



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

Investigator: Luk Devorski, MS, ATC

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because are between the ages 18-45, biological sex of male or female, have self-reported low back pain within the previous 6 months or greater than 3 episodes within the past 3 years.

You are not currently receiving and/or received care from an athletic trainer, physical therapist, or other rehabilitation specialist in the previous 6 months. You do not have any low back pain conditions such as lumbar spondylosis, herniated disc, spondylolisthesis, previous spine surgery, currently pregnant, experiencing neurological symptoms or other muscular abnormalities. You are not currently using lidocaine patches or prescription pain medicine. You are able to assume the exercise starting position of a prone bridge plank, torso elevated side plank, foot elevated side plank, dead bug, and bird dog.

Why is this research being done?

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 (leaderboard group) compared to a take home packet exercise program (take-home exercise packet group). Additionally, to measure the change of ultrasound thickness of the abdomen wall before and after a competitive home exercise program compared to a take home packet exercise program. The difference between the two exercise programs being compared is that the leaderboard group will receive a weekly leaderboard of hold times for each exercise and the take-home exercise packet group will not. In the leaderboard group, you will be able to compare your exercise durations to the average durations and overall longest duration of other participants in your group. Additionally, the leaderboard group will also have reference values of healthy individuals overall hold times per each exercise.

How long will the research last and what will I need to do?

We expect that you will be in this research study for 6-weeks with follow up questionnaires at 3-weeks, 6-weeks, 12-months, 18-months and 24-months.

You will be randomized into one of two groups, 1) leaderboard group: a group that receives on demand videos of the exercises or 2) take-home packet group: a group that receives a

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paper take home exercise packet. You will complete a weekly exercise form that consists of each exercise's duration of completion.

You will be asked to complete questionnaires asking previous and current health history, demographic information (age, sex, height, and weight). Also, questionnaires asking about low back pain, disability, your feelings toward exercise that may influence anxiety, thoughts and feelings you have when you are in pain, and beliefs of avoiding motion or exercise due to fear of pain.

The first exercise session and last exercise session will take place in the READY laboratory. Ultrasound images of your abdomen will be obtained during resting positions and exercise starting positions for each exercise and resting position. There will be 30 images taken of both sides of the abdominal wall, creating a total of 60 images during rested positioning and exercise starting positioning.

You will be asked to complete exercise sessions of the prone bridge plank, torso elevated side plank, foot elevated side plank, dead bug, and bird dog at your home environment for 6-weeks. The first and second week of exercise will include one repetition of the seven exercises completed until discontinuation, three times a week. Weeks 3-4 will require two repetitions of the seven exercises, three times a week. Weeks 5-6 will require three repetitions of exercises, three times a week.

You will be asked to complete the same questionnaires through REDCap asking about low back pain, disability, your feelings toward exercise that may influence anxiety and beliefs of avoiding motion or exercise due to fear of pain. These will be done after 3 weeks and after 6 weeks. Additionally, you will complete a current mood questionnaire the morning after each exercise session and on Sundays. You will also be asked to complete a system usability and exercise adherence scale after 3 weeks and 6 weeks. Lastly you will complete a global rating of change score after the 6th week. All questionnaires related to pain and disability will be completed again through REDCap at the 12-, 18-, and 24-month time points. We will get in touch with you weekly either using zoom (video call) or by email to answer any comments or concerns regarding the exercise completion. If you are in the take-home packet group you will receive a packet of the exercises during the first visit. If you are in the leaderboard group, you will be provided an email during the first visit that will contain private YouTube links of videos describing and demonstrating the exercises only accessible via the link provided to you.

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be in this research?”***

Is there any way being in this study could be bad for me?

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.

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include decrease in pain and disability.

What happens if I do not want to be in this research?

Your participation in this study is voluntary. You are free to withdraw your consent and discontinue participation in this study at any time without prejudice or penalty. Your decision to participate or not participate in this study will in no way affect your continued enrollment, grades, employment or your relationship with UCF or the individuals who may have an interest in this study.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team: at luk.devorski@ucf.edu or lauren.mangum@ucf.edu

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 407-823-2901 or irb@ucf.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect 40 people will be in this research study.

What happens if I say yes, I want to be in this research?

The take-home 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. 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.

Consent and Screening: (~15-20min)

After you sign this informed consent form, you will fill out a questionnaire asking about your previous and current health history. Demographic information will also be collected at this time, including, age, sex, height, and weight. You will also complete questionnaires asking about your low back pain, disability, your feelings toward exercise that may influence anxiety, thoughts and feelings you have when you are in pain, and beliefs of avoiding motion or exercise due to fear of pain. The remaining study procedures will begin immediately after we determine your eligibility, or you can return at another date to complete the remainder of the study procedures for the first visit.

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 you how the exercises should be performed. The exercises are pictured on page 6 & 7 of this consent form.

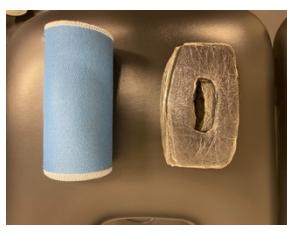
Dynamic Ultrasound setup and exercise completion (up to ~45 min)

The ultrasound probe will be placed 10cm from your belly button to the right side of the torso.

- 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 probe will then be moved to your left abdomen and pictures will be repeated.

Upon the collection of 60 images, we will remove the ultrasound probe. You will then complete the PBP, TESP, FESP, dead bug, and bird dog until you can no longer hold the correct exercise form. The TESP and FESP will be completed bilaterally (for both sides) so the left and right elbow will be placed on the ground.



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

When you complete the exercises at this in-person visit, we will explain how you will upload the completed weekly exercise form to REDCap during your at-home exercise weeks. The form will include exercise duration and an exercise form rating. We will also discuss the

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weekly video meetings. An example of the weekly exercise form is below. This form will be completed and uploaded to REDCap before or by the end of the day each Sunday, the last day of the exercise week.

Week 1	Repetitions	Day 1 Time	Day 2 Time	Day 3 time
PBP	Rep 1			
	Rep 2			
	Rep 3			

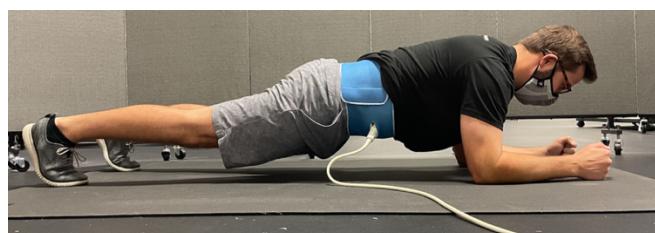
Group comparison:

We will use your weekly exercise forms to compare outcomes of the leaderboard group that is using the on-demand videos with the outcomes of the take-home packet group that is using the exercise packet. If you are in the leaderboard group, we will provide you with a “leaderboard” (pictured below) that shows the averages and top times of other people in your group.

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

PBP static position and starting position:



TESP static position and starting position:



FESP static position and starting position:



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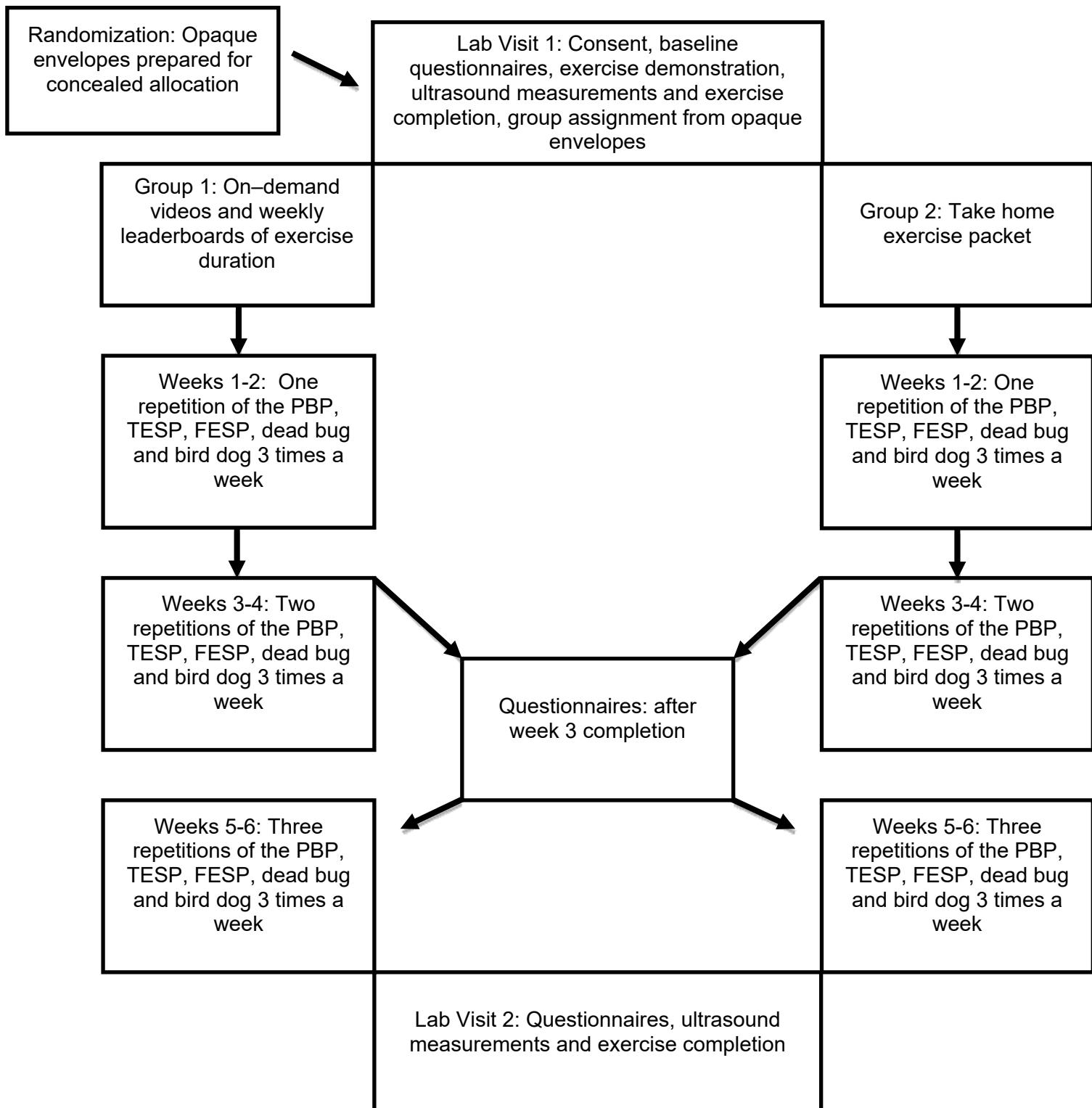
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Dead bug static position and starting position:



Bird dog static position and starting position:





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The treatment you get will be chosen by chance, like flipping a coin. A 3rd party not involved with the study will complete concealed allocation with opaque envelopes to determine what treatment you get. You will have an equal chance of being given each treatment.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to: Complete the first and last exercise session with the researcher in the READY laboratory. Complete questionnaires at baseline, after 3 weeks, after 6 weeks. Complete 3 exercise sessions of 1 repetition for the first 2 weeks, complete 3 exercise sessions of 2 repetitions for weeks 3 to 4 and complete 3 exercise sessions of 3 repetitions for weeks 5 to 6.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. It will not be held against you. If you decide to stop, please tell us right away. The researchers may still use the information about you that was collected before you ended your participation.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

What else do I need to know?

If you do not have a UCF parking pass, you will be responsible for any parking fees for coming to the READY laboratory. If you agree to take part in this research study, we will pay you up to \$75 in gift cards for your time and effort. \$20 will be given after completion of week 3, then \$25 will be given after completion of week 6 and then \$10 for each of the long term follow up times at 12, 18 and 24 months.

Signature Block for Capable Adult

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

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent