NIH Collaboratory Ethics and Regulatory Core: UG3 Consultation Call
Remote Tai Chi for Knee Osteoarthritis: An Embedded Pragmatic Trial (TAICHIKNEE)
July 24, 2023; 11:00 am-12:00 noon ET (via Zoom)

Attendees:

- Core, Coordinating Center, and NIH: Sekai Chideya (NCCIH), Beda Jean-Francois (NCCIH), David Magnus (Stanford University), Kevin McBryde (NCCIH), MariJo Mencini (Duke University), Stephanie Morain (Johns Hopkins University), Lanay Mudd (NCCIH), Pearl O'Rourke (retired), Damon Seils (Duke University), Kayte Spector-Bagdady (University of Michigan), Dave Wendler (NIH), and Qilu Yu (NCCIH)
- Demonstration Project team: Elise Coash (Tufts University), Eric Roseen (Boston University), Robert Saper (Cleveland Clinic), and Chenchen Wang (Tufts Medical Center/Tufts Medicine)

AGENDA ITEMS	DISCUSSION	ACTION ITEMS	CURRENT STATUS as of January 10, 2025
Brief review of Demonstration Project	Meeting attendees received the Research Strategy and Data Management and Sharing Plan for TAICHIKNEE with the meeting agenda (see supplementary material attached). Stephanie Morain facilitated the discussion. Core members, TAICHIKNEE team members, NIH representatives, and staff from the NIH Pragmatic Trials Collaboratory Coordinating Center introduced themselves. The TAICHIKNEE team members present included principal investigators Chenchen Wang, Robert Saper, and Eric Roseen and research assistant Elise Coash. **Project overview**: Chenchen Wang and Robert Saper gave an overview of the project. TAICHIKNEE will study real-world effectiveness and implementation of remotely delivered Tai Chi vs Routine Care for knee osteoarthritis pain across 4 healthcare systems in the United States with diverse patient populations. **Healthcare system partners**: Tufts Medical Center/Tufts Medicine, Boston Medical Center, UCLA Health, Cleveland Clinic Ohio, Cleveland Clinic Florida		The trial's primary outcome is now knee pain. Secondary outcomes are now pain interference, function, use of pain medication, and quality of life. Sherwood Alexis is now the trial's project manager.

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	NIH Institute Providing Oversight: National Center for Complementary and Integrative Health (NCCIH) **Study design**: The project will be a pragmatic, multisite, 2-arm randomized trial comparing the effects of a 3-month, twice-weekly, web-based Tai Chi intervention vs Routine Care for patients with knee osteoarthritis pain. **Outcomes**: The primary outcome to be measured at 3, 6, and 12 months is pain interference. Secondary outcomes include knee pain and function, use of pain medication, and quality of life. Core members had no questions about the project overview (see supplementary material attached). During the UG3 planning phase, the study team will finalize trial design, sample size calculations, and study outcomes. The study team will also conduct qualitative interviews during the planning phase with patients, clinicians, Tai Chi instructors, and healthcare system leaders. The interviews will be used to plan educational materials for the UH3 implementation phase and will explore anticipated and potential barriers to and facilitators of implementation. Both the UG3 and UH3 phases will measure implementation outcomes. Two additional rounds of stakeholder interviews in the UH3 implementation phase will explore these implementation outcomes and transferability to other healthcare systems. Kayte Spector-Bagdady asked who will conduct the qualitative analysis of the interviews. Eric Roseen replied that the interviews will be conducted locally; coding will be performed across sites with deidentified transcripts; and the study team will seek to publish the results. David Magnus encouraged the study team to use general category descriptions of interview participants (for example, "health system leadership staff" rather than "chief operating officer") to		

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	minimize the risk of reidentification or deductive disclosure of interview participants.		
Status of IRB approval	The study will use the Tufts Health Sciences IRB as the single IRB of record. The UG3 qualitative study (consisting of the interviews described above) received an IRB determination on April 27, 2023, that the study is exempt from full IRB review in accordance with 45 CFR 46.104(d). For the UH3 implementation phase, the IRB protocol and the informed consent document are in development.		The study team has received IRB approval at Tufts, Boston Medical Center, and UCLA. IRB approval at Cleveland Clinic is pending. The IRB protocol and the informed consent form have been finalized and approved.
Risk (Does the project meet regulatory criteria for being considered minimal risk?); and consent (planned processes for relevant subjects)	For the UH3 implementation phase, the IRB protocol and the informed consent document are in development. The study team anticipates that the project will meet the regulatory criteria to be considered minimal risk. The study will use an electronic consent. Stephanie Morain encouraged the study team to recognize that use of an online meeting platform for the study will place Tai Chi instructors in participants' homes virtually, allowing them to see or hear things in the background that the participants may not have intended to share (for example, the presence of family members). Robert Saper noted that the intent is to set up the virtual meetings so that participants cannot view other participants, only the instructor, and instructors will only use participants' first names. Standard precautions will be taken with respect to protected health information in terms of any data sharing.		The IRB determined that the study meets the regulatory criteria to be considered minimal risk. There have been no changes to the intended plan to use electronic consent. Note: The protocol approved by the IRB and the DSMB states, "Classes will be in a

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	David Magnus encouraged the study team to be aware of the potential for virtual meeting platforms and other software applications to track participants' information without their knowledge.		virtual group live-streamed format."
Privacy (including HIPAA)	For the UG3 planning phase, HIPAA is not applicable. For the UH3 implementation phase, the IRB protocol and the informed consent document are in development.		
Monitoring and oversight	The study team intends to use a data and safety monitoring board (DSMB) and has shared the names of potential members with NIH representatives. Chenchen Wang requested advice from the Core about the typical size of a DSMB for a study like this one. Stephanie Morain encouraged the study team to view materials on the NIH Collaboratory website regarding DSMBs and recommended including people familiar with pragmatic clinical trials and the use of electronic health records for research. Pearl O'Rourke recommended using the same group for protocol review. Qilu Yu added that a single statistician is sufficient.		The plan for data monitoring and oversight has not changed. On September 30, 2024, the study team completed its first DSMB meeting. On October 29, the DSMB approved all study documents and authorized study accrual.
Issues beyond this project (regulatory and ethics concerns raised by the project, if any)	Kayte Spector-Bagdady asked what the UH3 informed consent form will say about data sharing. Chenchen Wang replied that the study team is still working on the informed consent document and would appreciate advice on this matter. Robert Saper noted that most healthcare systems do not routinely collect data from pain assessments, but the study team will collect utilization data from the EHR and deidentify it. David Magnus asked if the trial will assess patients who were recruited to the Tai Chi intervention or patients who actually engaged in the intervention. Robert Saper replied that they will use an intention-to-treat approach for the analysis.		

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	Certainly, they will also look at recruitment rates based on recruitment approaches. David Magnus agreed that the intention-to-treat approach is appropriate. He also encouraged the study team to consider tracking which patients are actually engaging in the intervention, such as by capturing IP addresses during intervention delivery. The study team should also ensure that the web-based tools they use do not inappropriately track or collect participant data.		
Other matters	None.		
Additional follow-up information			The study team has not encountered any additional regulatory or ethics issues since the July 24, 2023, consultation. The study team may include an additional site through the Care for Health initiative at the University of New Mexico.