Document Coversheet

Study Title: Development of a Mind Body Program for Obese Knee Osteoarthritis Patients With Comorbid Depression: Does a Mind Body Program Reduce Osteoarthritis Pain?

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KEY INFORMATION FOR

Development of a mind body program for knee osteoarthritis patients withcomorbid depression: does a minD bOdy prOgram Reduces oSTEoarthritisPain? (DOORSTEP Clinical Trial)

We are asking you to choose whether or not to volunteer for a research study about knee osteoarthritis, unhealthy weight, and depression. We are asking you because you have these 3 common conditions. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions.If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn more about 2 on-line programs for people with knee arthritis, depressive symptoms, and unhealthy weight. Your participation in this research will last 8 weeks (1 week before the program starts and 1 week after the program ends), with a 45-minute online session done once per week for 6 weeks followed by a 30-minute online interview after youcomplete the 6-week program. Your participation in this research will last 6 hours over 8 weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

This research study is designed to explore the potential success of different on-line programs for people who have knee osteoarthritis, depression, and unhealthy weight.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might choose not to volunteer for this study if you do not want to be audio recorded during the online sessions or you do not want to have the 2 blood draws or urine collection done as partof the study. Also, you might not want to volunteer because you will be required to provide the contact information of two people whom investigators could contact if you exhibit signs of suicidality during the study.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Caitlin Conley, PhD of the University of Kentucky, Departmentof Orthopedic Surgery and Sports Medicine. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: Address: Caitlin Conley, PhD, 740 S Limestone, Suite K401, Lexington, KY 40536-0284, Phone: (859)
257-1939, and email: caitlin.conley2@uky.edu.

If you have any concerns or questions about your rights as a volunteer in this research, contactstaff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the businesshours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866- 400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

You should not take part in this study if:

- your doctor has recommended you have knee replacement surgery,
- unable to walk/wheelchair-bound,
- do not speak or read English,
- taking high doses of opioid pain medication (equivalent to more than 50 mg of morphine per day),
- have rheumatoid arthritis,
- have a history of cancer within the past 5 years,
- have a disorder requiring the use of systemic corticosteroids,
- have another condition or injury that is your primary source of pain such as fibromyalgia, low back pain, or apainful joint replacement in your other knee or either hip,
- have a medical illness expected to worsen in the next 6 months (e.g., malignancy),
- have a history of schizophrenia, bipolar disorder, or other psychotic disorder,
- suicidal thoughts or were hospitalized in the past year for a psychiatric condition,
- current substance abuse or dependence, or a substance use disorder within the past 6 months,
- you have practiced yoga, meditation, or other mind body techniques once per week for 45 min or more withinthe last 3 months, or
- you participate in regular moderate or vigorous physical exercise for more 30 min daily.
- do not have a computer/smart phone with internet access

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at a place of your choosing such as your home. Most of the study activities can be done on a computer or tablet in your own home or another place of your choosing that has a stable internet connection. Depending on which physician is treating you, the 2 test sessions will either be at theUK Healthcare - Turfland offices located at 2195 Harrodsburg Rd, Suite 125, Lexington, KY 40504 or the UK Healthcare Good Samaritan Medical Office Building located at 125 E Maxwell St, Suite 201, Lexington, KY40508.

The initial questionnaires to see if you qualify for the study will take about 15 minutes to complete. If you qualify for the study, you will then be asked to participate in remote sessions via secured telehealth on your computer or tablet. The study will last 8 weeks. During the first week, you will attend a testing session at the UK Turfland offices where you will complete study questionnaires, have a blood draw and provide a urine sample. You will also be asked to take a activity tracker that looks like a wrist watch home with you and wear it for the next 7 days. Once you have completed the baseline testing, the next 6 weeks of the study will involve you attending a 45-minute online session one per week. After completing the online sessions, you will be asked to return to the UK Turfland offices and complete the same questionnaires and study procedures that you had done at the beginning of the study including wearing the activity tracking wrist watch for 7 days. Lastly, you will be asked to provide blood and urine samples at the beginning and end of the study and each of those visits will last about 45 minutes. The total amount of time required for the study is about 6 hours over the course of 8 weeks.

WHAT WILL YOU BE ASKED TO DO?

First, we will use demographic information from your medical records to determine your eligibility and then we will ask you to complete a series of questionnaires about your medical history, your knee pain and symptoms, and depressive symptoms. Only those with mild to moderate knee pain and depressive symptoms will be askedto participate in this study.

Pre- and post-testing

During the week before and the week after the on-line program, you will be asked to travel to the University of Kentucky to complete study assessments including collection of biological data which includes blood and urine samples which will be used to test inflammatory markers. We will collect about 2 teaspoons of blood from your arm. We will also ask you to complete a 40 meter walk test. During the walk test, you will be asked to walk 10 meters (33 feet), then walk back to where you started, and then again walk 10 meters (33 feet) again and again return to the start. In total you will walk 40 meters which is a little less than half the length of a football field. We will ask you to walk this distance as fast as you feel that can be safely done, and we will record how fast you can you are able to go. You can use a cane, crutches, or walker if needed. You will also pick up a digital device called an Actigraph that looks like a wrist watch and tracks your movement and will help track of how active you are.

You will be asked to wear it around your wrist like a watch for 7 days before and 7 days after you complete the on- line program. You will be instructed on how to wear the accelerometer and you will log your activity in an activitylog. It is important to know that the Actigraph accelerometer, will be reused with other study participants. It is not yours to keep and we will give you a prepaid envelope for you to mail the Accelerometer back to us.

The on-line programs

The two on-line programs will be delivered remotely by a psychologist based at Massachusetts General Hospital via secure telehealth and we will assess symptoms and monitor any technical difficulties. You will only take partin one of the programs, and both programs are designed to specifically help people with arthritis that also have depression and unhealthy weight. Both programs consist of 6 sessions that will last about 45 minutes. The sessions are done on your smartphone or computer, and will include a group of 4 to 5 other people with knee arthritis who are also taking part in the study with you at the same time.

Exit interview

You will be asked to complete an exit interview in which we will ask for your feedback about the program. We will audio record our conversation, and then transcribe it to remember everything we say. The only people who will read this transcript will be our trained research staff. If we use anything you share, we will do so in a way that you cannot be personally identified.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There is a risk that someone could get access to the stored information. People outside of the University of Kentucky will have access to identifiers. In spite of the security measures and safeguards we will use; we cannot guarantee that your identity will never become known.

Blood draws: There is a risk of local pain, soreness, bleeding, bruising and swelling, as well as lightheadedness, dizziness and rarely, fainting and/or a local infection.

In addition to risks described in this consent, you may experience a previously unknown risk.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. Your willingness to take part may; however, increase knowledge regarding the treatment of knee osteoarthritis and help other people with arthritisin the future.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

You will be responsible for transportation to the testing site (University of Kentucky)

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

Therefore, the costs of the on-line study programs done strictly for research will be paid by the University of Kentucky.

In addition, the following costs will be paid by the study:

- Laboratory tests of blood and urine samples collected
- All questionnaires

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. The study information collected from your participation in the study willbe entered into a secure computer system. The study doctor is committed to maintaining the privacy of everystudy subject and any personal information submitted. They follow the principles of the Health Insurance Portability and Accountability Act (HIPAA) of 1996. All data is stored at a secure site behind a firewall, which monitors and protects against unauthorized access.

Your research information or any other items containing confidential information about you will be stored in Caitlin Conley's office (Kentucky Clinic, Suite K401).

You should know that in some cases we may have to show your information to other people. For example, thelaw may require us to share your information with:

- authorities if you pose a danger to yourself or someone else.

To ensure the study Is conducted properly, officials of the University of Kentucky, Harvard University,Massachusetts General Hospital, and the National Institutes of Health (NIH) may look at or copy pertinent portions of records that identify you.

To help us protect your privacy, this research has a Certificate of Confidentiality. The researchers canuse this Certificate to refuse to disclose information that may identify you to anyone not connected with thisstudy, or in any legal proceedings. The exceptions to this rule are release of information:

- you have requested us to provide, for instance, to your insurance company or doctor;
- to the sponsor (e.g., National Institutes of Health) or agency auditing the research (e.g., Food and Drug Administration);
- about child or elder abuse, neglect, or harm to yourself or others; and
- about you if it involves a reportable disease.

This policy does not prevent you from releasing information about your own participation in this study.

Your information will be stored online using REDCap. REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online platforms, we cannot guarantee the security of data obtained by way of the Internet.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking partin the study.

If you choose to leave the study early, data collected until that point will remain in the study database and maynot be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions, or
- you do not meet the inclusion/exclusion criteria for the study, or
- you exhibit signs of suicidality during the study, in which case you will be referred for treatment. Youwill be required to provide the name, email and phone number of two people who can be contacted in case of such an emergency.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAMETIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?
If you believe you are hurt or if you get sick because of something that is due to the study, you should call Caitlin Conley at 859-257-1939 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm

- will be your responsibility
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances)
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?
If your knee pain or depressive symptoms disqualify you from taking part in the study, you will not receive payment for completing the initial questionnaires. For those that do qualify, you will need to complete a form verifying your address and contact information.

You will receive $30 after completing the in-person baseline testing and $30 returning the Actigraph activity monitor in the mail in the self-addressed stamped envelope that we will give you. Similarly, you will receive another $30 after completing the in-person testing after you have completed the program, and again will receive an additional $30 for returning the Actigraph activity monitor to us in the mail. You will also receive $50 for completing the exit interview. This is a total compensation of $170 for attending both test sessions, returning the Actigraph activity monitor before and after the program, and completing the exit interview. Payment, in the form of a check, will be sent approximately 4 to 6 weeks following each of the 2 test sessions. If you decide to withdraw before the end of the study, you will still receive the baseline $30 to $60 but will not be able to receive the second $30 to $60 compensation or $50 for the exit interview.

With a few exceptions, study payments are considered taxable income reportable to the Internal Review Service (IRS). A form 1099 will be sent to you if your total payments for research participation are $600 or more in a calendar year.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?
Generally, tests done for research purposes are not meant to provide clinical information. Since the results are only important for research, the study has no plans to provide you with individual test results.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISIONTO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?
The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 2 times per year.

Do you give your permission to be contacted in the future by Caitlin Conley, PhD or his staff regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 60 people to do so. The National Institutes of Health (NIH) is providing financial support for this study.

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

WILL YOUR INFORMATION OR SAMPLES BE USED FOR FUTURE RESEARCH?

Your information or samples collected for this study will NOT be used or shared for future research studies, even if we remove the identifiable information like your name, medical record number, or date of birth.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

Your health information that may be accessed, used and/or released includes:

- Demographic information including age, sex, height, weight, ethnicity, and race
- Medical history related to this study
- Physical exam results related to this study
- X-ray results related to this study
- Questionnaires and responses completed as part of the study
- Laboratory results from your blood and urine samples completed as part of the study
- Physical activity information collected with the Actigraph as part of the study

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity
- The University of Kentucky's Center for Clinical and Translational Science
- Law enforcement agencies when required by law
- University of Kentucky representatives
- Massachusetts General Hospital representatives
- Harvard University representatives
- National Institutes of Health (NIH)

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You may not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**
- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) collect or release yourhealth information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Caitlin Conley, PhD, 740 S Limestone, Suite K401, Lexington, KY40536-0284 to inform him of your decision.
- Researchers may use and release your health information already collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

You understand that you will not be allowed to review the information collected for this research study until after the study is completed. When the study is over, you will have the right to access the information.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have anyquestions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

Signature of research subject	**Date**
Printed name of research subject	
Printed name of [authorized] person obtaining informed consent and HIPAA authorization	Date