Cover Page

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Informed Consent Form (ICF)

Official Study Title:
Increasing Physical Activity in Older Adults With Osteoarthritis Pain: Examining a Brief Behavioral Intervention

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Principal Investigator:
Jennifer Plumb Vilardaga, PhD

Sponsor:
National Institutes of Health (NIH)

Participating Sites:
Duke University

DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
(Engaging in Physical Activity)

CONCISE SUMMARY:

The purpose of this study is to evaluate how older adults might benefit from sessions that teach behavioral coping skills for increasing physical activity as compared to treatment per usual. Participants will attend an initial study visit that includes learning about the study and completing an initial assessment. This initial visit will take 45-60 minutes. Once the initial assessment is complete, participants will be randomized (like the flip of a coin) to either receive 2 individual sessions (the Engage condition) with a behavioral therapist or will continue treatment as usual. All participants will then receive their own personal fitness tracking device, which can be worn like a wrist watch that will be used to track physical activity levels such as number of daily steps. All participants will write down their daily steps each night. The Engage condition participants will attend two 45-minute sessions with a study therapist, approximately two weeks apart. Participants will be asked to complete a total of two assessments in the study; one at the beginning of the study, and one 6 weeks after starting the study. Each assessment includes answering a set of questions on a computer or paper/pencil for 7 days in a row. The online questionnaires should take about 20 minutes to complete each time. Study staff will have access to data collected from your personal fitness tracker only during the time you are in the study. Total study duration is approximately 8 weeks. The greatest risks of this study include the possibility of loss of confidentiality.

You are being asked to take part in this research study because you have been diagnosed and treated for osteoarthritis. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Jennifer Plumb Vilardaga, PhD, will conduct this study and it is funded by the National Institutes of Health (NIH). The sponsor of this study, the National Institute of Health, will pay Duke University to perform this research, and these funds may reimburse part of Dr. Plumb Vilardaga's salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, you will not have a different medical doctor. Your regular doctor will continue to be your doctor throughout the time that you are in the study. A member of the study team may be in contact with your doctor throughout the time you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate how older adults might benefit from sessions that teach behavioral coping skills for increasing physical activity as compared to treatment per usual. The purpose

of this study is to investigate if a behavioral skills program, Engage, will help patients with osteoarthritis pain increase physical activity such as number of steps walked per day and better manage their pain. Engage consists of working with a trained therapist learning methods to increase physical activity and manage your pain.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 50 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you decide to participate in this study, you will be asked to sign and date this consent form.

You will then complete questionnaires using a computer or paper/pencil. The questions asked will be about your pain, physical functioning, and how you think and feel about your pain. We expect these questions to take about 20 minutes to complete.

In this study, you will receive a personal fitness tracker to use throughout the duration of the study and will get to keep at the study's end. At your first visit you will be asked to wear the personal fitness tracker around your wrist and to write down your daily steps for 7 days in a row.

Following this, you will be randomized (like flipping a coin) to either receive two Engage sessions with a behavioral therapist or will continue treatment as usual. All participants will continue to write down their daily steps each night. Data from the personal fitness trackers will be available to study staff only during study participation.

The Engage participants will attend two 45-minute sessions with a study therapist, approximately two weeks apart. Engage consists of working with a trained therapist learning methods to increase physical activity and manage your pain, such as strategic activity pacing, goal setting, and linking physical activity goals to meaningful personal life activities. Your Engage appointments will take place in person at our research offices or in the clinics in which you receive your medical care at Duke University Medical Center. Visits with your study therapist will be audio recorded. Audio files will be reviewed by Dr. Plumb Vilardaga and trained study staff for research purposes.

Six weeks after joining the study, you will be asked to fill out questionnaires using a computer or paper/pencil. You will continue to wear the personal fitness tracker and to write down your daily steps for 7 days in a row. At the end of the second assessment, you no longer need to write down your daily steps.

You will participate in these assessments for a total of two times; at the beginning of the study, and approximately 6 weeks after joining the study. The online questionnaires should take about 20 minutes to complete each time. Total study duration is approximately 8 weeks.

HOW LONG WILL I BE IN THIS STUDY?

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You will be in the study for up to 8 weeks. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
There are no physical risks associated with this study. There is some risk of loss of confidentiality due to the use of an automated study email to invite you to complete online assessment questionnaires. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Discussing stressors associated with pain may be upsetting. You also have the option of not discussing concerns you find upsetting.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefits to you. You may find that your participation in the study intervention increases your physical activity, and/or improves your pain, psychological coping skills and/or other symptoms. We also hope the information learned from this study will benefit other patients with osteoarthritis.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Plumb Vilardaga's office located at 2200 W. Main St. Suite 340 Durham NC 27705.

All audio recordings will be stored on an encrypted laptop and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke Office of Audit, Risk and Compliance, Duke University Health System Institutional Review Board. If your research record is reviewed by this group, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

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The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As part of this study, Dr. Plumb Vilardaga and her study team will ask you to complete assessments. Results of the assessments done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

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WHAT ARE THE COSTS TO YOU?

There will be no costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?

You will receive $30 for completing each of the two major study assessments (two sets of questionnaires that take approximately 20 minutes each). Total compensation may be up to $60. If you choose to withdraw from the study, you only will receive compensation for the parts of the study that you completed.

WHAT ABOUT RESEARCH RELATED INJURIES?

Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact Dr. Plumb Vilardaga at (919) 668-6123 during regular business hours or after hours at 775-247-3955.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Plumb Vilardaga in writing and let her know that you are withdrawing from the study. You may keep your personal fitness tracker. Her mailing address is Jennifer Plumb Vilardaga, PhD, 2200 West Main St., Suite 340, Durham, NC 27705.

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

If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them. The use of your data may result in commercial profit. You will not be compensated for the use of your data other than what is described in this consent form.

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A description of this clinical trial will be available on https://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.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Plumb Vilardaga at (919) 668-6123 during regular business hours and at 775-247-3955 on evenings, weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

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STATEMENT OF CONSENT

"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time