NIH Collaboratory Rethinking Clinical Trials®

Health Care Systems Research Collaboratory

Ethics and Regulatory Core Consultation Call:

Group-Based Mindfulness For Patients With Chronic Low Back Pain In The Primary Care Setting (OPTIMUM)

Wednesday, December 18, 2019

Meeting Participants

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Overview of Demonstration Project	• **Overview:** The OPTIMUM pragmatic trial will evaluate a group-based mindfulness program for patients with chronic low back pain within primary care. Mindfulness is an effective treatment for chronic low back pain, yet it remains underutilized as it has not been regularly integrated into the outpatient clinical setting and is not reimbursed by health insurance companies. Mindfulness-based Stress Reduction (MBSR) is now recommended by the American College of Physicians for initial treatment of chronic low back pain. The goal of OPTIMUM is to inform decision makers about how this program can work in a real-life clinical setting and assess its impact on patient outcomes.		

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	• **Collaborative network partners:**
	  ○ Boston Medical Center (BMC), Boston, MA
	  ○ Piedmont Health Services, in partnership with the University of North Carolina, Chapel Hill, NC
	  ○ University of Pittsburgh, Pittsburgh, PA
	• **NIH Institute:** National Center for Complementary and Integrative Health (NCCIH)
	• **Study design:** The OPTIMUM trial tests an evidence-based mindfulness intervention conducted at three partnering sites, two of which have a large proportion of patients from underserved or underrepresented populations (Boston Medical Center, Piedmont Health Services). In the UG3 phase, the trial will be piloted at each site with 5 patients. The study team expects to randomize 450 patients during the UH3 phase.
	The intervention consists of 8 weekly, 90-minute, group-based mindfulness sessions delivered in the primary care setting. Patient-level randomization and stratification will be by clinic and sex. Inclusion criteria are broad to include most patients referred for chronic low back pain to a primary care physician (PCP) at a
			• The study design remains the same. However, the group-based intervention will be delivered virtually for the entire UH3 phase due to the COVID-19 pandemic.

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	participating practice. The two study arms will be the intervention plus usual care with the PCP compared with PCP usual care. Usual care consists of both pharmacologic and nonpharmacologic approaches. Questionnaires and follow-up will be the same for both study arms. • **Primary and secondary outcomes:** The primary patient outcome will be a 6-month assessment using the PEG scale (Pain, Enjoyment, General Activity). Secondary outcomes will be collected via the electronic health record (EHR), tracking healthcare utilization as indicated by opiate prescriptions, magnetic resonance imaging, injections, hospitalization, provider visits, emergency department visits, urgent care, PCP visits, physical therapy, and surgery. The PROMIS-29 mindfulness questionnaire will also be used to assess outcomes. This health-related quality of life assessment will include domains for depression, anxiety, physical function, sleep, and psychological measures.		• The primary outcome is unchanged. For secondary outcomes, 7 telehealth questions and 1 ethics question were added. Ethics questions regarding possible issues that may have arisen that are related to the group intervention were also added to the participant exit interviews.
Status of IRB approval	• The University of Pittsburgh IRB is the single IRB of record for OPTIMUM. • The study team has obtained IRB approval for the UG3 phase. The team expects to work on the IRB application for the UH3 phase starting in Spring 2020. Boston		• The pilot study was approved. The current protocol will be modified for the UH3 and submitted for IRB approval.

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	Medical Center has been onboarded and UNC onboarding is pending.		
Risk classification	• The study team considers OPTIMUM to be a minimal risk study because it involves no medication, is evidence-based, and includes turning ordinary daily activities such as breathing and walking into a mindfulness meditation. • Those on the call agreed that the study appears to be minimal risk.		• The University of Pittsburgh made a minimal risk determination.
Consent	• The study will obtain individual written informed consent from 5 participants at each site enrolled in the MBSR program for the UG3 pilot phase. • The consent process for the UH3 phase will involve individual written informed consent. However, the study team is interested in pursuing online consent for the UH3 phase and plans to work with the sIRB to implement. • It was confirmed on the call that the University of Pittsburgh IRB has reviewed and approved online consent for other studies under their purview.		• For the pilot study and for the UH3, oral consent is being obtained as a result of COVID-19. A process for online consent is also being developed.
Privacy/HIPAA	• Participants are asked to sign the health system's confidentiality agreement for the group mindfulness sessions. • The team has obtained a partial waiver of HIPAA to recruit patients through the EHR.		• Participants are not signing confidentiality agreements; instead confidentiality is reviewed at the first session of the intervention, which is delivered via Zoom, the videoconferencing platform.

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	• The study team noted that CMS has clarified that it is acceptable for billing purposes for a clinician to address an individual patient in a group setting with other patients present in the group. • The study team will ensure that participants are reminded that the group mindfulness sessions are intended to be confidential, and request that all participants take action to maintain confidentiality and not disclose what is discussed within the sessions. • The PRO data for research will not be populated in the EHR. Research and medical data will be kept separate. • PRO data will be completed by the patients online, through email, or during office visits. • Those on the call discussed whether there might be clinical triggers (eg, suicidality, opioid abuse, depression) contained in the PROs that would prompt further action for notifying the patient's PCP. The study team noted that suicidality questions are not included in the PROs, but other questions might raise issues that warrant notifying the PCP and they will consider what such thresholds might be and including consent to contact the PCP in the final consent document. • Those on the call discussed questions around recruitment. The PI clarified that multiple methods will be needed, given	Tammy sent the link for the HEAL Initiative's data sharing policy to those on the call (completed December 18, 2019): NIH HEAL Initiative Public Access and Data Sharing Policy: https://heal.nih.gov/about/public-access-data The Ethics and Regulatory Core will discuss this policy to identify any potential concerns specific to pragmatic clinical trials.	• Due to the following site-specific issues, neither the University of North Carolina nor the University of Pittsburgh will bill participants: ○ Approximately half of UNC's participants do not have health insurance and are billed $50 up front when they come for an office visit. Because participants at UNC would be billed for each of the weekly sessions, there was consensus that this would impede participation, and so they will not be billed. ○ The University of Pittsburgh IRB does not allow reimbursement for copays, so it was decided not to bill participants since paying a copay for each of the 8 sessions would likely impede participation. • In contrast, Boston Medical Center (BMC) is billing because copays are not an issue for participants, partly because during the pandemic telehealth copays are waived and also because the majority of patients have little to no copays at BMC given their insurance (mainly public). • The PRO data can be completed online or via telephone with a research assistant. In-person participation is no longer required due to the COVID-19 pandemic. Because of

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	differences in operations and workflows of the three health systems. The primary way of recruiting will be through the EHR. In the Boston system, the team is not intending to mail recruitment letters because in that setting, recruitment works best in-person within the clinic. • The PI clarified that clinic-based providers will be recruited through internal email and faculty presentations. • Regarding data sharing, the PI clarified that there is a central data repository at BMC, and a dedicated data team that will be using REDCap. Each site will have access to their own data but not the other sites' data. EHR data will be deidentified before going to BMC. • The NIH Project Officer will forward information to those on the call regarding requirements for public access and data sharing for HEAL/PRISM trials. There is a special repository used for HEAL/PRISM trials for deidentified data that meets privacy requirements. • The PI clarified that the single IRB process at the University of Pittsburgh involves assuring data security is in place.		the generic nature of the PRO (PROMIS 29), mental health information that would be reportable to the clinician is not being collected. • Recruitment was very challenging for the pilot, and the team has come up with a list of potential additional approaches for recruitment. For example: ○ Primary care providers review their own patients' medical record and identify patients with low back pain and then email them through the electronic health record, inviting them to participate. ○ Letters are emailed or mailed to participants based on electronic health record review of eligible patients with low back pain (at BMC this would be done through the clinical data warehouse and at University of Pittsburgh through the R3, which is their procedure for obtaining electronic health record data). ○ Email patients with low back pain about the study using their email address obtained from the medical record.

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			○ Search electronic health record for patients recently seen in the primary care setting with low back pain who had a virtual visit and invite them to participate. ○ Talk to staff about the study. ○ Talk to clinic staff leadership about the study. ○ Talk to providers at staff meetings about the study.
Monitoring and oversight	• The NIH Project Officer confirmed that for the UG3 pilot phase, no formal data and safety monitoring board (DSMB) is needed. • During the UH3 phase OPTIMUM plans to use a standard DSMB, with members who are not affiliated with the study.		A DSMB has been set up for the UH3, and the first meeting was held 11/26/20.
Issues beyond the study	• A certificate of confidentiality for the study will be automatically provided per new NIH policy. • The study team was encouraged to carefully review this certificate as they craft their final protocol, especially regarding protected health information. • Those on the call suggested that given that group medical visits are relatively new, the study provides an opportunity to systematically evaluate issues of privacy. It could be useful for future trials if the team devised a method of tracking how patients	The Ethics and Regulatory Core will discuss issues related to privacy of group-level interventions in pragmatic clinical trials.	An ethics question was added to the 8-week post-intervention assessment regarding feeling pressured to stay in the study and additional questions on privacy were added to the exit interview.

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	respond to group visits and whether there are feelings of invasion of privacy.		