

Appendix 1. Aim 1 Physical Therapist Consent

PI: Jake Magel
Physical Integrated with Mindfulness for Patients with Chronic Musculoskeletal Pain and Long-term Opioid Treatment
06/02/23

Consent Cover Letter

Physical Therapy Integrated with Mindfulness for Patients with Chronic Musculoskeletal Pain and Long-Term Opioid Treatment.

The purpose of this research study is to describe patients' and physical therapists' thoughts and perceptions and impressions about a mindfulness-based physical therapist led treatment protocol. The protocol will be used for patients with chronic musculoskeletal pain and long-term opioid treatment. We are doing this study because we wish to understand how patients and physical therapist feel about the protocol and how they might modify the protocol. The modified protocol will be used in a future study to train physical therapists.

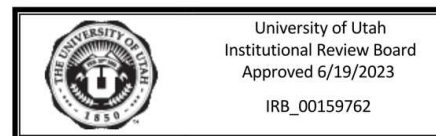
This is a multisite study and is being conducted by Dr. Jake Magel at the University of Utah and Dr. Jason Beneciuk at the University of Florida. This project is registered with clinicaltrials.gov.

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

If you decide to participate in this study, you will first complete a brief 5-minute questionnaire that collects basic information about you (age, sex, etc.). Next, if you are a patient, you will be provided with a 10-minute video that outlines the protocol, which you will be asked to review. If you are a physical therapist, you will be provided with a 5-minute video that introduces the protocol in manual form, which you will be asked to review. If you are a physical therapist, you will also be asked to review the protocol in manual form. After reviewing these resources, you will be contacted by research staff to participate in an interview lasting about 30 minutes. The interview might contain questions related to your overall thoughts about the protocol and what suggestions you might have for modifying the protocol. Your participation is completely voluntary. You may choose not to answer a question or are free to withdraw consent and discontinue participation at any time for any reason without penalty or loss of benefits.

We will do everything in our power to keep your information confidential. However, in some circumstances, the National Institutes of Health (NIH) may review research records that contain participant identifiable information.

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There are no known risks associated with participating in this study. You may experience a benefit in the form of increased insight and awareness into how patients might be managed by physical therapists.

The interview will take place in virtually by a researcher in a private office. The recorded interviews will be stored as digital audio files on a password-protected computer. The files will be destroyed at the end of the study. A pseudonym will be attached to the interview transcript. You will not be identified in any publications. The interviews collected in this research will be used to modify the treatment protocol for a future study. The information about you (age, sex, etc.) will not be used for future research studies. 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 (352-273-6696).

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 University of Utah Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

By completing the survey, you are giving your consent to participate in this research and to be audio-recorded during the interview. Research staff will contact you to schedule a time for the interview.

There is no cost to participate in this study. If you participate in the interviews, you will be compensated for your participation totaling \$50.00. It is necessary for us to collect your email address or home address and we may need your date of birth date to compensate you.

Since you will be paid for participating in this study, it is also 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. Accounts Payable will have limited access to the study information (e.g. the name of the study) for payment purposes. 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

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Security Number for this form and still participate in this study; however we may not be able to pay you as outlined in this consent form.

Additional information that will be included in our research records include demographic and identifying information like:

- Name, email address
- Contact information including phone number, home address and date of birth.

Thank you for your willingness to participate!

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