Wake Forest®
School of Medicine

Department of Anesthesiology,
Division of Pain Medicine

A Mobile Intervention to Reduce Pain and Improve Health (MORPH) – Phase II

Informed Consent Form to Participate in Research

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Introduction

You are invited to take part in this research study. Research studies are designed to give scientific knowledge that can help other people in the future. You have been asked to be involved in this study because you are 55-85 years old, fit the health and weight requirements, and because you are interested in participating in MORPH. Remember that your participation is voluntary. We encourage you to take your time making your decision as to whether or not you would like to participate. Please ask the study staff to explain any and all words or information in this informed consent document that you do not understand fully. We may also discuss this study with your doctor, friends, and family.

Why are we Conducting the MORPH Study?

This study will help us understand how we can help those with chronic pain to move more and lose weight, and then better understand how these help to manage pain symptoms.

How Many People Will Take Part in MORPH?

A total of 35 individuals will take part in this study. To have 35 individuals participate in this study, we may need to screen as many as 90 individuals, as some may not qualify for the study.

What is Involved in this Study?

If you agree to participate in MORPH by signing this informed consent form, you will be asked to attend a total of 2 assessment visits (V1 and V4) at a Wake Forest Baptist Medical Center facility. During your time in the active intervention study period, you may be asked to attend 2 orientation sessions, 3 in-person group coaching sessions (one per week), followed by 9 group internet-based coaching sessions (one per week).

Visit 1 (V1)

During this visit, we will:

- Review this consent form with you
- Measure your height, weight, blood pressure and pulse
- Ask you to complete a series of questions about your background, medical history, medications, feelings, and memory

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00046364
Meeting Date Approved 9/27/2019
Version Valid Until: 2/13/2020

- Ask you to complete a short series of physical tasks that involve balancing, walking over short distances, and rising from a chair.
- You will be randomized in person at this visit or by phone after the visit to your study group

This visit will take 2-3 hours to complete.

Randomization

During or following V1, you will be randomly assigned to one of the two study groups listed below. One small group of approximately 5 individuals will participant in an initial wave and will all be assigned to the MORPH Immediate Intervention group. All other participants have a 1 in 2 (equal) chance of being placed into either group. You must agree to be in any of the groups and you may not pick or change the group that you are placed in. You will participate in your assigned group for a total of about 14 weeks before the final testing visit is conducted.

The groups are:

1. MORPH Immediate Intervention
2. MORPH Delayed Intervention

We will provide *all* participants with an activity monitor (Fitbit), which is a small watch-like device that gives you information about your activity level, and we will ask that you wear this daily. All participants will also receive an electronic scale that allows you to keep track of your weight over time. Participants that complete the program will be allowed to keep the activity monitor but are asked to return the scale. If either device breaks during the study, you will receive a replacement at no charge but we ask that you take care of both to ensure you are able to use them both throughout the study. Additionally, all participants will receive the thigh-worn activity monitor (Activpal) in-person or by mail. You will be asked to wear the device prior to the start of the study and once more throughout the final week of the study and return it at your last visit.

The MORPH Intervention program

When you start your MORPH intervention program (either immediately or after your delay) you will have 2 orientation sessions. The first orientation will focus on the technology in the study and be an introduction to a smartphone app, a weight scale, and two activity monitors: (1) an activity monitor watch that will be worn for the duration of the study (Fitbit), and (2) an activity monitor that is worn on the thigh for one week (ActivPal). This visit is expected to take between 60 and 90 minutes. The second orientation will focus on your diet instructions. This orientation is also expected to last 60-90 minutes. These orientations will be in a small group setting at a Wake Forest Baptist Medical Center facility.

Participants will receive a weight scale and access to the MORPH study app. During the first 3 weeks of the 12-week program, participants will be asked to attend one in-person group coaching session at a Wake Forest Baptist Medical Center facility per week. For the remaining 9 weeks, participants will be asked to "attend" virtual group coaching sessions by using a computer or smartphone, and participants will receive instruction for these sessions during the initial 3 weeks.

Throughout the program, you will use your activity monitor and scale, alongside the app and the group sessions, to learn about how your movement, sitting, and weight affect your pain and how

you can use these behaviors to help manage your pain symptoms. You will set goals for movement with the group leader, and will receive feedback on your movement in real time within the app. You will track the food that you eat throughout the program either using study-provided logs or electronic tracking software, and the group leader will help you to set weight loss goals. Finally, during weeks 1, 5, and 9, you will complete a series of 6 short daily surveys that take 60-90 seconds to complete. These will allow you to report things like your current level of pain and your current mood, and we will use this information to send you encouraging prompts to move. In summary, these participants will be asked to attend once-weekly sessions, check in with the study app, complete smartphone-based surveys, and use the activity monitor and scale daily.

The MORPH Delayed Intervention

Participants assigned to the delayed intervention will receive an activity monitor watch. This watch comes with an application that allows the participants to monitor activity behaviors over time. Participants in this condition will be asked to wear the activity monitor each day for the duration of the study period. If you are in this group you will have a brief orientation session to help you understand this monitor. You will receive a monthly call from the study staff to check in during this time. After you have completed your Visit 4 (V4) assessment visit, you will have the option of enrolling in the active intervention program. If agreed, you will be scheduled for your two orientations and the 12-week MORPH intervention program.

Visit 4 (V4) at about 14-19 weeks after V1

During this visit, we will:

- Measure your height, weight, blood pressure and pulse
- Ask you to complete a series of questions about your medical history, medications, and feelings
- Ask you to complete a short series of physical tasks that involve balancing, walking over short distances, and rising from a chair.

This visit will take up to 2 hours to complete.

How Long Will I Be in the Study?

You will be in the study for approximately four to eight months depending on your group assignment. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the study investigators or study staff first to learn more about potential health or safety consequences.

What are the Risks of the Study?

Being in this movement and weight loss study involves some risk. You should discuss the risk of being in this study with the study investigators or staff. A Data Safety and Monitoring Committee, an independent group of experts, will be reviewing the data from this research throughout the study. Risks and side effects related to the study programs and procedures include:

1. Diet Program

There are no known serious risks associated with using caloric restriction to lose weight. Changes in usual bowel function (diarrhea and/or constipation) may occur when beginning the new diet due to differences between this diet and your usual diet. Under conditions of rapid weight loss (more than 5 pounds per week), there is a very small chance of developing gallbladder disease.

2. Movement Program

The risks of the exercise program are minimal, but may include fainting, dizziness, irregular heartbeat, chest pain, heart attack, exacerbation of pain symptoms, or in extremely rare circumstances, sudden death. They may also include stresses and strains of muscles, twisted ankles, or falls. During the program, be sure to report any such changes in your health to study staff.

3. Physical Performance Tests

There is a slight risk of falls while participating in the balance test. However, you will be positioned beside a step or wall that can be reached immediately if you feel that you are going to lose your balance. Additionally, the staff member conducting the test will stand next to you at all times. There is a small possibility that you may stumble, fall or aggravate one of your joints/muscles during the walking test. You will not be asked to conduct these tests if you have a pre-existing and serious leg injury.

4.Activity Monitors

Risks associated with wearing the activity monitors are minimal, but may include minor skin irritations. You will be instructed to note these on your log and if it becomes bothersome to remove the device and call staff for further instructions.

5. Confidentiality

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe. As part of this study, you will wear a Fitbit activity monitor, receive text messages to complete brief surveys about your mood and pain severity, and use a web application to view feedback. These data will be transmitted on a secure connection and any potentially sensitive information (e.g., survey responses) will be encoded using a secret key stored separate from your information before they are stored on a password-protected server operated by 1&1 Internet Inc. Finally, once you complete the study, we will destroy the link with your encoded phone number.

As part of this research study, you will be videotaped/audiotaped. This is being done to assess how user-friendly the app is. You should understand that you will not be able to inspect, review, or approve the videotapes and audiotapes. These tapes will be destroyed once their use in this study is finished.

Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. The benefits of participating in this study include receiving information about your physical function, your weight, and your movement, and we hope that you begin to learn how your movement levels affect your daily pain. A possible benefit is that by losing weight you may reduce your risk for diabetes and heart disease. However, because individuals respond differently to diet, no one can know in advance if it will be helpful in your particular case.

What Other Choices Are There?

This is not a treatment study, and so the alternative is to not participate in this study.

What About My Health Information?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: health history, your family health history, how you respond to study activities or procedures, and information from study visits, phone calls, and surveys.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) The study investigators and their staff, or others at Wake Forest University Health Sciences who oversee research,

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell a study PI that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

WFU School of Medicine
Institutional Review Board
IRB Number: IRB00046364
Meeting Date Approved 9/27/2019
Version Valid Until: 2/13/2020

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center may indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record may be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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

What Are the Costs?

There are no costs to you for taking part in this study. All study costs, including any procedures related directly to the study will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

You will receive a parking voucher that will cover the cost of parking for each of your visits if needed.

Will You Be Paid for Participating?

You will receive no payment or other compensation for taking part in this study.

Will Your Research Records Be Confidential?

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have

consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by Bayer Healthcare Pharmaceuticals which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Who is Sponsoring this Study?

This study is being sponsored by The National Institute of Health (NIH)/National Institute on Aging (NIA). The sponsor is providing money or other support to Wake Forest Baptist Health to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related

illness, adverse event, or injury you should call Amber Brooks, MD, [redacted] after hours.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because:

- your study doctor feels it is in your best interest;
- you may not be following the instructions properly;
- you do not later consent to any future changes that may be made in the study plan;
- or for any other reason.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Amber Brooks, MD, at [redacted] after hours.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted]

You will be given a copy of this signed consent form.

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Signatures

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____

Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____

Date: _____ Time: _____ am pm

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