

Appendix 5. Aim 3 Stakeholder Consent

Jake Magel, PT, PhD, DSc, FAAOMPT
Physical Therapy Integrated with Mindfulness for Patients with Chronic Musculoskeletal Pain and Long-Term Opioid treatment
01/10/2024

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Consent Form
Physical Therapy Integrated with Mindfulness for Patients with Chronic Musculoskeletal Pain
and Long-Term Opioid Treatment (PT-IN-MIND)

KEY INFORMATION: The purpose of this research study is to understand stakeholders (clinic support staff, managers, executives), thoughts and perceptions related to physical therapists using PT-IN-MIND in your clinic or healthcare system. If you participate in this study, you will be asked to participate in a 30-minute interview. During the interview, you will be asked your thoughts about integrating mindfulness-based interventions into physical therapy. There is a potential risk of loss of confidentiality of your audio recording/or personal information collected for this study, though the study team will do everything they can to reduce this risk. This research will help us to improve the management of patients with chronic musculoskeletal pain and long-term opioid treatment. This study is voluntary, and it is up to you to decide whether you want to participate.

BACKGROUND

PT-IN-MIND is a physical therapist led treatment approach that integrates mindfulness-based interventions into routine physical therapy for patients with chronic musculoskeletal pain and long-term opioid treatment.

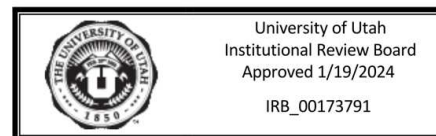
Eric Garland is a co-investigator for this research study, his intellectual property (MORE - Mindfulness-Oriented Recovery Enhancement) will be used in the study. This intellectual property is licensed through BehaVR, a company with which the investigator reports significant financial interest, as determined by the University of Utah conflict of interest policy.

Procedures: If you decide to participate in this study, you will be interviewed for approximately 30 minutes by a researcher over the phone or a virtual platform such as Zoom. The interview will involve discussing your impressions about and experience with physical therapists using PT-IN-MIND. The interviews may include discussing whether you feel that PT-IN-MIND is a treatment approach that fits well into an outpatient physical therapy environment. You may also be asked to provide your perspective on how to improve the ability of physical therapists to integrate mindfulness based treatments into routine physical therapy.

The interviews are recorded and transcribed. If you choose not to be audio recorded you will not be able to participate in this study. The transcript will be analyzed by investigators on the research team. Access to the interview will be limited to study personnel only. Any summary interview content or direct quotations from the interview that are made public through academic publications or other academic outlets will be anonymized so that you cannot be identified. The risks to participation in this study are minimal and include a potential breach of confidentiality for the information provided to researchers. Care will be taken not to reveal your identity through any information obtained in the interview.

There are no direct benefits to you. The possible benefit to society is to understand more about the physical therapy management of patients with musculoskeletal pain and long-term opioid use.

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VOLUNTARY PARTICIPATION

Your participation is completely voluntary. You may choose to withdraw from any part of this study at any time for any reason without penalty.

Confidentiality: If you do participate, all data including interview transcripts including the interviews, which will be recorded and stored as digital audio files, will be stored on a password-protected computer or a University of Utah approved cloud-based HIPAA-compliant server. The files will be destroyed at the end of the study. A pseudonym will be attached to all data files including the interview transcript. You will not be identified in any publications. The data and interviews collected in this research will be used to improve the training of physical therapists in mindfulness-based treatments for future studies. The information about you (age, sex, etc.) will not be used for future research studies.

RISKS

There are no known risks to being interviewed about your experiences with physical therapists using interventions. While unlikely, you may experience stress if you are interviewed about your experience. Additional risks include a breach of privacy related to the data, including audio recordings of patient encounters and interviews.

BENEFITS

We cannot promise any benefit from your being in the study. However, you may benefit from knowing that patients may receive benefit from improved management of their chronic painful conditions.

ALTERNATIVE PROCEDURES

You may choose not to be in the study. If you choose not to participate, there are no alternate procedures.

COSTS AND COMPENSATION TO PARTICIPANTS

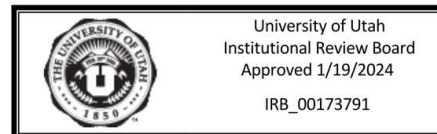
There is no cost to participate in this study. If you agree to participate, you will be provided with \$50.00 as a way to thank you for your participation.

Since you will be paid for participating in this study, it is necessary for us to collect your Social Security Number. You will provide this information for a Federal W-9 Form that is filed with our Accounts Payable department. The amount you receive for taking part in this study will be turned into the Internal Revenue Service (IRS) as taxable income. You can choose not to provide us with your Social Security Number for this form and still participate in this study; however, we will not be able to pay you as outlined in this consent form.

PERSON TO CONTACT

If you have any questions or complaints or if you feel that you have been harmed by this research please contact Jake Magel, PT, PhD, Department of Physical Therapy and Athletic Training, University of Utah (801-581-4709), or Jason M. Beneciuk, PT, DPT, PhD, MPH, Brooks Rehabilitation (904-303-2103).

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Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints, or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

To contact the UF Institutional Review Board (IRB) by phone at (352) 273-9600, or via the IRB Compliance Hotline at (352) 294-5549.

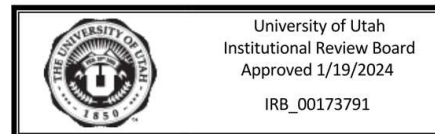
Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

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 the most, the website will include a summary of the results. You can search this website at any time.

NUMBER OF PARTICIPANTS

We expect to enroll up to 90 patients combined from the University of Utah and Brooks Rehabilitation.

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CONSENT

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

Printed Name of Participant

Signature of Participant

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

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