Participant's Name: _____ **Date:** _____

Title of Study: A Pragmatic Trial to Determine the Benefit of Exercise Incentives and Corticosteroid Injections for Osteoarthritis of the Knee: Marching On for Veterans with Osteoarthritis of the Knee (MOVE OK)

Principal Investigator's Name: Joshua F. Baker, MD, MSCE

SUMMARY OF STUDY

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

We are asking you to choose whether or not to volunteer for a research study being funded by VA Rehabilitation Research & Development. This initial material is to give you key information to help you decide whether to participate. We have included detailed information about this study. Ask the research team questions. Taking part in this study is completely voluntary. In this study we are hoping to learn whether joint injections combined with a web-based interactive program can help veterans with osteoarthritis increase their physical activity and improve their symptoms.

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

If you participate in this study, you will be given a FitBit activity monitor and you will sign up to the study website and download the FitBit app. The website will have your phone number and you will receive text messages from our team. You may be asked to choose a support person to root you on. During the study you will receive two injections. One only contains numbing medicine and one also contains corticosteroids (depomedrol). The study will enroll about 40 veterans.

By doing this study, we hope to learn how to help veterans increase their physical activity and reduce symptoms of arthritis. Your participation in this research will last about 8-10 months.

Another purpose of this research is to gather information on the safety and effectiveness of joint injections with depomedrol, an FDA-approved treatment for knee osteoarthritis that you have been getting or were planning to get. The use in the study is consistent with labeling indications.

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

You may be interested in volunteering if you have longstanding knee pain. You may also consider participating if you are interested in increasing your physical activity. For a complete description of benefits, refer to the Research Details section of this document.

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

If you participate, you will not receive your usual injections and you will receive an injection at some point that does not include corticosteorids but only numbing medicine. You will have to provide your cell phone number to the website and sign up to the FitBit app. For a complete description of risks, refer to the Research Details section of this document. If you do not want to participate, you can continue your usual care with your doctor. For a complete description of alternate treatment/procedures, refer to the Research Details section of this document.

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 Joshua Baker of the Corporal Michael J. Crescenz VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: 3900 Woodland Avenue, Research, Building 21, Room A212, Philadelphia, PA 19104. Office Phone: 215-823-5800, extension 6174.If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

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Principal Investigator's Name: Joshua F. Baker, MD, MSCE

RESEARCH DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to see if corticosteroid (cortisone) injections and web-based and other encouragements to increase physical activity can promote physical activity and improve disability and pain in patients with knee osteoarthritis. With this research we hope to learn whether interacting with a website and receiving text messages and other feedback from the study and/or other family members or friends can help veterans increase their physical activity and, in doing so, reduce the symptoms of their arthritis.

Another purpose of this research is to see if steroid injections are safe and effective for treating your knee osteoarthritis.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

Your individual participation in this study will be for up to one year. You will have a total of 3 research visits at the Corporal Michael J. Crescenz VA Medical Center (CMCVAMC). Each visit will take about 2 hours. We plan to enroll about 40 Veterans from the CMCVAMC.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY AND WHAT IS EXPECTED IF I TAKE PART IN THIS STUDY?

Before you are fully enrolled in the study, you will be scheduled for an initial visit at the CMCVAMC to see if this is the right study for you to participate in. This visit will take place in the Rheumatology Clinic or in the Clinical Research Center (4th floor, Room A433).

During this visit, your informed consent for participation will be obtained, study staff will review all study related procedures and ask you to fill out questionnaires about your feelings of your knee pain and other questions regarding your medical history. You will be provided with a Fitbit activity tracker and asked to download on your smartphone the Fitbit application and register on the Way to Health platform to link your Fitbit account. Study staff will assist you with setting these things up. You will have to sign up to the FitBit application and enter your name and email address. You will also be prompted by the FitBit application to enter your date of birth so that the program can calculate your age. However, if you do not feel comfortable sharing your date of birth you do not have to. You will not be require to pay for any applications.

You then will be shown how to use the Way to Health mobile platform, which is a software application developed at the University of Pennsylvania. This application allows the ability to

connect with your Fitbit activity tracker, which will remotely send the study team your daily activity levels. You will also be asked to use this platform to set your steps goals and fill out the required study questionnaires at various time points within the study (more information is provided below).

After completion of your initial visit, there is a 2-4 week trial period to see if this is the right study for you to participate in. During this time, you will be expected to wear your Fitbit activity tracker each day and "sync" it with the Way to Health platform. Syncing means to merge the data from the Fitbit to the Fitbit App on the smartphone. Usually this is automatic. If you do not sync your Fitbit regularly or use the Fitbit regularly during this time, you might be asked not to continue in the study.

Following this period, you will be scheduled for two knee injections. While you get injections as part of your usual clinical care, the injections in this study will be different as explained below. The first of these injections will occur after your next research visit and the second will occur about 4 months after your first injection. If you currently receive injections every 3 months, you may have to wait an extra month between the injections. These injections will take place within the Rheumatology Clinic located on the 1st floor of the CMCVAMC in Module E.

Prior to your first injection visit, you will meet with study staff for another research visit. Based upon your average steps acquired in using the FitBit device, you will be asked to choose a step goal that you would like to reach. You will receive a daily reminder to sync your Fitbit. Depending on each individual's cell phone plans, text messaging fees may apply.

You will be asked to complete a series of questionnaires using the Way to Health website about your medical history, pain medication use, pain, pain related behaviors, feelings about your knee pain, physical activity, disability, fatigue and sleep quality. These surveys will be asked at different times in follow-up as well. You will answer questionnaires at your initial visit, prior to both injection visits, and every 2 weeks during your study participation. These surveys are expected to take between 10 and 25 minutes to complete each time you take them.
The study coordinator will also use an "algometer" to measure your sensitivity to pain at each injection visit (2 separate times). The algometer is pressed on different areas of your body. You will be asked to tell the coordinator performing the test when you start to experience pain. This can cause some minor pain similar to what you might experience during a physical exam with your doctor.

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The next part of the study involves two different "randomization" steps. Randomization is like a flip of a coin. One randomization will be the type of injection you get. The other randomization will be to determine what incentives you get to exercise. So you will be placed into one of 4 different study arms.

At your injection visits, you will meet with the study team and have an injection administered by a physician or nurse practitioner on the study team. If your provider is on the study team, they may be able to continue to give the injections. Otherwise, you would receive your injection from another provider that is part of the study team. You will have a chance of receiving one of two injections. Some individuals will receive both corticosteroids (cortisone) and Lidocaine (numbing medicine), while others will receive only Lidocaine (numbing medicine) injections. This assignment is completely random and you will not know which one you will be receiving until you have completed your study participation. The syringe will have tape on it so that you cannot see what is being injected. Thus, for one of the two injections you get during your participation in this study will **not** be with steroids and this is different than what you would be getting if you did not participate in this study.

If you develop pain after an injection, we will help you get an urgent appointment in rheumatology clinic. If you and your provider believe you would benefit from another injection, you will be permitted to receive another injection at this visit. Being in the study means that there is a change you would receive an additional injection which carries the same risk as the other injections.

The other randomization that occurs in this study is whether you will have social incentives or not. If you are assigned to a group with incentives, you will receive incentives to exercise and be asked to share your progress with a family member or friend. You will be asked to enter their telephone number into the website so they can receive information about your exercise. You may also receive a report of your step performance via text message or email. We will also send you a text message to remind you to sync the FitBit with your phone and to complete assessments every 2 weeks.

If you are assigned to a group that does not get incentives, we will just send you text messages to remind you to sync the FitBit with your phone and to complete assessments every 2 weeks.

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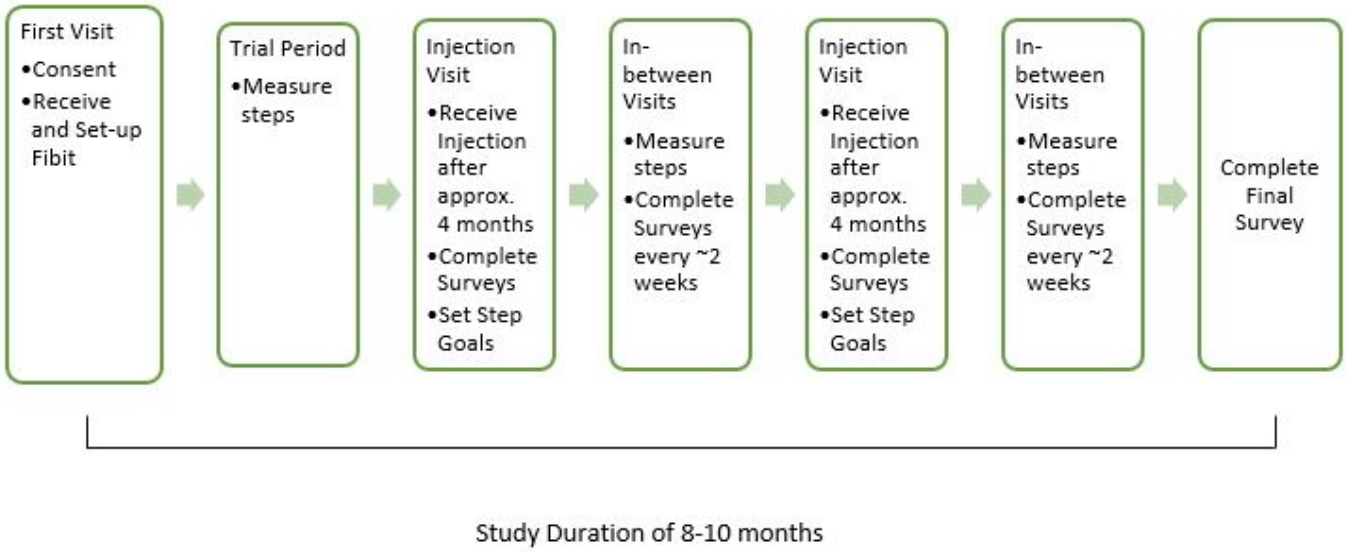

The image above is an overview of the visitation schedule (described previously) if you consent to participate in the study.

During the course of your participation in this study, we will be leaving research notes in your chart. In these notes, we will include clinically relevant information related to your participation in this study. Study results such as your survey responses and step counts will not be shared with your clinical providers. This will include whether you received an injection, though the medication you received will not be put in the notes.

For your participation, you will be compensated:

- $30 for your initial visit
- $30 for each injection visit
- $30 for completing the end of study questionnaires.

You will also receive:

- $10 for each set of surveys completed (occurring every 2 weeks)
- $20 each month ($5 per week) for syncing the FitBit at least once a month.

Total participation equals up to $400 over the course of 10 months if you complete all tasks. The amount you receive will be based upon the study activities you actually complete. You will be

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sent a check for each amount about every 3 months. You will also be able to keep your FitBit at the end of the study.

All study procedures will be done at the CMCVAMC Rheumatology Clinic (1st floor Module E) and/or the Clinical Research Center (4th Floor, Room A433).

If your clinical provider collects synovial fluid from your joint when you receive the injection, we would like to store and use any leftover fluid for future testing in our research lab. You will not be able to profit from any commercial product developed from your specimens.

☐ **YES,** I **AGREE** to have my synovial fluid stored for future research
☐ **NO,** I do **NOT** agree to have my synovial fluid stored for future research.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Risks associated with injection: If you are being enrolled in this study, you have been receiving cortisone injections or have planned to receive them. The doctor or nurse practitioner performing the procedure will discuss the risks of the procedure before performing the procedure and you will sign a separate consent for the procedure. These injections can be associated with pain and swelling where the needle enters the skin. Local bruising is also possible. Approximately 1 in 10,000 to 50,000 people receiving an injection will get a joint infection which can require hospitalization, surgery, and/or treatment with antibiotics. If you are on blood thinners there is also a small risk of bleeding into the joint. A possible risk is that you may not receive as much benefit in terms of pain with the lidocaine only injection. If, as a result, you require another injection to reduce your pain, the same risks of an injection will apply to that extra procedure. You will also receive a standard dose of the steroid if you participate in the study. If you have been receiving a different dose up until now, you will be required to get a different dose that may affect how well it works.

Risks associated with Algometer: You may feel some tenderness in the areas where the pressure is being measured.

Risks associated with Fitbit: You may feel uncomfortable wearing the Fitbit for extended periods of time. You may experience minor frustration with syncing the Fitbit to the Way to Health platform. If you have any questions, please feel free to contact the study staff at any time. Finally, increasing your physical activity could possibly result in injury or a flare of your arthritis.

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Risks from sharing your information: Your directly identifible information will be recorded by the study team and stored on the VA servers in a password-protected folder. Your other study information (step counts and survey results) will be stored on the Way to Health platform over at the University of Pennsylvania along with a study identifier (a unique code). Your name and date of birth will not be stored on the University of Pennsylvania database. However, you will be required to share your phone number and/or e-mail address with the Way to Health platform so that you can receive text messages and/or emails. The Way to Health platform is protected with software that is similar to what is used to protect medical record information.

You may also feel uncomfortable about sharing your activity progress with social contacts you may designate if randomized to the group that are getting incentives.You might also experience anxiety about receiving updates on your progress by text message every day.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

You may not benefit from participating in this research study. The study may benefit you increasing your physical activity level and reducing the symptoms of your arthritis. Additionally, this study may lead to information that can aid in the clinical care of people with osteoarthritis of the knee.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. You may choose not to participate and continue with the routine care (and get injections) provided by your primary rheumatologist.

FUTURE USE OF DATA AND RE-CONTACT

During the course of this study, It is possible you may be contacted and asked if you want to participate in future studies related to this study. You do not have to participate in these future studies if you do not want to.

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☐ **YES**, I would be interested in being re-contacted for future research related to this study.

☐ **NO**, I am **not** interested in being re-contacted for future research related to this study.

Identifiers might be removed from the identifiable private information that are collected (and from identifiable biospecimens if you agreed to let us collect them). After that removal, the information (or biospecimens) could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not have to pay for any research procedures, tests or equipment that result from participating in this study. Depending on your cell phone data plan, standard text messaging fees may apply.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

During this study, we will collect personal information such as:

- your name,
- address,
- telephone number,
- email address,
- date of birth,
- social security/medical record number,
- personal medical history,
- results from physical examinations,
- tests or procedures, and nicotine and alcohol use.

Your name and social security/medical record number will be used only as necessary within the CMCVAMC. The funding agency will not have access to your study data. You will be require to enter your phone number into the web-based "Way To Health" platform at the University of Pennsylvania. The "Way To Health" platform will also collect your step information from the FitBit app but will not collect any information such as your name, date of birth, or address.

To protect the confidentiality of your records, all written or printed documents collected for this research study will be stored in a locked file cabinet in a locked office at the CMCVAMC. Any electronic research data collected will be stored on a secure CMCVAMC server. As explained

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previously, because some study activities will be done using the Way to Health platform some personal information (cell phone number and/or email address), will be stored within the system. If you have an accident or reaction during the course of the study, your entire medical record may be used and disclosed as clinically necessary.

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

This informed consent document will be added to your medical record.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

All research records, including the investigator's research records, must be retained according to the National Archives and Records Administration VHA's Records Control Schedule.

Health Information Portability and Accountability Act (HIPAA)
There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the HIPAA Privacy Rule, also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the HIPAA Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records such as your medical history. You will be required to enter your phone number into the web-based "Way To Health" platform at the University of Pennsylvania. The "Way To Health" platform will also collect your step information from the FitBit app and the answers you provide to surveys throughout the study, but will not collect any information such as your name, date of birth, or address.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include the local Institutional Review Board, Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), and the Government Accountability (GAO).

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Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Joshua Baker and his or her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

It is important that you tell the study doctor, Joshua Baker, MD, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call him at (215)-823-5800, extension 6174. You are also encouraged to tell your VA or non-VA Primary Care Physician if you experience any injury or medical problem while you are in the study.

DO I HAVE TO TAKE PART IN THE STUDY?

You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you withdraw, you may be asked to return for a final study visit in order to assure your safety. You should withdraw in writing using the Revocation of Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration Research form. Even if you withdraw, we can continue to use information about you that has been collected up to that point. No information will be collected after you formally withdraw in writing.

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time without your consent because:

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- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions. For example, not syncing your Fitbit or not completing surveys for a prolonged period or you lose your FitBit.
- Your medical condition changes or if you require hospitalization.
- The Sponsor or the Principal Investigator has decided to stop the study.

If your study participation is stopped early, you will keep the Fitbit and continue your medications as directed by your primary care physician. The study team will help ensure you have follow-up with your usual arthritis doctor. Early withdrawal from the study poses no health risks for you.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

In case there are medical problems, research related injuries or questions, you have been told that you should call Dr. Baker at (215)-823-5800, extension 6174, or the study coordinator at (215)-823-4240 during the day. After hours, you should call the VA operator at 215-823-5800 and ask for Dr. Joshua Baker. If the operator is unable to reach Dr. Baker, you should ask to speak to the rheumatology fellow on call.

If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subject or you want to check the validity of the study and its personnel within the VA, you should contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM Monday through Friday.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Research and Development (R&D) Administrative Officer at (215)-823-6020 or R&D Associate Chief of Staff at (215)-823-5893.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

If new information comes to attention that alters the risks of you participating in the study, we will inform you of these changes in risk. You should not expect that any clinically-relevant research

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results will be provided to you from this study.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr. Baker or a member of his research team has explained the study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information for this study. You also confirm that you have read this consent document, or it has been read to you. You will receive a copy of this consent after you sign it. A copy of this signed consent will also be put in your medical record.

I agree to participate in this research study as has been explained in this document.		
Print Participant's Name	**Participant's Signature**	**Date Signed**

Individual Obtaining Consent (required)		
Print Individual's Name Obtaining Consent	**Signature of Individual Obtaining Consent**	**Date Signed**

Subject ID#_____ Date:_____

Informed Consent Mini Quiz for Study:

A Pragmatic Trial to Determine the Benefit of Exercise Incentives and Corticosteroid Injections for Osteoarthritis of the Knee: Marching On for Veterans with Osteoarthritis of the Knee (MOVE OK)

Please answer the following questions by circling the best possible response listed below the question.

1. What is the total time required for the participation of this study?
    a. 5 years
    b. 1 week
    c. 8 – 10 months
    d. 2 years

2. What is the research team hoping to gain or understand better by conducting this research study?
    a. to learn what ways are effective at helping veterans increase their physical activity, improve their function, and reduce their joint pain.
    b. is to gather information on the safety and effectiveness of corticosteroid injections on knee osteoarthritis.
    c. Both a and b
    d. None of the above

3. Which of the following statements is true about this study?
    a. You can choose to stop participating at any time
    b. Your participation in this study is required
    c. If you have a bad experience in the study, you must wait until it is over before you tell the study team

4. To participate in the study, you will be asked to:
    a. Wear Fitbit everyday
    b. Fill out surveys on your smartphone/tablet
    c. Receive injections with “cortisone”
    d. All of the above
    e. None of the above