type of interventions used. Table 2 describes the type of commonly used physical therapy interventions that could be used in the cohorts.

Guideline to help determine the stage of Irritability is based on both history and examination findings*

High	Moderate	Low
• Pain >= 7/10 • Consistent night or resting pain • Pain before end of range • AROM < PROM • High disability	• Pain (4-6/10) • Intermittent night or rest pain • Pain at end of range • AROM and PROM close • Moderate disability	• Pain (<= 3/10) • Absent night or rest pain • Minimal pain with overhead • AROM = PROM • Low disability
Approach: Minimize physical stress • Activity modification	Approach: Mild-moderate physical stress • Basic-level functional activity restoration	Approach: Mod-high physical stress • High-demand functional activities

*Taken from Staged approach (STAR) for rehabilitation classification by McClure et al.

Table 1. McClure's staged approach to shoulder intervention based on different impairments

Impairments	Irritability	Intervention Approaches	Examples of Intervention**
Restricted passive mobility due to joint/muscle/neural tissues	Low	• ROM • Stretching • manual therapy: tolerable stretch sensation at end-range • Hold longer duration and frequency	• Aggressive active and passive stretches (e.g., sleeper stretches; foam roller T's, Y's, I's; Doorway stretch)
Restricted passive mobility due to joint/muscle/neural tissues	Moderate	• ROM • Stretching • Comfortable end-range manual therapy	• Active and passive stretches (e.g., gentle sleeper stretches; Foam roller T's, Y's, I's; modified to ½ to full foam roller T's, Y's, I's; Modified doorway stretch)
Restricted passive mobility due to joint/muscle/neural tissues	High	• ROM • Stretching • Pain-free manual therapy • Avoid end-range	• AAROM/PROM (e.g., ½ roller; towel rolls; wall crawl)
Excessive passive mobility	High	• Protect joint/tissue from end-range	• Gentle isometrics

Impairments	Irritability	Intervention Approaches	Examples of Intervention**
		• Manual therapy to reduce pain	• Parascapular strengthening
Excessive passive mobility	Mod	• Develop active control in mid-range while avoiding end-range in basic activity Address hypomobility of adjacent joints or tissues	• Isometrics to isokinetic (e.g., ER/IR/ABD/Flex, parascapular stabs)
Excessive passive mobility	Low	• Develop active control during full-range, high-level functional activity Address hypomobility of adjacent joints or tissues	• Isokinetic to dynamic (e.g., ER/IR/ABD/Flex, parascapular stabs)
Neuromuscular weakness due to atrophy, disuse, and/or deconditioning	High	• AROM within pain-free ranges	• AAROM/AROMS via Pulleys, table slides • Isometrics (e.g. ER/IR/ABD/Flex, parascapular stabs)

Impairments	Irritability	Intervention Approaches	Examples of Intervention**
Neuromuscular weakness due to atrophy, disuse, and/or deconditioning	Mod	• Light or moderate resistance to fatigue Mid-ranges	• Isometrics to isokinetic • Rotator cuff strengthening (ER/IR) in neutral to variations of ABD via weights or T-band (i.e., ER/IR/ABD/Flex, parascapular stabs)
Neuromuscular weakness due to atrophy, disuse, and/or deconditioning	Low	• Moderate or high resistance to fatigue Include end-ranges	• Isokinetic to dynamic resistive movements • Rotator cuff strengthening (ER/IR/Flex/ABD) in progression from neutral to variations of movements via weights or T-band
Neuromuscular weakness associated with poor motor control or neural activation	High	• AROM within pain-free ranges • Biofeedback, • Neuromuscular electrical stimulation, or other activation strategies	• Isometrics (e.g., ER/IR, parascapular stabs) • Mirror/manual cue feedback for AROM/AAROM; Scapular clock exercises

Impairments	Irritability	Intervention Approaches	Examples of Intervention**
Neuromuscular weakness associated with poor motor control or neural activation	Mod	• Basic movement training with emphasis on quality/precision rather than resistance according to motor learning principles	• Isometrics to isokinetic (e.g., ER/IR, parascapular stabs) • loaded motor control exercises with mirror feedback
Neuromuscular weakness associated with poor motor control or neural activation	Low	• High-demand movement training with emphasis on quality rather than resistance according to motor learning principles	• Isokinetic to dynamics (e.g., ER/IR, parascapular stabs) • Progressive loaded motor control exercises with mirror feedback
Restricted tolerance to functional activity	High	• Maximum joint or tissue protection from end-range • Advocate use of unaffected regions	• Patient education (e.g., anatomy; biomechanics; supplemental youtube videos; Tissue healing timelines; Pain science) • CBT • Graded activity and graded exposure

Impairments	Irritability	Intervention Approaches	Examples of Intervention**
			exercises / functional activities
Restricted tolerance to functional activity	Mod	• Progressively engage in basic functional activity	• Patient education (e.g., anatomy; biomechanics; supplemental youtube videos; Tissue healing timelines; Pain science) • CBT • Progress graded activity and graded exposure exercises / functional activities
Restricted tolerance to functional activity	Low	• Progressively engage in basic functional activity	• Patient education (e.g., anatomy; biomechanics; supplemental youtube videos; Tissue healing timelines; Pain science) • CBT • Progress graded activity and graded

Impairments	Irritability	Intervention Approaches	Examples of Intervention**
			exposure exercises / functional activities
Limited patient understanding of condition leading to inappropriate or avoidance of activity	Low/Mod/High	• Select appropriate patient education	• Patient education (e.g., anatomy; biomechanics; supplemental youtube videos; Tissue healing timelines; Pain science) • CBT • Motivational interviews

**Not a comprehensive list of interventions/exercises

Table 2. General Category of Physical Therapy Interventions

Intervention Categories	Description	Type of Interventions	Examples of Intervention**
Therapeutic Exercises	Systematically planned performance of bodily movement, postures, physical activities relevant to patient's condition*	• Flexibility • Strengthening • Endurance • Neuromuscular reeducation • Functional task training	• Strengthening - ER/IR in neutral position with T-band • Flexibility - Wall slides in standing • Functional activities training
Patient Education	Informing, educating, training patients related to their condition	• Disease condition • Anatomy • Activity modification • Ergonomics • Cognitive Behavior Therapy/Motivational Interview • Symptom management	• Patient education on glenohumeral joint and surrounding tissues • Precautions of activities for shoulder joint
Manual Therapy	Skilled passive movements of joints/soft tissue	• Joint mobilization • Soft tissue mobilization • Neural tissue mobilization • Therapeutic massage	• Passive accessory motion of anterior-posterior of glenohumeral joint • Passive physiological motion of glenohumeral joint

			• Myofascial decompression (Cupping)
Biophysical Agents/Modalities	Use of a broad group of modalities for therapeutic purposes	• Electric Stimulation • Ultrasound • Heat/Ice • Taping • Biofeedback	• Electrical muscle stimulation (EMS) • Neuromuscular electrical stimulation (NMES)

*Definition is taken from APTA Guide to Physical Therapists Practice

**Not a comprehensive list of interventions/exercises