NIH PRAGMATIC TRIALS COLLABORATORY

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NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call
Reaching Rural Veterans: Applying Mind-Body Skills for Pain Using a Whole Health Telehealth Intervention (RAMP)
November 13, 2023; 4:00-5:00 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Andrew Garland (Bob Jones University), Karen Kehl (NINR), David Magnus (Stanford University), Kevin McBryde (NCCIH), Kayla Mehl (Johns Hopkins University), MariJo Mencini (Duke University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Caleigh Propes (Johns Hopkins University), Damon Seils (Duke University), Kevin Weinfurt (Duke University)
- Trial team: Lee Cross, Julie Toth

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of December 18, 2024
Brief review of Demonstration Project	Meeting attendees received the Research Strategy and the Resource and Data Sharing Plan for RAMP with the meeting agenda (see supplementary material attached). Pearl O'Rourke facilitated the discussion. Core members, RAMP team members, NIH representatives, and staff from the NIH Pragmatic Trials Collaboratory Coordinating Center introduced themselves. The RAMP team members present included Lee Cross (project manager) and Julie Toth (human research protection program director for the Minneapolis VA Health Care System). **Project overview**: Lee Cross gave an overview of the project. The goal of RAMP is to evaluate the use of a 12-week mind-body skills training program for patients with pain, including a one-on-one session with a "whole health coach" followed by 11 weekly group sessions to include prerecorded expert-led education videos, mind-body skills training and practice, and group discussions.		The study team is now referring to the previously described "whole health coaches" as "health coaches."

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	Healthcare system partners: Minneapolis VA Health Care System, University of Iowa, and University of Minnesota **NIH Institute Providing Oversight**: National Institute of Nursing Research (NINR) **Study design**: In the UG3 planning phase, the study team will conduct stakeholder engagement activities, including identifying and developing new community partnerships and using mixed-methods data collection from patients, community partners, and VA healthcare system leaders and staff to learn about factors that affect long-term adoption. The study team will also conduct a pilot study to assess the feasibility of delivering the intervention. In the UH3 implementation phase, the study will use 1:1 individual randomization of 500 patients to either usual care or the intervention. Potentially eligible patients with chronic pain will be identified via the electronic health record and will then receive an introductory postcard followed by a screening email to confirm eligibility and interest. For patients who are interested in participating, there will be a follow-up phone call describing the project in detail and obtaining oral consent. At the time of this call, individuals will be randomized and details of their participation described. **Outcomes**: The primary effectiveness outcome will be pain interference at 13 and 26 weeks. Secondary outcomes will include opioid use and other outcomes in the NIH HEAL Initiative–recommended domains. Pearl requested more information about randomization (whether 1-to-1 or by cohort) and about whether there will be balancing by patient characteristics. After the meeting, Lee followed up with the study team and confirmed that the trial will use 1-to-1 randomization. The study team is working with the Biostatistics and Study Design Core to explore potential correlation of outcomes between individuals in the intervention arm who participate in the same discussion group. In a prior similar study, such correlation was small and had no impact on the study results.		The study team confirmed that the trial will use 1-to-1 randomization.

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Status of IRB approval	The Minneapolis VA Health Care System IRB deemed the UG3 stakeholder engagement activities to be exempt from full IRB review; the research and development committee approved these activities. The study team obtained an exception to the single IRB requirement. The Minneapolis VA Health Care System IRB and the research and development committee provided expedited approval for the UH3 implementation of the trial. The status of IRB review at the University of Iowa and the University of Minnesota is pending. Pearl requested more information about the engagement of the University of Minnesota and the University of Iowa and, hence, what activities will be reviewed by an IRB. The study team will provide more information as work with these sites proceeds.	Study team: Provide more information about the engagement of the University of Minnesota and the University of Iowa	All study activities have been approved by the University of Iowa IRB and the Minneapolis VA Health Care System IRB. The University of Minnesota IRB will only oversee the sharing of identifiable data. The study will be submitted to the institution's IRB in early 2025.
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The study meets the regulatory criteria to be considered minimal risk. The study team has received a waiver of documentation of informed consent from the IRB. David Magnus suggested that it may be appropriate for the control group to receive the unmodified LAMP intervention (pending ongoing analysis to determine the efficacy of LAMP in prior work). This would allow the study team to compare the modified LAMP approach used in RAMP to the unmodified LAMP approach. This proposal was made in light of both ethical and scientific considerations. Lee will share this suggestion with the study team. After the meeting, Lee shared this comment with the study team and reported back that, because there is no plan for the LAMP intervention to become usual care within the VA, the study team believes it is reasonable not to use that intervention as a comparator in the trial.		Minneapolis VA Health Care System IRB deemed the study to be minimal risk.

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Privacy (including HIPAA)	The study team has received a waiver of HIPAA authorization for recruitment purposes only. Participants will need to sign a HIPAA authorization form prior to enrollment. The study team is exploring a VA-approved electronic signature option, likely using either a DocuSign or Qualtrics platform, as these vendors have experience meeting VA security standards. HIPAA authorization forms will be used for both the UG3 stakeholder engagement activities and the UH3 study implementation.		
Monitoring and oversight	The study team has identified members for the data and safety monitoring board and is working on the charter. Pearl referred the study team to the Data and Safety Monitoring chapter of the Living Textbook: https://rethinkingclinicaltrials.org/chapters/ethics-and-regulatory/data-and-safety-monitoring/introduction-data-and-safety-monitoring/.		The DSMB met once and approved the charter, the study protocol, and the data and safety monitoring plan (DSMP). The study team made several minor changes to these documents in response to comments from the DSMB. The DSMB will meet again in 2025.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		
Other matters	None.		
Additional follow-up information			No other issues.

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