UNIVERSITY OF CENTRAL FLORIDA

PROTOCOL TITLE:

The Effects of a Gamified Rehabilitation Protocol Compared to an At-Home Exercise Packet in Individuals with Low Back Pain

PRINCIPAL INVESTIGATOR:

Luk Devorski MS, ATC
READY Lab
Institute of Exercise Physiology and Rehabilitation Sciences
Luk.devorski@ucf.edu

VERSION NUMBER/DATE:

Version 1 08/29/2022

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
1	09/08/22	Addressed track changes and comments	Yes

Table of Contents

Study Summary

Study Title	The Effects of a Gamified Rehabilitation Protocol Compared to an At-Home Exercise Packet in Individuals with Low Back Pain
Study Design	Randomized Controlled Trial
Primary Objective	To measure the change in pain and disability before, during and after a competitive home exercise program compared to a take home packet exercise program.
Secondary Objective(s)	To quantify adherence and compliance of individuals completing a competitive, gamified home exercise program compared to a traditional autonomous exercise program. To measure the change of Ultrasound thickness and onset of muscle activation of the lateral abdominal wall in individuals with non-specific low back pain during static and exercise positioning following a 6-week home exercise program
Research Intervention(s)/ Investigational Agent(s)	None
IND/IDE #	N/A
Study Population	Individuals aged 18-45 with non-specific low back pain *Inclusion Criteria*: ages 18-45*,* biological sex of Male or Female, self-reported low back pain within the previous 6 months or greater than 3 episodes within the past 3 years *Exclusion Criteria:* Currently seeing and or receiving care from an athletic trainer, physical therapist, or other rehabilitation specialist in the previous 6 months, low back pain conditions such as lumbar spondylosis, herniated disc, spondylolisthesis, previous spine surgery, currently pregnant, experiencing neurological symptoms or other muscular abnormalities. Unable to assume the exercise starting position. Current use of lidocaine patches or prescription pain medicine.

Sample Size	40
Study Duration for individual participants	6-week intervention + 12, 18, 24-month follow-ups
Study Specific Abbreviations/ Definitions	NSLBP: non-specific low back pain; ODI: Oswestry Disability Index; NPRS; Numeric Pain Rating Scale; SUS: System Usability Scale; EARS: Exercise Adherence Rating Scale; CES: Credibility and Expectancy; PCS: pain catastrophizing scale; PBP: Prone Bridge Plank; GROC; Global Rating of Change Scale; TESP: Torso Elevated Side Plank; FESP: Foot Elevated Side Plank; TrA: Transverse abdominis; IO: Internal oblique; EO: External oblique

Objectives*

The purpose of the study is to measure the change in pain and disability, quantify adherence and compliance before, during and after a competitive home exercise program compared to a traditional home exercise program. Additionally, to measure the change of ultrasound thickness of the lateral abdominal wall before and after a competitive home exercise program compared to a take home packet exercise program.

We hypothesize that the individuals in the gamified, competitive home exercise program will have decreased pain and disability, increased adherence and increased lateral abdominal wall activation compared to the traditional home exercise program during and after the 6-week protocol.

Background*

Non-specific low back pain (NSLBP) can be defined as low back pain with the absence of a known cause.[1] NSLBP diagnoses are concluded when all other pathologies (specific spinal pathology and radicular syndrome) are excluded. In the primary care setting, 90-95% of all low back cases are non-specific.[2] Individuals of all ages experience NSLBP and are affected at a societal level and personal level.[1] Recent recommendations to decrease low back pain include exercise interventions such as trunk strengthening and endurance, trunk muscle activation, aerobic exercise and multimodal interventions.[3] Other guidelines recommend maintaining a physically active lifestyle.[4] In many cases, maintaining a physically active lifestyle requires exercises to be completed at home via prescribed home exercise programs.[5] In order for the efficacy of the home exercise program to be achieved, consistent exercise adherence must occur. Individuals who adhere to their exercise programs have a greater increase in physical function compared with those who have a lack of adherence.[6] Unfortunately, up to 70% of individuals who suffer from chronic low back pain do not adhere to prescribed home exercise.[7–10]

The lateral abdominal wall is commonly evaluated in individuals that experience NSLBP. The transverse abdominis, internal oblique and external oblique create the lateral abdominal wall. In individuals with NSLBP, the onset of activity of the deep abdominal muscles is delayed.[10,11] The use of ultrasound imaging can measure the onset of muscle activation as well as muscle thickness of the lateral abdominal wall.[10–12] Ultrasound imaging is a non-invasive method to visualize and measure muscle thickness. Images can be

produced during static (non-moving) and functional (moving) positions, demonstrating the change in muscle thickness during rest and during movement. Muscle thickness can be obtained during brightness-mode (B-mode) and Motion-mode (M-mode) by measuring the distance between fascial borders (outward tissue layer of the muscle). M-mode ultrasound is unique as it can also detect the onset of muscle activation.[13] Ultrasound imaging can be implemented to understand trunk strengthening, endurance as well as trunk activation to complement the previous recommended guidelines for decreasing low back pain.

Preliminary data includes muscle activation of the rectus abdominis, middle trapezius, middle deltoid, external oblique (EO), erector spinae, gluteus medius, latissimus dorsi during the prone bridge plank (PBP), torso elevated side plank (TESP), and foot elevated side plank (FESP) completed until discontinuation.[14] The rectus abdominis and external oblique elicited moderate to high activation during the 3 exercises.[14] This preliminary data also included subjective measures of reasoning of termination, and in relevance to the present study, only 5.8% of individuals terminated the TESP due to back pain.[14]

General exercise that includes trunk strengthening and endurance, trunk muscle activation, and multimodal interventions are recommended for individuals with NSLBP.[3] Sixty six percent of people who seek treatment for low back pain will have a reoccurrence in the same year.[15] Individuals may not seek additional medical treatment due to time and financial constraints. The implementation of home exercise has increased tremendously over the past years, allowing individuals to stay active in the comfort of their home.[16]

3.3 Specifically, exercises such as the PBP,TESP, FESP, dead bug, and bird dog are commonly used to target the muscles of the core and aid in progression of rehabilitation.[14,17,18] Although the implementation of home exercise has increased, exercise adherence remains to be an issue. A lack of adherence influences the effects of outcomes in research as well as patient-oriented outcomes such as pain and disability. With up to 70% of individuals not adhering to their prescribed home exercise programs, home exercise methodology must change to increase adherence and decrease pain and disability. Although home exercise has increase in the past years, exercise duration and intensity has decreased.[19,20] Duration and intensity of exercise may increase by focusing on task and ego-oriented goals.[21,22] Individuals can focus on the

proper completion of the exercise as well as their performance compared to others. The implementation of a gamified, competitive home exercise program may increase the efficacy and adherence to home exercise while decreasing pain and disability in the NSLBP population. The use of a leaderboard creates a “game” between the participants as they are comparing their hold times to the average and top hold times of others. A leaderboard that includes exercise average hold times, top hold times and reference values, creates a competitive environment with the participants goal to increase their exercise hold times.

Study Endpoints*

For this study, the endpoint is defined as collecting 40 NSLBP individuals.

N/A

N/A

Study Intervention/Investigational Agent

5.1 There will be two groups in this study, the leaderboard group, and the take-home packet group. The leaderboard group and the take-home packet group will be completing the same exercise program throughout the 6-weeks. The exercises included the PBP, TESP (left and right side), FESP (left and right side), dead bug and bird dog exercise until discontinuation. The exercises will increase with repetitions every two weeks and that outline is listed below in procedures involved. The leaderboard group will have on demand video access to the exercises and the take-home packet group will have a take-home packet. The leaderboard group will also be receiving weekly leaderboards of average and top exercise durations of the leaderboard group participants. The audio description of exercise in the on-demand video group is the same script as the written description in the take-home packet. Both groups will be completing the same questionnaires which are described later.

6.0 Procedures Involved*

6.1 This 6-week randomized controlled trial includes two groups completing at-home exercise program of the PBP, TESP (left and right side), FESP (left and right side), dead bug and bird dog exercise until discontinuation. The exercises will be

completed 3 times a week for 6 weeks. The leaderboard group will be receiving on demand videos of the exercises and weekly leaderboards of exercise duration. The weekly leaderboards are what make the leaderboard group competitive and gamified. Competition is created with the comparison between ones hold times to top hold times and average hold times in the group as well as reference values. The take-home exercise packet group will receive take home at-home exercise packet. The participants in both groups will complete the first exercise session and last exercise session in the READY laboratory. The other exercise sessions will be completed on the participant's own. The take-home exercise packet group will be using a take-home packet to refer to the exercises (PBP, TESP, FESP, dead bug and bird dog) they are to complete within the 6-weeks. The leaderboard group will be using on-demand videos to refer to the exercises (PBP, TESP, FESP, dead bug and bird dog) they are to complete within the 6-weeks. The leaderboard group will also be receiving weekly leaderboards of average and top exercise durations of the leaderboard group participants.

Participants will be randomized into the two separate groups using a random number generator and allocation will be concealed in opaque envelopes prior to data collection.

Weeks 1 to 2 individuals will complete 3 exercise sessions of 1 repetition of the 7 exercises.

Weeks 3 to 4 individuals will complete 3 exercise sessions of 2 repetitions of the 7 exercises

Weeks 5 to 6 individuals will complete 3 exercise sessions of 3 repetitions of the 7 exercises.

First and Last Exercise Session - Upon Arrival:
Participants will be advised to park near the Education Complex and either use UCF parking pass (if they already have one) or will pay to park using a kiosk. They will be instructed to enter the Education Complex doors facing the A and I parking garages/parking lot.

Only 1 participant will be scheduled for a 1.5-2-hour period, as the data collection could take up to 2 hours. Reminders about collection will be sent on the day before and if applicable (e.g., afternoon collection) on the same morning.

The reminder emails will provide an opportunity for participants to confirm or reschedule.

Subjects will report to the Rehabilitation, Athletic assessment Dynamic, Imaging (READY) laboratory in the Institute of Exercise Physiology and Rehabilitation Science for the beginning of the study procedures and first and last exercise sessions.

***Consent and Screening**: (~15-20min)*

Informed consent will be obtained for all subjects as outlined in the consent process selection for this protocol. The informed consent document will ask the participant to self-report any exclusion criteria that is listed. After obtaining informed consent, subjects will fill out a questionnaire asking previous and current health history (health history form). Demographic information will also be collected at this time, including, age, sex, height, and weight (basic demographic form) . Participants will also complete questionnaires asking about their low back pain (NumericPainRatingScale_Question), disability (ODI2.1a_QuestionnairesRCTLBP), credibility and exercise expectancy (CEQ_questionnairesRCTLBP), Pain Catastrophizing questionnaire (PCS_QuestionnairesRCTLBP) and fear avoidance beliefs (FABQ_QuestionnairesRCTLBP). The remaining study procedures will begin immediately after eligibility determination or subjects can return at another date to complete the remainder of the study procedures. Consent, questionnaires, and surveys will be collected using REDCap.

Exercise familiarization (Up to ~10 min)

The PBP, TESP, FESP, dead bug, and bird dog will be demonstrated by the researcher. The researcher will demonstrate and teach the participants how the exercises are expected to be performed. The exercises are pictured below.

Dynamic Ultrasound setup and exercise completion *(up to ~45 min)*

The ultrasound transducer will be placed 10cm from the umbilicus over the right lateral abdominal wall with the thoracolumbar fascia visible on the ultrasound screen. The transducer will be secured with a nylon belt and foam block.

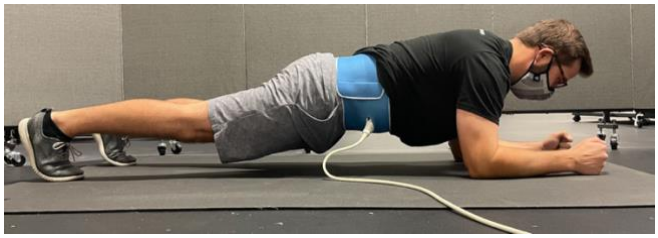
- 3 images of the PBP static position and 3 images of the PBP starting position will be obtained.
- 3 images of the TESP static position and 3 images of the TESP starting position will be obtained.
- 3 images of the FESP static position and 3 images of the FESP starting position will be obtained.

- 3 images of the dead bug static position and 3 images of the dead bug starting position will be obtained
- 3 images of the bird dog static position and 3 images of the bird dog starting position will be obtained.

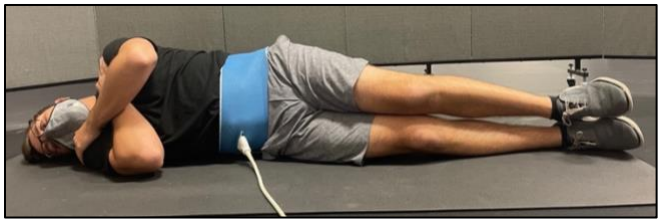
A total of 30 images for the right abdominal wall will be obtained. The ultrasound transducer will then be moved to the participants left lateral abdominal wall and pictures will be repeated.

Upon the collection of 60 images, the ultrasound transducer will be taken off the participant and they will complete the PBP, TESP, FESP, dead bug and bird dog until discontinuation. The TESP and FESP will be completed bilaterally so the left and right elbow will be placed on the ground.

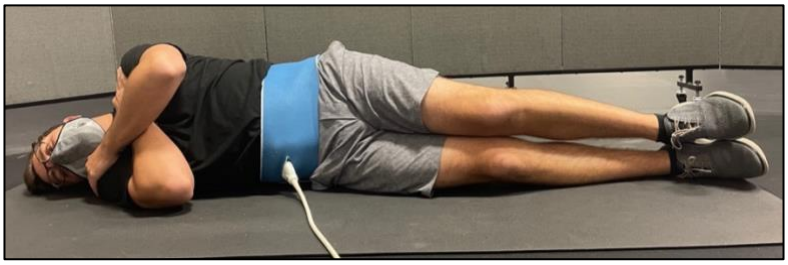
PBP static position and starting position:

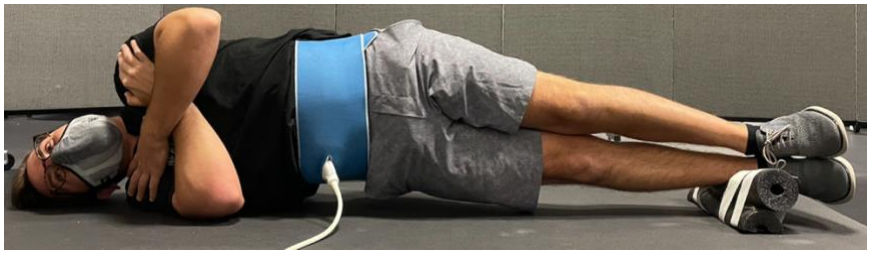


TESP static position and starting position:

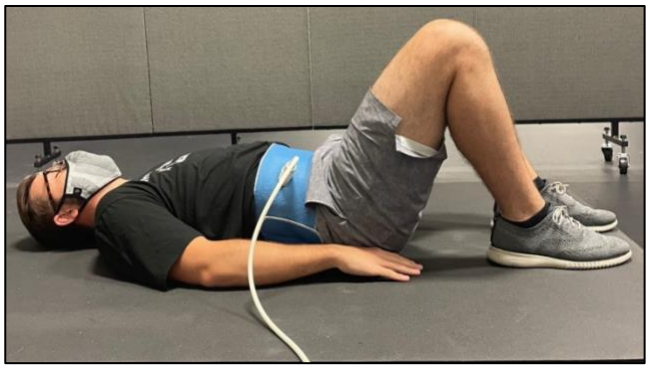


FESP static position and starting position:



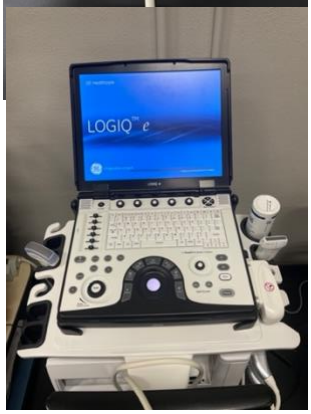


Dead bug static position and starting position:



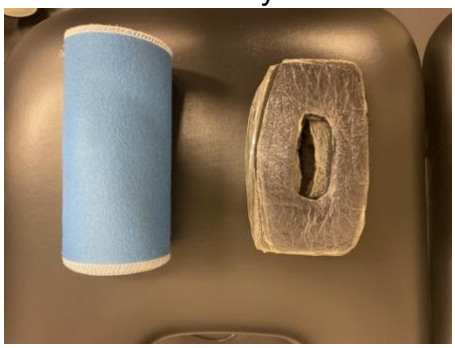
Bird dog static position and starting position:

Ultrasound, transducer, nylon belt and foam block to secure to lateral abdominal wall.



Protocol Description and Participant Reporting *(up to ~ 20 min)*

Upon completion of the exercises, participants will be explained the weekly exercise form that each participant in both groups will be completing and reporting back to the researcher via REDCap. The form will include exercise duration and an exercise form rating (Weekly Exercise Form). This is also the time weekly meetings will be discussed. We will get in touch with the participants weekly either using zoom (video call) or by email to answer any comments or concerns



regarding the exercise completion. The participants email will be provided to the principal investigator when they email showing interest in the study or listed on the "basicdemographic_questionnaire". Additionally, this is the time when the exercise videos are emailed to the participants in the leaderboard group. The email will contain private YouTube links only accessible via the link provided to them (ExerciseVideoLinksEmail). The weekly exercise form is described below.

Weekly Exercise Completion Form

A blank weekly exercise form will provide to the participants via email during the first exercise session and another blank form can be provided if participants misplace or delete the form. The participants will then be emailed a link via REDCap to upload their weekly exercise form once the week is over.

Week 1	Repetitions	Day 1 Time	Day 2 Time	Day 3 time
PBP	Rep 1			
	Rep 2			
	Rep 3			
TESP (R)	Rep 1			

	Rep 2			
	Rep 3			
TESP (L)	Rep 1			
	Rep 2			
	Rep 3			
FESP (R)	Rep 1			
	Rep 2			
	Rep 3			
FESP (L)	Rep 1			
	Rep 2			
	Rep 3			
Dead bug	Rep 1			
	Rep 2			
	Rep 3			
Bird dog	Rep 1			
	Rep 2			
	Rep 3			

Leaderboard Distribution

Upon receiving the exercise forms, a leaderboard will be constructed and sent out over that exercise week's following weekend to the individuals in the leaderboard group. The de-identified leaderboard for week 1 – week 2 will contain each participant's average exercise durations of the 7 exercises. Weeks 2 – weeks 6 will contain each participants average session times and will be stratified into 3 categories. The weekly leaderboard contains reference times from healthy individuals who have completed the same exercises until discontinuation. The reference values come from a previous data collection by the principal researcher and are from a different study population. Healthy, active participants

completed the same exercises in this study until discontinuation.

Weekly Leaderboard

Exercise	Avg Day 1 time (s)	Avg Day 2 Time (s)	Avg Day 3 Time (s)	Avg Time (s)	Top Time (s)	Reference time (s)
PBP						95
TESP (R)						59
TESP (L)						59
FESP (R)						43
FESP (L)						43
Dead bug						100
Bird dog						135

- All questionnaires and surveys that will be collected from the subjects are listed below.

Patient Reported Outcomes (Subjective Questionnaires)

Each group will be completing the ODI, NPRS, CEQ, FABQ, PCS, Hooper and MacKinnon and Pain Catastrophizing questionnaire at baseline, after 3 weeks and after 6 weeks. The SUS, EARS will be completed after 3 weeks and 6 weeks. The GROC will be completed after the 6th week. All questionnaires will be completed again through REDCap at the 12, 18, and 24-month time points.

Lateral abdominal wall muscle thickness will be collected during the baseline session and during the last exercise session of the 6th week.

6.4 Data collected during the study will include the ODI, NPRS, CEQ, FABQ, Hooper and MacKinnon and PCS questionnaire at baseline, after 3 weeks and after 6 weeks. The SUS, EARS will be completed at 3 weeks and 6 weeks. The GROC will be completed after the 6th week. All questionnaires will be

completed again through emails notification for participants to complete through REDCap.

6.5 All questionnaires will be completed again through REDCap at the 12, 18, and 24-month time points.

6.6 N/A

7.0 Data and Specimen Banking*

7.1 Ultrasound data will be stored on password protected lab computer for measurement. All data will be de-identified at all stages of collection and analysis. There will be a separate file that includes the name of a participant and participant number that will stored separately. This file will also be destroyed at least 5 years after the study closure (ParticipantIdentifierDoc). De-identified data will be stored until study closure, then will be maintained on password protected lab computer and stored for at least 5 years after study closure, then destroyed. All questionnaire information will be recorded and kept through REDCap, which requires a UCF login with NID and password. Only members of the study team will have access to the REDCap forms and data associated with this protocol.

7.2 The data to be stored with each participant will include the ultrasound images, weekly exercise forms, questionnaires.

7.3 Data will be stored and maintained through analysis by the study team and will not be released for any reason.

8.0 Sharing of Results with Subjects*

8.1 Results will not be shared with subjects unless any incidental findings arise and only the PI will notify the subject directly of the finding and consult with them and discuss if they believe they should seek further medical attention if appropriate. Results will not be shared with any other medical providers without the subject's knowledge or permission within the scope of this study. The investigators do not anticipate this situation to occur frequently due to the nature of this protocol.

9.0 Study Timelines*

9.1 This is 6-week randomized controlled trial that consists of all subjects to complete 2 in person visits of 1.5-2 hours in the READY Laboratory (first and last exercise sessions). There are planned follow up visits with questionnaires through REDCap at 12-, 18-, and 24-months following completion of the intervention. We expect to enroll and collect data for all subjects within a 4-month time frame from the start of enrollment. We estimate this study to be completed and

primary analyses to be completed within 8 months of the start of enrollment.

10.0 Inclusion and Exclusion Criteria*

10.1 Individuals will be screened for inclusion and exclusion criteria by self-reporting while reading the consent form and prior to giving consent.

10.2 Inclusion Criteria: ages 18-45*,* biological sex of Male or Female, self-reported low back pain within the previous 6 months or greater than 3 episodes within the past 3 years

Exclusion Criteria:

- Currently seeing and or receiving care from an athletic trainer, physical therapist, or other rehabilitation specialist in the previous 6 months,
- low back pain conditions such as lumbar spondylosis, herniated disc, spondylolisthesis, previous spine surgery, currently pregnant, experiencing neurological symptoms or other muscular abnormalities.
- Unable to assume the exercise starting position.
- Current use of lidocaine patches or prescription pain medicine.

10.3 Adults unable to consent, pregnant women, prisoners, and individuals who are not yet adults, including, infants, children, and teenagers will not be allowed to participate in this study.

11.0 Vulnerable Populations*

N/A

12.0 Local Number of Subjects

12.1 Based on previous research regarding home exercise and disability with low back pain we determine that 40 participants (20 in each group) will be necessary, alpha set *a priori* to .05. 40 participants include a 15% attrition rate.

12.2 A total of 34 individuals (17 per group) will be adequate with 80% power at an alpha level of .05. We include a 15% attrition rate which results in a total sample size of 40 individuals, 20 in each group

13.0 Recruitment Methods

13.1 Potential subjects will be recruited from the local community and university area through flyer advertisements,

emails, social media (twitter, Instagram and facebook), digital advertisement on the College of Health Professions and Sciences Research Participant Website as well as word of mouth. The same advertisement will be used for flyers, social media, and digital. Individuals interested in the study will use the email listed on the advertisement flyer. Upon receiving an email for a potential participant, the initial email will be sent to schedule an appointment for the first visit for screening and consent (initial email doc). Reminders about collection will be sent on the day before and if applicable (e.g., afternoon collection) on the same morning. The reminder emails will provide an opportunity for participants to confirm or reschedule (ReminderEmailRCTLBP).

13.2 Subjects will be from the local community and that may consist greatly of the university community.

13.3 Emails (containing the advertisement flyer) and social media advertisements (same text for both) will be posted to university groups throughout the Institute of Exercise Physiology and Rehabilitation Science (which is where the PI's laboratory is located) as well as targeted toward active groups on campus, i.e. Campus Recreation. All content is the same for the flyer that will be used for email and social media recruitment.

13.4 Printed advertisements, email, and social media (twitter, Instagram and facebook) advertisement will be utilized and are included in the IRB submission. All advertisements will be that of the flyer uploaded under "Recruitment materials"

13.5 Participants will be paid up to $75 in gift cards for their time and effort. $20 will be given after week 3, then $25 will be given after week 6 and then $10 for each of the long term follow up times at 12, 18 and 24 months. Due to the lengthy protocol, the completion of 3 weeks, 6 weeks and long term follow up times will be used as times the participants get paid in the event a subject withdraws.

14.0 Withdrawal of Subjects*

14.1 If subjects no longer meet eligibility requirements or injure themselves, they will be withdrawn from the study by the principal investigator.

14.2 N/A

14.3 When subjects withdraw, data collected prior to collection may be used for analysis, however they may exit the study at any point. Due to the compensation for the week 3, week 6, and long term follow up benchmarks, the subjects should be able to withdraw with no major issues.

15.0 Risks to Subjects*

15.1 There is a minimal risk for injury. Minimal risks that may occur related to study participation include muscle soreness during or after exercise, discomfort in joints of lower and upper extremity during or after exercise, which both are expected to occur infrequently.

15.2 N/A

15.3 N/A

15.4 N/A

16.0 Potential Benefits to Subjects*

16.1 Potential benefits that individual participants may experience from taking part in the research include decrease in pain and disability.

16.2 N/A.

17.0 Data Management* and Confidentiality

17.1 For this study, the endpoint is defined as based on previous research regarding home exercise and disability with low back pain we determine that 40 participants (20 in each group) will be necessary, alpha set *a priori* to .05. 40 participants include a 15% attrition rate. Descriptive statistics will be used for age, height, mass. Mean differences, confidence intervals and effect sizes will be used to analyze questionnaires. An activation ratio will be used for the lateral abdominal wall measurements. The static positioning measuring will be used as the numerator and the exercise starting position will be used at the denominator to calculate a ratio.

17.2 All computers storing electronic data will be password protected and only study team members will have access to the passwords. Computers will always remain behind locked doors when not supervised by study team members. All external hard drives used to back up storage will be password protected. Only study team members will have access to these passwords. These passwords will be changed frequently and will be changed immediately if compromised at any point in time.

Participant numbers will be generated by using the IRB # and will be assigned a number (i.e. IRB#12345_001) as they are enrolled in the study. This number will be utilized in place of any other identifier for the remainder of the study.

Identifiers with de-identified coding will be stored electronically on Redcap and will be deleted after a minimum of 5 years from the time the study closes.

17.3 To ensure quality control of collected data, the 7 exercises performed by participants at their home setting will be demonstrated and taught during the first exercise session with the researcher. Weekly video calls through zoom and emails will be conducted to answer any comments or concerns regarding the exercise completion. We will get in touch with the participants weekly either using zoom (video call) or by email to answer any comments or concerns regarding the exercise completion. The participants email will be provided to the principal investigator when they email showing interest in the study. The leaderboard group will have on demand video that can be accessed at any time and the control take-home packet group will have a packet with pictures and descriptions of the exercises.

17.4 Questionnaire data will be collected electronically through REDCap. All data will be de-identified at all stages of collection and analysis. Data will be stored until study closure, then will be maintained on password protected lab computer and de-identified for at least 5 years. Signed electronic consent forms will be stored for a minimum of 5 years before being destroyed as well. All questionnaires and surveys will be kept in de-identified electronic folders on REDCap, separate from electronically signed consent forms, also for a minimum of 5 years before being destroyed. Only the PI and study team will have access to the data. Ultrasound measurements of the lateral abdominal wall will be de-identified and stored on password protected laboratory computer.

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

18.1 N/A

19.0 Provisions to Protect the Privacy Interests of Subjects

19.1 In order to protect subjects' privacy interests, the study team is small and trained to communicate with the subject that the READY laboratory is a quiet and private area where their information will be protected.

19.2 Subjects will be given as much time as necessary to review and look over any forms or questionnaires to determine comfort level and ask any questions or express concerns

throughout the study. The READY Lab is in a private area where others will not be able to observe their participation in the study if that is a concern for the subject. If there is an overwhelming sense of intrusiveness, the subject always has the right to remove themselves from the study at any time. The study team takes all measures to keep the READY Lab quiet, private, and welcoming for all individuals to feel comfortable participating, but also understands that the nature of some questioning and procedures may provoke an early exit for a subject. All questionnaires completed not in the laboratory will be recorded and kept through REDCap, which requires a UCF login with NID and password. Only members of the study team will have access to the REDCap forms and data associated with this protocol.

19.3 The research team will not be accessing any source of information not self-reported by the subject for this protocol.

20.0 Compensation for Research-Related Injury

20.1 N/A

20.2 N/A

21.0 Economic Burden to Subjects

21.1 Subjects will be responsible for any travel and parking costs incurred getting to and from the data collection session. All testing and questionnaires will be provided free of charge to the subjects.

22.0 Consent Process

22.1 Written informed consent will be obtained for all subjects electronically on REDCap.

The consenting process, including answering any questions and obtaining verbal consent as well as electronic consent, will take READY laboratory in the Education Complex on the UCF Main Campus. There will be no waiting period between informing the prospective subject and obtaining the consent.

This protocol will follow the “SOP: Informed Consent Process for Research (HRP-090).”

The READY Lab is in a private area where others will not be able to observe their participation in the study if that is a concern for the subject. If there is an overwhelming sense of intrusiveness, the subject always has the right to remove themselves from the study at any time.

The researcher will be close by to answer any questions and concerns about the consent process. This aid in minimizing the risk of coercion or undue influence as well as ensuring the subjects understanding.

23.0 Process to Document Consent in Writing

23.0 Electronic consent will be obtained. A signed copy of the consent will not be provided to the participant.

24.0 Setting

24.1 In person research will be conducted in the READY laboratory in the Education Complex on the main campus of the University of Central Florida.

Potential subjects will be recruited from the local community and university area. Research procedures will be performed in the READY laboratory main campus of UCF and at participants home exercise environment. There is no community advisory board involved in this study.

25.0 Resources Available

25.1 Due to the number of individuals in the university area and surrounding East Orlando community, recruiting, and enrolling 40 healthy subjects within a 4-month timeframe is very feasible. Out of the number of students, faculty, and staff on the main campus in general, we do not foresee an issue with recruitment.
The PI will be the primary contributor in conducting and completing the research.
The Rehabilitation Athletic assessment & Dynamic Imaging Laboratory is located in the Education Complex on the first floor in Room 174. It is a 7x11 foot space equipped with a GE NextGen Logiq e ultrasound unit, Delsys Trigno Avanti Electromyography+Inertial Measurement Unit+Biofeedback System, hand-held dynamometer, digital inclinometer, adjustable high/low treatment table, and rehabilitation and exercise equipment.
There is an automated external defibrillator (AED) located just outside of the READY Lab in the hallway leading to Room 174 and a first aid kit for any small wounds. The PI is also a certified and licensed Athletic Trainer in the state of Florida, as well an American Red Cross Certified Professional Rescuer in CPR/AED and First Aid. We are also located near Student Health and CAPS, if the subject happens to be a UCF student, and study team members are also trained to call 911 in case

of any emergency. Any events that would result in an emergency would be reported to the IRB appropriately.
All study team members have thoroughly read and studied the protocol and are up to date on all appropriate training. They have met and discussed with the PI their role and clearly described and agreed to that designated in the protocol. They were given time to answer questions to insure they had time to fully understand or clear up any misunderstanding prior to contact with any subjects or commencement of the protocol.

N/A

Multi-Site Research*

N/A

REFERENCES

1. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. *Lancet*. 2017;389(10070):736-747. doi:10.1016/S0140-6736(16)30970-9

2. Bardin LD, King P, Maher CG. Diagnostic triage for low back pain: a practical approach for primary care. *Med J Aust*. 2017;206(6):268-273. doi:10.5694/mja16.00828

3. George SZ, Fritz JM, Silfies SP, et al. Interventions for the management of acute and chronic low back pain: revision 2021. *J Orthop Sports Phys Ther*. 2021;51(11):CPG1-CPG60. doi:10.2519/jospt.2021.0304

4. Tonosu J, Takeshita K, Hara N, et al. The normative score and the cut-off value of the Oswestry Disability Index (ODI). *European Spine Journal*. 2012;21(8). doi:10.1007/s00586-012-2173-7

5. National Collaborating Centre for Primary Care (UK). *Low Back Pain: Early Management of Persistent Non-Specific Low Back Pain*. Royal College of General Practitioners (UK); 2009. Accessed June 9, 2022. http://www.ncbi.nlm.nih.gov/books/NBK11702/

6. Di Fabio RP, Mackey G, Holte JB. Disability and Functional Status in Patients With Low Back Pain Receiving Workers' Compensation: A Descriptive Study With Implications for the Efficacy of Physical Therapy. *Physical Therapy*. 1995;75(3):180-193. doi:10.1093/ptj/75.3.180

7. Friedrich M, Gittler G, Halberstadt Y, Cermak T, Heiller I. Combined exercise and motivation program: Effect on the compliance and level of disability of patients with chronic low back pain: A randomized controlled trial. *Archives of Physical Medicine and Rehabilitation*. 1998;79(5):475-487. doi:10.1016/S0003-9993(98)90059-4

8. Härkäpää K, Järvikoski A, Mellin G, Hurri H, Luoma J. Health locus of control beliefs and psychological distress as predictors for treatment outcome in low-back pain patients: results of a 3-month follow-up of a controlled intervention study. *Pain*. 1991;46(1):35-41. doi:10.1016/0304-3959(91)90031-R

9. Reilly K, Lovejoy B, Williams R, Roth H. Differences between a Supervised and Independent Strength and Conditioning Program with Chronic Low Back Syndromes. *Journal of Occupational and Environmental Medicine*. 1989;31(6):547-550.

10. Hodges PW. Is there a role for transversus abdominis in lumbo-pelvic stability? *Man Ther*. 1999;4(2):74-86. doi:10.1054/math.1999.0169

11. Hodges P, Cresswell A, Thorstensson A. Preparatory trunk motion accompanies rapid upper limb movement. *Exp Brain Res*. 1999;124(1):69-79. doi:10.1007/s002210050601

12. Bunce SM, Moore AP, Hough AD. M-mode ultrasound: a reliable measure of transversus abdominis thickness? *Clinical Biomechanics*. 2002;17(4):315-317. doi:10.1016/S0268-0033(02)00011-6

13. Bunce SM, Hough AD, Moore AP. Measurement of abdominal muscle thickness using M-mode ultrasound imaging during functional activities. *Manual Therapy*. 2004;9(1):41-44. doi:10.1016/S1356-689X(03)00069-9

14. Devorski L, Bazett-Jones D, Mangum LC, Glaviano NR. Muscle activation in the shoulder girdle and lumbopelvic-hip complex during common therapeutic

exercises. *Journal of Sport Rehabilitation*. 2021;1(aop):1-7. doi:10.1123/jsr.2020-0485

15. Ferreira GE, Lin CWC, Stevens ML, et al. Exercise Is Medicine, But Perhaps Not for Preventing Low Back Pain: A Randomized Trial of Exercise and Education to Prevent Low Back Pain Recurrence. *J Orthop Sports Phys Ther*. 2021;51(4):188-195. doi:10.2519/jospt.2021.10187

16. Vancini RL, Andrade MS, Viana RB, et al. Physical exercise and COVID-19 pandemic in PubMed: Two months of dynamics and one year of original scientific production. *Sports Med Health Sci*. 2021;3(2):80-92. doi:10.1016/j.smhs.2021.04.004

17. McGill SM, Karpowicz A. Exercises for spine stabilization: motion/motor patterns, stability progressions, and clinical technique. *Archives of Physical Medicine and Rehabilitation*. 2009;90(1):118-126. doi:10.1016/j.apmr.2008.06.026

18. Durall CJ, Greene PF, Kernozek TW. A comparison of two isometric tests of trunk flexor endurance. *The Journal of Strength & Conditioning Research*. 2012;26(7):1939-1944. doi:10.1519/JSC.0b013e318237ea1c

19. Flanagan EW, Beyl RA, Fearnbach SN, Altazan AD, Martin CK, Redman LM. The impact of COVID-19 stay-at-home orders on health behaviors in adults. *Obesity (Silver Spring)*. 2021;29(2):438-445. doi:10.1002/oby.23066

20. The impact of coronavirus on global activity. Fitbit Blog. Published March 24, 2020. Accessed January 27, 2022. https://blog.fitbit.com/covid-19-global-activity/

21. Nicholls JG. Achievement motivation: Conceptions of ability, subjective experience, task choice, and performance. *Psychological Review*. 1984;91(3):328-346. doi:10.1037/0033-295X.91.3.328

22. Bugten JB, Lugo RG, Steptoe K. Validation of the need for competing inventory. *Frontiers in Psychology*. 2021;12. Accessed January 26, 2022. https://www.frontiersin.org/article/10.3389/fpsyg.2021.721903