FORM D – INFORMED CONSENT DOCUMENT

Volunteer Name:	

375th MDG (Scott AFB), 99th MDG (Nellis AFB), 60TH MDG (Travis AFB)
INFORMED CONSENT DOCUMENT

Title of Protocol:	Use of a Self-Guided Mindfulness Mobile Application to Improve Pain Outcomes in Individuals with Knee Osteoarthritis
FWH #:	FWH20190033H

KEY INFORMATION ABOUT STUDY PARTICIPATION: We are asking you to consider participation in a research study because you are a DoD beneficiary between the ages of 18 and 74 years old and meet the criteria for knee osteoarthritis. This goal of this study is to see if a mindfulness training via a smartphone mobile application is effective at improving osteoarthritis related knee pain. Once you are deemed eligible to participate, you will be randomized (like flipping a coin) into either the intervention or control group. The intervention group will be provided with a pre-paid 12-week subscription to the mindfulness app, and showed how to use it. The control group will be provided with the My Water Balance app, and shown how to use it. Both groups will be instructed to their respective app for 10 minutes per day/5days per week and receive patient education regarding osteoarthritis. Everyone will be asked to complete questionnaires and a study diary at baseline, every week for 12 weeks, week 26, week 52, and week 104. Inadvertent breach of confidentiality is the primary risk associated with this study. This study will require the use of a third party app, namely Headspace or My Water Balance. Each of these apps store users' personal data, including name and email address, as well as user-inputted data within the application. There is a risk that this data may be compromised in the event of a breach of each application's third party secure servers. Both applications will store cookies on user's phones for the purpose of identifying users and remembering their preferences.

INFORMATION ABOUT THIS CONSENT FORM: You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign your name in more than one place in this document, as needed. Please take time to review this information carefully. You should talk to the researchers and ask any questions you may have about the study. You may also wish to talk to your friends, family, or a doctor about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the purpose and procedures of the study, including risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION: Your participation in this study is completely voluntary. If you choose not to participate in this research study or leave before the study is completed, your decision will not affect your eligibility for care or any other benefits to which you are entitled as a DoD beneficiary. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

PRINCIPAL INVESTIGATOR: The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety, and welfare as a participant in the research. The PI for this study is:

PI Name and Degrees:	Rank:	Branch:	Department and Base:
Jillian Sylvester, MD	Capt	USAF	FMR/ Scott AFB

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PURPOSE OF THIS STUDY (Why is this study being done?)**:** The purpose of this study is to see if mindfulness training via a smartphone mobile application is effective in improving osteoarthritis related knee pain. You are being asked to consider participation in this study because you are having symptoms of osteoarthirists of the knee and have access to a smartphone. This study will enroll approximately 360 subjects overall, with approximately 120 at Scott AFB O'Fallon Family Medicine Residency Clinic located at 3 St. Elizabeth's Blvd, Suite 4000, O'Fallon, IL and Scott AFB Family Health Clinic on-base, 120 at David Grant Medical Center 101 Bodin Cir, at Travis AFB, and 120 Mike O'Callaghan Federal Medical Center, 4700 Las Vegas Blvd North at Nellis AFB.

PROCEDURES: If you decide to take part in this research study, you will be asked to sign this consent form. During your participation in this study, you will be asked to make approximately 2 in-person research visits and 15 electronic contacts with the study staff over the course of 2 years (104 weeks). As a research participant, you will undergo the following research-related procedures.

If you decide to take part in this research study, you will be asked to sign this consent form.

SCREENING PROCESS TO QUALIFY FOR PARTICIPATION IN THIS STUDY:

- Obtain your Informed Consent Document and HIPAA Authorization.
- Review past medical history.
- We will record your age, gender, information regarding your knee osteoarthritis diagnosis, name of standard of care medications (over-the-counter and prescription), current email address (to be used for scheduling), height (in inches), weight (in pounds), current level of exercise, physical therapy in the past year, and prior experience with mindfulness.
- We will ask you to complete the a medical history questionnaire

This screening visit will take approximately 30 minutes. The results of the research-related screening procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Assignment to Research-Related Study Groups: When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin into 1 of 2 study groups.

- **Group 1:** Education regarding osteoarthritis, its natural history, and common treatments plus the mindfulness app. You will be provided with a pre-paid 12-week subscription to the mindfulness app (Headspace), and provided an in-person demonstration on how to use it. You will be asked to use the mindfulness app 10 minutes per day/5 days per week.

  Headspace employs brief audio-guided sessions that teach the principles of mindfulness. You will be asked to register for an account within the application using your name, an email address, and a password of your choosing. The application will collect usage data, tracking your time spent using the application and which specific mindfulness session (known as a "Pack") you used. Aggregate usage data will be provided to the study team by Headspace following the 12-week intervention period. This information will be associated with your subscription code, alone. No other information will be provided by Headspace to the study team.

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- **Group 2:** Education regarding osteoarthritis, its natural history, and common treatments plus the My Water Balance app. My Water Balance calculates a recommended daily water intake based on your weight and gender and assists in logging your water intake. It is a free application and you will be provided an in-person demonstration on how to use it. You will be asked to log your water intake for the 12-week duration of this study, with a minimum use of 5 days per week to create an equal control. Information logged in the application may be stored on a third party server; however, data placed in this application will not be extracted by the study team.

Study Procedures – as a participant, you will undergo the following study-related procedures:

Visit 1 (Baseline, in-person visit):

- You will receive education regarding osteoarthritis, its natural history, and common treatments.
- You will receive education about the Rx3 Home Exercise Program.
- You will be asked to perform the Rx3 Home Exercise Program 3 times weekly.
- You will be assigned a study ID# and will be given the following surveys on-line using Google Forms or Survey Monkey. You will use you pre-assigned study code to record on each completed questionnaire (*It will take approximately 20 minutes to complete these surveys*):
  - Knee injury and Osteoarthritis Outcome Score (KOOS).
  - Short Form-12 (SF-12).
  - Five Facet Mindfulness Questionnaire-15 (FFMQ-15) surveys.
- All participants will receive instructions per the randomization instructions above.
- All participants will be given a Medication Diary to complete on a weekly basis.

Weeks 2-11: You will receive weekly reminders (via email) asking that you use the app throughout the week. You will be asked to complete a short weekly survey using Google Forms or Survey Monkey (*It will take approximately 5 minutes to complete these surveys*) to include:

- The frequency and minutes used for the app (My Water Balance and Mindfulness app 10 minutes per day/5 days per week)
- The frequency and minutes spent performing the Rx3 Home Exercise Program in the past week (3 times weekly)
- Your use of NSAIDs or other over-the-counter pharmacologic methods of pain control in the past week.

Visit 2 (Week 12, electronic contact):

- You will complete the following anonymous surveys via Google Forms or Survey Monkey using your study ID# (*It will take approximately 20 minutes to complete these surveys*):
  - KOOS
  - FFMQ15
  - SF-12
  - 12 Week Survey
- At this visit, you will no longer have free access to the Headspace application.
- At this visit, you will be asked to cease use of the My Water Balance application.

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Visit 3 (Week 26, electronic contact):

- You will complete the following surveys and asked the following questions via Google Forms or Survey Monkey (*It will take approximately 25 minutes to complete these surveys*):
  - KOOS
  - FFMQ15
  - SF-12
- You will be asked about your continued use of the Rx3 Home Exercise Program, and over-the-counter analgesic use.
- ***Group 1***: will be asked about your continued use of mindfulness techniques.
- ***Group 2***: will be asked about your continued use of diet and exercise techniques.

Visit 4 (Week 52, electronic contact):

- You will complete the following anonymous surveys and asked the following questions via Google Forms or Survey Monkey using your study ID# (*It will take approximately 25 minutes to complete these surveys*)::
  - KOOS
  - FFMQ15
  - SF-12
- You will be asked about your continued use of the Rx3 Home Exercise Program, and over-the-counter analgesic use.
- ***Group 1***: will be asked about your continued use of mindfulness techniques.
- ***Group 2***: will be asked about your continued use of diet and exercise techniques.

Visit 5 (Week 104, electronic contact):

- You will complete the following anonymous surveys and asked the following questions via Google Forms or Survey Monkey using your study ID# (*It will take approximately 25 minutes to complete these surveys*)::
  - KOOS
  - FFMQ15
  - SF-12
- You will be asked about your continued use of the Rx3 Home Exercise Program, and over-the-counter analgesic use.
- ***Group 1***: will be asked about your continued use of mindfulness techniques.
- ***Group 2***: will be asked about your continued use of diet and exercise techniques.

RISKS OR DISCOMFORTS: There are no known risks associated with this study other than those related to an inadvertent breach of confidentiality.

Group 1: Headshpace (Intervention App): Participants in Group 1 will be asked to agree to the Terms and Conditions and Privacy Policy of the Headspace application during registration. As outlined in these documents, Headspace will maintain a record of an individual's name and email address. They will also track time spent on the application, the specific mindfulness sessions or packs employed, and the operating system upon which the app was accessed (iOS, Android, etc.). While this information is stored on an encrypted server, there is a risk of a security breach that would result in this data being compromised. While not a component of registration for this study, it is possible to link one's account with social media accounts such as Facebook. Linking one's social media account is not recommended and may result in compromise of more data, including Facebook profile information.

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Group 2: My Water Balance (Control App): Participants in Group 2 will be asked to download and My Water Balance on their personal smart phone and register for a free individual account. Doing so represents an agreement to their Terms and Conditions and Privacy Policy. This application will store user screennames, email addresses, chosen passwords, gender, and weight. In addition, it may store participants' recorded intake of water. During initial application setup, the application will be denied access to users' geographic location; however, there is a risk that individual users may reverse this option and the application may store this information. This information may be stored on a third party server and is subject to security breach and loss of confidentiality.

As a free application, you may be exposed to ads and will be offered the chance to upgrade to an ad-free, paid version. This study advises against all in-app purchases, as they are not a part of this study. It is possible to link use of this application to one's social media account on Facebook, Twitter, and Instagram. Doing so will allow the application to store their social media information, including username and profile contents. Linking one's social media account is not recommended and may result in compromise of more data in the event of a security breach.

WITHDRAWAL FROM THE STUDY: If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled.

COULD YOUR PARTICIPATION END EARLY? The researcher may withdraw you from the study prior to the study's end without your consent for one or more of the following reasons:

- Failure to follow the instructions of the researchers and study staff.
- The researcher decides that continuing your participation is not in your best interests.
- You become ineligible to participate.
- You need treatment not allowed in the study.
- The study is cancelled.
- Unanticipated circumstances.

If you lose your status as a military health care beneficiary, you can no longer be included in the study. Please let the Principal Investigator and study staff know as soon as you become aware of your situation.

BENEFITS: There is a potential for subjects to experience an improvement in their knee osteoarthritis, however, this is not a guarantee. There may be no direct benefit to you for participating in this study. We hope the information learned from this study may help future patients.

COSTS: Will taking part in this study cost anything? The investigators have designed this study so that there is no cost to you to participate in this study.

PAYMENT (COMPENSATION): You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS: You may choose not to participate in this study and still receive care for your knee osteoarthritis.

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CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION: Records of your participation in this study may only be disclosed in accordance with Federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, *Privacy Act Statement- Military Health Records*, contains the Privacy Act Statement for the records. By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further the generalizable knowledge of the medical science community. You will not be personally identified; all information will be presented as anonymous data. Your records may be reviewed by the Air Force, the DoD, other government agencies that oversee human research, and the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. All research data will be kept in an electronic database, which will be double password protected, firewall-protected, encrypted, and access-restricted to people involved in this study. The research data will be coded. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. Personal identifying information will be destroyed no later than at the closure of the study. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE: In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations, and if you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may contact the Director, 59 MDW Clinical Research Division at (210) 292-7069, 99th Medical Group Human Subject Research Protections POC at (702) 653-3298, 375th Medical Group Human Subject Research Protections POC at (618) 256-7638 or 60th Medical Group Human Subject Research Protections POC at (707) 423-7206.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

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PROTECTED HEALTH INFORMATION (PHI) AND PERSONAL IDENTIFYING INFORMATION (PII) DATA: All de-identified research data that will be used in the database repository will be kept at the Mike O'Callaghan Military Medical Center, Department of Family Medicine Residency and will be handled and disposed of in accordance with federal regulations. No unauthorized individual or agency outside of 99MDG will have access to this database without permission of the "Mike O'Callaghan Military Medical Center General Research Data Repository (FWH20180064H)", Manager, Col Paul Crawford, and the Wilford Hall Ambulatory Surgery Center (WHASC) 59th MDW Institutional Review Board (IRB).

The Investigators are asking for your permission to store your de-identified research data in the database repository for future use in research studies. The specifics of these research studies are unknown at this time. Your stored de-identified research data will be information such as your responses to the survey questions. This data is considered non-identifying information and cannot be traced back to you as a donor when added to a database. The Principal Investigator and Database Repository Manager will take every precaution possible to safeguard your information to eliminate the possibility of any breach of confidentiality. This is explained above in the section, "Confidentiality".

The Database Repository Manager, Col Paul Crawford, is responsible for all de-identified research data stored in the repository. All recipient investigators requesting data from the repository must have approval from the Database Repository Manager and must have a research study approved through a DoD Institutional Review Board (IRB) and the 59th MDW IRB. Only de-identified data (no personal identifiers or information) will be released to recipient investigators, so specific information can't be traced back to you as the donor of the data. Recipient investigators may only receive limited data sets of de-identified information necessary to conduct their research. Generally, you will not be provided with the results of these research studies using your de-identified data from the repository. Any results would be of unclear value and unknown clinical meaning, since your de-identified data will be combined with other de-identified data from numerous residents and/or patients used for the study. You will not be able to request that your de-identified research data be withdrawn from the database repository since we will have no way of identifying whom the data belongs to. If you have any questions, you can contact the Database Repository Manager at Col Paul Crawford or mailing your request to the following address: Col Paul Crawford, MD, c/o Department of Medical Education, 4700 Las Vegas Blvd North, Nellis AFB, NV 89191.

_____NO: I do not authorize the storage of my de-identified research data for future use in research studies.

_____YES: I authorize the storage of my de-identified research data for future use in research studies.

_____
Signature of Study Participant

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Principal Investigator (PI): The principal investigator and alternate member of research staff will be available to answer any questions concerning procedures throughout this study.

Location	Title	Name	Duty Phone	After-Hours Phone
375th Medical Group	Principal Investigator	Jillian Sylvester, MD, Capt	(618) 256-7311	(636) 364-8477
99th Medical Group	Associate Investigator	Matthew Hess, MD, Capt	(702) 653-3298	(702) 349-0452
60th Medical Group	Associate Investigator	Alexander Knobloch, MD, Capt	(707) 423-5349	(309) 631-0046

Institutional Review Board (IRB): The 59 MDW Institutional Review Board (IRB), the 59 MDW committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at 210-292-4683. You can contact the IRB by calling the Chairperson of the 59 MDW IRB at 210-916-8251, or by mail to IRB at 59 MDW/STC, 1100 Wilford Hall Loop, Bldg 4430, JBSA Lackland, Texas 78236. If you have any questions about your rights as a research subject, research-related injuries or any other concerns that cannot be addressed by the PI, you can also contact the 99th Medical Group Human Subject Research Protections POC at (702) 653-3298, 375th Medical Group Human Subject Research Protections POC at (618) 256-7638 or 60th Medical Group Human Subject Research Protections POC at (707) 423-7206.

All oral and written information and discussions about this study have been in English, a language in which you are fluent. If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form has been given to you for your records.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

VOLUNTEER'S PRINTED NAME

_____ _____ (_____)_____-_____

ADVISING STUDY STAFF SIGNATURE **DATE** **PHONE#**

_____

PRINTED NAME OF ADVISING STUDY STAFF

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