NIH Collaboratory Ethics and Regulatory Core: UG3 Planning Phase Consultation Call
Adapting and Implementing a Nurse Care Management Model to Care for Rural Patients With Chronic Pain (AIM-CP)
November 15, 2023; 12:30-1:30 pm ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Joe Ali (Johns Hopkins University), Beda Jean-Francois (NCCIH), David Magnus (Stanford University), Kevin McBryde (NCCIH), Kayla Mehl (Johns Hopkins University), Stephanie Morain (Johns Hopkins University), Pearl O'Rourke (retired), Caleigh Propes (Johns Hopkins University), Tammy Reece (Duke University), Kevin Weinfurt (Duke University), Dave Wendler (NIH)
- Demonstration Project team: Kushang Patel (University of Washington)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS December 31, 2024
Brief review of the trial	Meeting attendees received the Research Strategy, Resources and Data Sharing Plan, and Protection of Human Subjects Plan for AIM-CP with the meeting agenda (see supplementary material attached). Stephanie Morain facilitated introductions and the discussion. The AIM-CP team member present was co–principal investigator Kushang Patel. **Project overview**: Kushang Patel gave an overview of the project, which has a 2-year UG3 planning phase and a 3-year UH3 implementation phase. The goal of AIM-CP is to address inequities in access to nonpharmacological treatment for chronic pain in rural populations. The study will test a care management program vs usual care. **Healthcare system partners**: Providence Northeast (Washington) and Atrium Health Wake Forest Baptist (North Carolina) for the UG3 planning phase **NIH Institute Providing Oversight**: National Institute of Nursing Research (NINR)		There have been no changes to the trial as it is described in the minutes of the November 15, 2023, consultation.

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS December 31, 2024
	Study design: The study is proposed to be a 2-arm pragmatic trial of adults with chronic pain. Participants will be assigned by individual randomization to either usual care or the care management program. The care management program will consist of care coordination by a nurse or other licensed health professional; 8 to 10 sessions of remotely delivered, one-on-one sessions of cognitive behavioral therapy provided by the care manager; and referral to EnhanceFitness, a widely available group-based tele-exercise program. **Outcomes**: The primary outcome is the Pain, Enjoyment of Life, and General Activity (PEG) scale at baseline, at 4 months after treatment, and at 6-month follow-up. Participants will be recruited to the study either through their primary care physicians' offices or through advertisements. For patients in the intervention arm, the study team will share summary notes with the primary care physician to inform them of the patient's enrollment in the study and the patient's self-identified goals of care. The study team will follow up during the trial and at the end of the program to provide information about the patient's progress. (Physicians of patients in the usual care arm will not be contacted.) The study team anticipates that most of the participating healthcare systems will recruit participants by searching the electronic health record for patients with relevant pain-related diagnosis codes, contacting the patients via email to notify them that they may be contacted by the study team, and offering the patients an opportunity to opt out. Services delivered by the healthcare system will be billed through the patient's health insurance. The study team will cover the costs of the care coordination, cognitive behavioral therapy, and the exercise program.		
Status of IRB approval	The study team received a determination that developmental work to adapt the interventions and trainings is not human subjects research.		The University of Washington, which is the single IRB of record, determined

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS December 31, 2024
	The study team plans to use the University of Washington IRB as the single IRB of record for the trial. For the 2-site pilot study, a reliance agreement is in place for the North Carolina site, and discussions are underway with the site in Eastern Washington. The group discussed whether the care managers might also be considered human subjects, since they will be interviewed about their experiences.		that the pilot phase of the study meets the regulatory criteria to be considered minimal risk. A reliance agreement is in place for the North Carolina and eastern Washington sites.
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk. The remotely delivered cognitive behavioral therapy is minimal risk, and the exercise program is being used in another study and was designated by the University of Washington IRB as minimal risk.		The IRB determined that the pilot phase of the study meets the regulatory criteria to be considered minimal risk. The study will use written informed consent for participation.
Privacy (including HIPAA)	Data collection will be managed through a REDCap platform, reducing confidentiality concerns. The exercise program is group-based but also includes people in the community who are not enrolled in the study. So there no expectation of a privacy concern related to the research.		
Monitoring and oversight	NINR will assemble a data and safety monitoring board and has asked the study team to provide names of potential members. The study team is proposing to include a physician pain specialist, a biostatistician, an exercise specialist, and possibly a psychologist.		There has been no change in the plan for data monitoring and oversight since it was discussed during the consultation on

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS December 31, 2024
	Stephanie recommended that the study team encourage NINR to include someone with experience in pragmatic clinical trials. David Magnus 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/.		November 15, 2023. The study team plans to assemble the DSMB for the full phase of trial (not for the pilot phase, since it was determined to be minimal risk). This plan was approved by NINR.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	None.		
Other matters	Joe Ali asked whether patients will have access to the intervention after the trial, if it is shown to be effective. Kushang clarified that the intent is for patients to complete the program and acquire the pain self-management skills as part of the study. The study team hopes, if the intervention is effective or seen as otherwise beneficial by the healthcare systems, that the healthcare systems will adopt the care coordination and exercise program, and perhaps even the cognitive behavioral therapy component. The EnhanceFitness exercise program is broadly available at relatively low cost. So it is conceivable that some patients will continue with this component of the intervention. Exit interviews will ask about this. In addition, it is possible that the participating healthcare systems will adopt the exercise program and offer it at a subsidized rate for patients in their rural catchment areas. Stephanie asked about the possibility of communicating aggregate study results back to the participants at end of the trial. Kushang expressed interest in learning more about this.		The study team plans to communicate aggregate results to participants.

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS December 31, 2024
Additional follow-up information			The study team has not encountered any additional regulatory or ethics issues since the November 15, 2023, consultation.