CLINICAL INVESTIGATION PLAN FOR MEDICAL DEVICE STUDIES

Full title of investigation:	Digital care program for chronic low back pain versus conventional physical therapy: a prospective, randomized controlled study
Version and date of Clinical Investigation Plan (CIP):	Version 1.5, 26 August 2020
Sponsor:	SWORD Health
Sponsor CIP number:	SH-RCT-LBP-US-01

REVISION HISTORY

Version	Date	Description	Author
1.0	06/10/2020	Original	FC and CD
1.1	07/22/2020	Content revision. Clarified procedures of participant and data intake.	FC and MM
1.2	08/05/2020	Content revision. Added intervention program for digital PT group.	FC and MM
1.3	08/19/2020	Content revision. Added intervention program for conventional PT group.	CD and FC
1.4	08/24/2020	Content revision. Clarification of method to collect session by session information, Added study contacts.	FC
1.5	08/26/2020	Updated patient stipend section. Updated intervention program for conventional PT.	CD and FC

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.

Principal Investigator

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Assistant Professor of Physical and Rehabilitation Medicine, Emory University, Atlanta, Georgia

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TABLE OF CONTENTS

1. BACKGROUND

Low back pain (LBP) has for long been the world's leading cause of years leaved with disability,[1] and, considering that the overall life expectancy is rising, this pandemic only tends to get worse. Nearly everyone is affected by LBP at some moment in life (70-80% of lifetime prevalence).[2–4] As a consequence, LBP is also presented as a leading cause of work absenteeism worldwide.[5–7] Thus, although the estimate costs of LBP may be difficult to compare between different countries, its overwhelming socio-economic impact in modern society is evident.[8]

In the absence of an effective treatment, LBP can become chronic, causing a huge impact in patients' daily life,[9,10] and ultimately promoting a high consumption of healthcare resources.[2,8,11] In the US alone, health expenditures for adults with spinal problems were estimated at $6000 per person, representing a total cost of $102 billion each year.[12]

The dim picture described above highlights the urgent need for effective interventions that minimize disability, improve quality of life and decrease productivity losses.[13]

Current guidelines on CLBP management recommend patient education, exercise, physical therapy (PT), and behavioural therapy as the mainstay treatments for this condition.[14]

Despite some discrepancy in the type of exercise program (e.g. aquatic exercises, stretching, back schools, McKenzie exercise approach, yoga, tai-chi) and mode of delivery (e.g., individually designed programs, supervised home exercise, and group exercise), exercise therapy is recommended nearly transversally,[14–17] with most studies concluding that exercise intervention programs should include a combination of muscular strength, flexibility and aerobic fitness exercises.[18–20] Moreover, home exercises with a regular therapist follow-up has proven highly effective.[21–25]

This is not, however, how LBP is currently managed. Appropriate patient education and structured behavioural training are rarely provided, and opioid prescription is also a common practice,[14,26] despite known opioid-related morbidity and mortality rates.[27] Because the prevalence of CLBP is

continuously rising, and opioid misuse is an issue of great concern globally, identifying effective nonopioid alternatives for CLBP is of paramount importance.

Further compounding this problem, from the patients who are directed to PT, almost half give up after just 4 sessions, and only 30% complete their programs.[28]

In this context, new ways of delivering care are much needed. Crucially, these need to: a) address the three pillars of care to achieve good and sustained clinical outcomes; b) overcome barriers to access; c) ensure patients are engaged throughout the programs; d) be scalable and cost-efficient.

Thus, SWORD Health has developed a digital care program to address these needs.

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 I 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.[29–31] 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 educational component is delivered through a smartphone 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.

A dedicated third-generation Cognitive Behavioural Therapy (CBT) program, which takes the form of a self-paced program consisting of written and pre-recorded audio materials, is also made available to the individual, through a secure email platform.

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 low back pain 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 functional disability measured through the Oswestry Disability Index score (patient reported outcome measure) between baseline and 8 weeks.

8.2 Secondary Outcomes

The secondary outcomes will include the following, measured between baseline and 8 weeks:

a) 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?"

b) Impact on work productivity and activity impairment

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

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 back surgery in the next 12 months"?

d) Medication consumption

Measured through the following questions:

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

h) Patient satisfaction

Measured through the Net Promoter Score

i) Impact on physical activity levels

Measured through the International Physical Activity Questionnaire- Short Form.

9. SAMPLE SIZE ESTIMATION

Sample size estimation calculations were performed taking into consideration the primary outcome measure – The Oswestry Disability Index (ODI). In the absence of similar studies, the calculations were made considering the study by Stankovic et al. (2012). This was a large study (n=160 patients), which compared two different rehabilitation protocols for CLBP and which used the same primary outcome as the present study. In this study, the standard deviation of the ODI at baseline was 17.83 points. A Minimal Clinically Important Change (MCIC) of 10 points was considered, based on the study by Ostelo et al.[32] Considering a power of 80% and a two-sided 0.05 significance level, 102 individuals will be necessary to detect a 10-point difference between the two groups.

10. INCLUSION/EXCLUSION CRITERIA

10.1 Inclusion Criteria

a) Subjects aged between 18 and 80 years of age at enrolment
b) Reporting intermittent or persistent low back pain for at least 12 weeks, and/or present at least 50% of the time in the past 6 months
c) Ability to understand complex motor tasks

d) Ability to interact with a tablet

10.2 Exclusion Criteria

a) Known pregnancy
b) Submitted to spinal surgery less than 3 months ago
c) Symptoms and/or signs indicative of possible infectious disorder
d) Known disorder with indication for spine surgery (i.e., tumor, cauda equina syndrome)
e) Cancer diagnosis or undergoing treatment for cancer
f) Cardiac, respiratory or other known disorder incompatible with at least 20 minutes of light to moderate physical activity
g) Concomitant neurological disorder (e.g. Stroke, multiple sclerosis, Parkinson's disease)
h) Dementia or psychiatric disorders precluding patient from complying with a home-based exercise program
i) Illiteracy and/or serious visual or auditory impairment interfering with communication or compliance

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

11. CANDIDATE IDENTIFICATION AND PROCEEDINGS

Candidates will be evaluated at the outpatient musculoskeletal clinic at Emory Orthopaedic and Spine Center (Atlanta, Ga). 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 a statistician blinded to allocation groups.

14. INTERVENTION

14.1 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 PT. 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 the upper and lower back,

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. 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.

14.2 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 protocol outlined in **Annex 3**, which can however be adapted by the physical therapist

will be considered as dropouts if they: a) choose to abandon the study; b) miss four consecutive scheduled PT sessions.

15. ASSESSMENTS AND SPECIFIC DATA COLLECTION

Patients will be assessed at baseline, 4 and 8 weeks. All questionnaires will be collected through the EDC system. These will need to be filled within 5 consecutive days. 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.

Regarding the **baseline assessment**, participants will be asked to complete the survey before the start of the program. This assessment will include all the information pertaining to the primary and secondary outcomes, as well as the following information:

a) date of birth
b) gender
c) height & weight
d) body mass index
e) formal education (years of schooling)
f) job type
g) baseline physical activity level
h) previous back surgery (> 3 months ago)
i) risk factors: working status, smoking status

For the **4- and 8-week assessment**, participants will be required to complete the questionnaire within a 5-day window beginning at the start of week 4 and 8. These assessments will include all the information pertaining to the primary and secondary outcomes. Physical activity will be measured only at baseline and 8 week 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. Total time spent on remote monitoring of the patient (digital group only)

When applicable, **adverse events** reporting will also be made through this portal and annexed to patient's file (beginning date, resolution date (if applicable), resolution state, severity, description).

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 12-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. 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.

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ANNEX 1 - INFORMED CONSENT FORM

RESEARCH SUBJECT CONSENT FORM

Title:	Digital care program for chronic low back pain versus conventional physical therapy: a prospective, randomized controlled study
Protocol No.:	SH-SA-MSK-US-01
Sponsor:	SWORD Health Technologies, Inc.
Investigator:	Cui Di, MD Assistant Professor of Physical and Rehabilitation Medicine Emory University Atlanta, Georgia
Study-Related Phone Number(s):	404-778-6857
Study-Related Email Contact:	lauren.glenney@emory.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 Emory Spine Center Outpatient Clinic.

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: 404-778-6857 or lauren.glenney@emory.edu.

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 contacts: phone 404-778-6857 or **lauren.glenney@emory.edu.** 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 equivalent of 50$ for each electronic milestone questionnaire you complete and hand over to your physician. There are 3 milestone questionnaires, for a total of $150.00

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

Low Back Pain Program – Initial Phase **Week 1**		
Goals		
Increase exercise complexity Gradually return to avoided movements Normalize movement patterns Increase trust in movement		
Intervention *Daily Digital Therapist Sessions* *Assessment/Deploy*		
Digital Therapist Exercises	**Mobility / Endurance Session A**	**Mobility / Endurance Session B**
Cat-camel	2 sets of 10 repetitions (alternating)	2 sets of 10 repetitions (alternating)
Child's pose	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Prone press ups	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Plank		
Plank with trunk rotation		
Plank and hand walking		
Sitting trunk flexion	2 sets of 10 repetitions (alternating)	2 sets of 10 repetitions (alternating)
Sitting trunk flexion with rotation	2 sets of 12 repetitions (alternating)	
Sitting trunk rotation		2 sets of 12 repetitions (alternating)
Sitting trunk extension	2 sets of 10 repetitions (alternating)	
Sitting trunk side bend	2 sets of 12 repetitions (alternating)	2 sets of 12 repetitions (alternating)
Siting trunk extension with rotation		2 sets of 8 repetitions (alternating)

Standing trunk flexion		
Standing trunk flexion with rotation		
Standing trunk rotation		
Standing trunk side bend		
Standing trunk extention		
Pelvic anterior-posterior tilt	1 sets of 10 repetitions (alternating)	1 sets of 10 repetitions (alternating)
Pelvic side tilt	1 sets of 10 repetitions (alternating)	1 sets of 10 repetitions (alternating)
Estimated Training Time	20 min	20 min

Low Back Pain Program – Intermediate Phase **Week 2 to 3**			
Goals			
Increase exercise complexity Gradually return to avoided movements Normalize movement patterns Increase trust in movement			
Intervention *Daily Digital Therapist Sessions*			
Digital Therapist Exercises	**Mobility / Endurance Session A**	**Mobility / Endurance Session B**	**Strength Session**
Cat-camel	2 sets of 10 repetitions (alternating)	2 sets of 10 repetitions (alternating)	
Child's pose	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Prone press ups	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Plank			2 sets of 1 repetitions (alternating)

Plank with trunk rotation			
Plank and hand walking			
Sitting trunk flexion	2 sets of 12 repetitions (alternating)	2 sets of 12 repetitions (alternating)	2 sets of 8 repetitions (alternating)
Sitting trunk flexion with rotation		2 sets of 16 repetitions (alternating)	2 sets of 10 repetitions (alternating)
Sitting trunk rotation			
Sitting trunk extension	2 sets of 12 repetitions (alternating)		
Sitting trunk side bend			
Siting trunk extension with rotation		2 sets of 10 repetitions (alternating)	2 sets of 10 repetitions (alternating)
Standing trunk flexion			2 sets of 8 repetitions (alternating)
Standing trunk flexion with rotation	2 sets of 14 repetitions (alternating)		2 sets of 16 repetitions (alternating)
Standing trunk rotation		2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)
Standing trunk side bend	2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)
Standing trunk extention	2 sets of 12 repetitions (alternating)		2 sets of 8 repetitions (alternating)
Pelvic anterior-posterior tilt	2 sets of 10 repetitions (alternating)	2 sets of 10 repetitions (alternating)	
Pelvic side tilt	2 sets of 10 repetitions (alternating)	2 sets of 10 repetitions (alternating)	
Estimated Training Time	27 min	28 min	30 min

Low Back Pain Program – Intermediate Phase **Week 4 to 5**
Goals

Increase exercise complexity Gradually return to avoided movements Normalize movement patterns Increase trust in movement			
Intervention *Daily Digital Therapist Sessions* *4-week Remote Assessment*			
Digital Therapist Exercises	**Mobility / Endurance Session A**	**Mobility / Endurance Session B**	**Strength Session**
Cat-camel	2 sets of 12 repetitions (alternating)	2 sets of 12 repetitions (alternating)	
Child's pose	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Prone press ups	2 sets of 1 repetitions (alternating)		2 sets of 1 repetitions (alternating)
Isometric cat pose	2 sets of 1 repetitions (alternating)		
Plank			2 sets of 1 repetitions (alternating)
Plank with trunk rotation			1 sets of 6 repetitions (alternating)
Plank and hand walking			
Sitting trunk flexion			
Sitting trunk flexion with rotation		2 sets of 16 repetitions (alternating)	2 sets of 8 repetitions (alternating)
Sitting trunk rotation		2 sets of 10 repetitions (alternating)	
Sitting trunk extension			
Sitting trunk side bend			
Siting trunk extension with rotation		2 sets of 12 repetitions (alternating)	2 sets of 6 repetitions (alternating)

Standing trunk flexion		3 sets of 10 repetitions (alternating)	3 sets of 6 repetitions (alternating)
Standing trunk flexion with rotation	3 sets of 16 repetitions (alternating)		3 sets of 12 repetitions (alternating)
Standing trunk rotation			3 sets of 12 repetitions (alternating)
Standing trunk side bend	3 sets of 16 repetitions (alternating)		3 sets of 12 repetitions (alternating)
Standing trunk extention	3 sets of 12 repetitions (alternating)		3 sets of 6 repetitions (alternating)
Pelvic anterior-posterior tilt	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	
Pelvic side tilt	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	
Estimated Training Time	30 min	25 min	30 min

Low Back Pain Program – Final Phase **Week 6**			
Goals			
Increase external load Explosion / Power exercises Return to all daily activities Maximum complexity on the exercises Specific activities training Focus on education and prevention of chronic			
Intervention *Daily Digital Therapist Sessions*			
Digital Therapist Exercises	**Mobility / Endurance Session A**	**Mobility / Endurance Session B**	**Strength Session**
Cat-camel	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	

Child's pose	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Prone press ups	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Isometric cat pose	2 sets of 1 repetitions (alternating)		
Plank			2 sets of 1 repetitions (alternating)
Plank with trunk rotation			2 sets of 6 repetitions (alternating)
Plank and hand walking			1 sets of 2 repetitions (alternating)
Sitting trunk flexion	1 sets of 10 repetitions		
Sitting trunk flexion with rotation		2 sets of 18 repetitions (alternating)	2 sets of 10 repetitions (alternating)
Sitting trunk rotation			
Sitting trunk extension			
Sitting trunk side bend			
Siting trunk extension with rotation		2 sets of 14 repetitions (alternating)	2 sets of 10 repetitions (alternating)
Standing trunk flexion		2 sets of 14 repetitions (alternating)	2 sets of 10 repetitions (alternated)
Standing trunk flexion with rotation	2 sets of 20 repetitions (alternating)		2 sets of 16 repetitions (alternated)
Standing trunk rotation		2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)
Standing trunk side bend	2 sets of 20 repetitions (alternating)	2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)
Standing trunk extention	2 sets of 14 repetitions (alternating)		2 sets of 10 repetitions (alternating)
Pelvic anterior-posterior tilt	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	

Pelvic side tilt	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	
Estimated Training Time	28 min	27 min	30 min

Low Back Pain Program – Final Phase **Week 7**			
Goals			
Increase external load Explosion / Power exercises Return to all daily activities Maximum complexity on the exercises Specific activities training Focus on education and prevention of chronic			
Intervention *Daily Digital Therapist Sessions*			
Digital Therapist Exercises	**Mobility / Endurance Session A**	**Mobility / Endurance Session B**	**Strength Session**
Cat-camel	2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)	
Child's pose	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Prone press ups	2 sets of 1 repetitions (alternating)		2 sets of 1 repetitions (alternating)
Isometric cat pose	2 sets of 1 repetitions (alternating)		
Plank			2 sets of 1 repetitions (alternating)
Plank with trunk rotation			2 sets of 8 repetitions (alternating)
Plank and hand walking			1 sets of 4 repetitions (alternating)
Side Plank			1 sets of 4 repetitions (alternating)
Sitting trunk flexion		1 sets of 10 repetitions (alternating)	

Sitting trunk flexion with rotation		2 sets of 14 repetitions (alternating)	
Sitting trunk rotation			
Sitting trunk extension			
Sitting trunk side bend			
Siting trunk extension with rotation		2 sets of 12 repetitions (alternating)	
Standing trunk flexion			3 sets of 10 repetitions (alternating)
Standing trunk flexion with rotation	2 sets of 22 repetitions (alternating)		3 sets of 12 repetitions (alternating)
Standing trunk rotation			3 sets of 12 repetitions (alternating)
Standing trunk side bend	2 sets of 22 repetitions (alternating)		3 sets of 12 repetitions (alternating)
Standing trunk extention	2 sets of 14 repetitions (alternating)		3 sets of 10 repetitions (alternating)
Pelvic anterior-posterior tilt	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	
Pelvic side tilt	2 sets of 14 repetitions (alternating)	2 sets of 14 repetitions (alternating)	
Estimated Training Time	28 min	28 min	31 min

Low Back Pain Program – Final Phase **Week 8**			
Goals			
Increase external load Explosion / Power exercises Return to all daily activities Maximum complexity on the exercises Specific activities training Focus on education and prevention of chronic			
Intervention *Daily Digital Therapist Sessions* *8-week Remote Assessment*			
SWORD exercises	**Mobility / Endurance Session A**	**Mobility / Endurance Session B**	**Strength Session**
Cat-camel	2 sets of 16 repetitions (alternating)	2 sets of 16 repetitions (alternating)	
Child's pose	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Prone press ups	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)	2 sets of 1 repetitions (alternating)
Isometric cat pose	2 sets of 1 repetitions (alternating)		
Plank			2 sets of 1 repetitions (alternating)
Plank with trunk rotation			2 sets of 8 repetitions (alternating)
Plank and hand walking			2 sets of 4 repetitions (alternating)
Side plank			1 sets of 4 repetitions (alternating)

Isometric side plank			1 sets of 2 repetitions (alternating)
Sitting trunk flexion			
Sitting trunk flexion with rotation			
Sitting trunk rotation		1 set of 10 repetitions (alternating)	
Sitting trunk extension			
Sitting trunk side bend			
Siting trunk extension with rotation			
Standing trunk flexion		3 sets of 12 repetitions (alternating)	3 sets of 8 repetitions (alternating)
Standing trunk flexion with rotation	3 sets of 14 repetitions (alternating)		3 sets of 12 repetitions (alternating)
Standing trunk rotation	3 sets of 14 repetitions (alternating)		3 sets of 12 repetitions (alternating)
Standing trunk side bend	3 sets of 14 repetitions (alternating)	3 sets of 16 repetitions (alternating)	3 sets of 12 repetitions (alternating)
Standing trunk extention		3 sets of 12 repetitions (alternating)	3 sets of 8 repetitions (alternating)
Pelvic anterior-posterior tilt	2 sets of 14 repetitions (alternating)	2 sets of 16 repetitions (alternating)	
Pelvic side tilt	2 sets of 14 repetitions (alternating)	2 sets of 16 repetitions (alternating)	
Estimated Training Time	31 min	30 min	31 min

ANNEX 3- CONVENTIONAL THERAPEUTIC EXERCISE PROTOCOL

Conventional Physical Therapy will be individualized according to the patient's symptoms and baseline physical capabilities. The therapy will include the following components

1) Therapeutic Exercises

These execises will be initiated by the physical therapist, with instruction to continue at home. Patient may progress along intensity level as tolerated under the guidance of the physical therapist. Additional sports/activity specific exercises maybe included and not listed below.

Conventional PT Exercises	**Low Intensity**	**Medium Intensity**	**High Intensity**
Dead Bugs (Supported Arm)	2-4 sets of 2 min set		
Dead Bugs (Unsupported Arm)		3-5 sets of 3 min Rep (alternating)	3-5 sets of 5 min Rep with weight in hands(alternating)
Partial sit up	Arm Reaching between the thighs 10 reps x 2 sets	Arm crossed at chest 10 rep x 3 sets	Hand behind head 20 rep x 3 sets
Bridging	Both foot on the floor 10 reps x 2-3 sets	Single Leg on the floor 20 reps x 2-4 sets	Balance on stability ball 20 reps x 5 sets
Plank (Forearm)	10 second hold 3 sets	30 second hold 3 sets	60 second hold 3 sets
Prone	Opposite Arm/leg lift 10 reps x 1-2 sets	Opposite Arm/leg lift (On balance ball) 10 reps x 1-2 sets	Opposite Arm/leg lift (On balance ball) 20 reps x 1-2 sets
Quadruped	Opposite Arm/leg lift 10 reps x 1-2 sets	Opposite Arm and leg lift 10 reps x 1-2 sets	Opposite Arm and leg lift (with weight in hand and ankle weight) 10 reps x 1-2 sets
Side plank (From Knee)	10 second hold 3 sets	30 second hold 3 sets	60 second hold 3 sets
Wall Slide (Or Ball slide against wall)	45 degree 10 -20 reps	90 degree 10 reps with 30 sec hold	90 degree, with weights and arm extended 10 reps with 30 sec hold

2) Manual Therapy: During the patient's physical therapy treatment manual therapy may be applied by skilled physical therapists as necessary for the patient's condition.

- Soft tissue mobilization
- Joint mobilization/manipulation
- Myofascial release
- Trigger point dry needling
- Cupping

3) Active and Passive Stretches

All stretches maybe completed by patient alone or be assisted/augmented by the physical therapist

- Hip flexor/quad stretch
- Hamstring stretch
- Glute/piriformis stretch
- QL stretch

4) Range of Motion exercises

These will be both active and passive under the assistance of the physical therapists and will be progress under the instruction by the physical therapist.

- Single knee to chest/double knee to chest
- Lumbar rotation in hook-lying
- Seated flexion
- Prone extension
- Book opening for rotation

5) Modalities

During patient's physical therapy treatment, patient may receive the following modalities as seen fit by the physical therapist.

- Heat/cold therapy
- Electrical stimulation/TENs
- Thermal ultrasound

Mechanical traction