NIH PRAGMATIC TRIALS COLLABORATORY

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BACK IN ACTION

Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (BackInAction)

Principal Investigators
Andrea J. Cook, PhD; Lynn DeBar, PhD, MPH

Sponsoring Institution
Kaiser Foundation Research Institute, Seattle, WA

Collaborators
- Kaiser Permanente Department of Research, Oakland, CA
- Sutter Health Research Institute, Palo Alto, CA
- Institute of Family Health, New York, NY
- RAND Corporation, Santa Monica, CA

NIH Institute Providing Oversight
National Center for Complementary and Integrative Health (NCCIH)

Program Official
Lanay Mudd, PhD (NCCIH)

Project Scientist
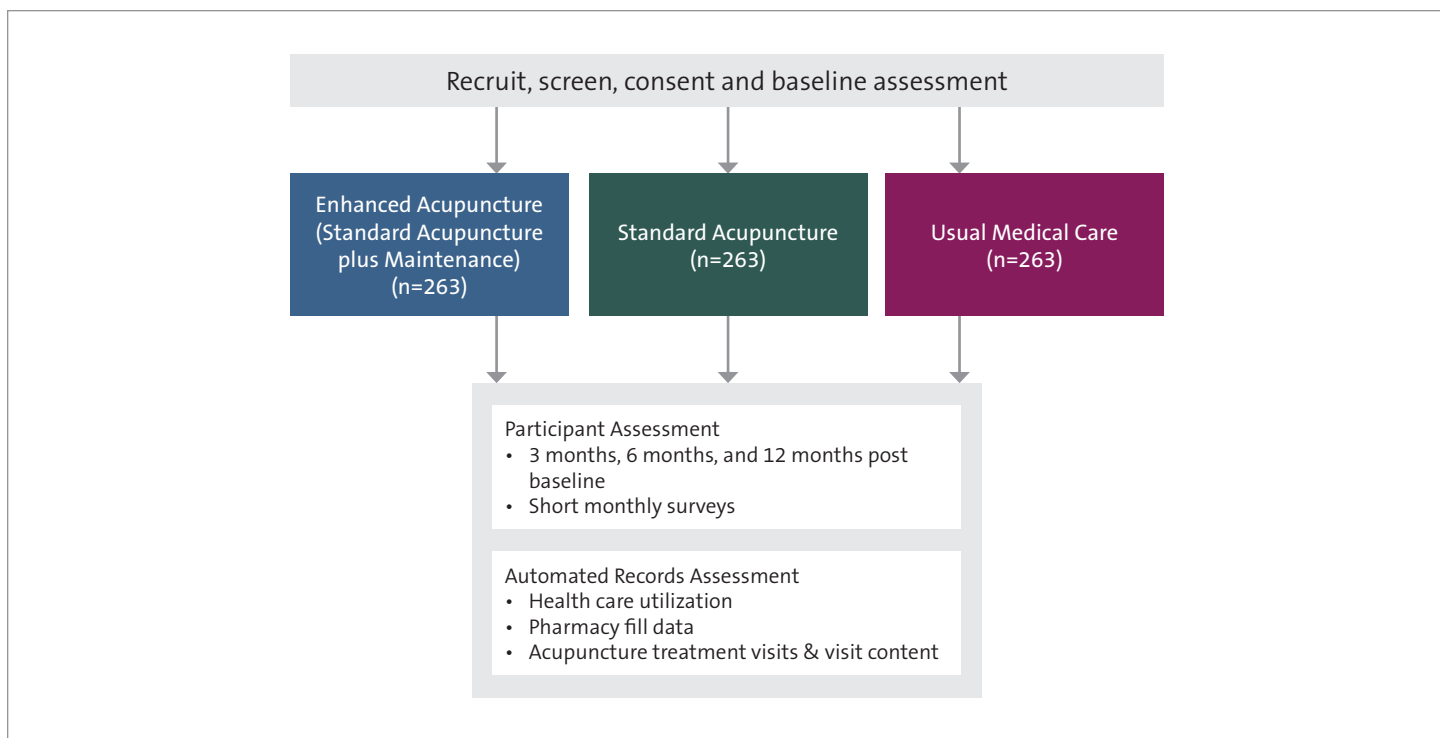Basil Eldadah, MD, MPH (National Institute on Aging)

ClinicalTrials.gov Identifier
NCT04982315

ABSTRACT

A critical gap exists in evidence about the safety and effectiveness of treatments for older adults with chronic low back pain (cLBP). Acupuncture has been found to be effective in treating cLBP in younger adults, yet trials have rarely included older adults, who have more comorbidities and may respond differently from typical trial participants. The implementation phase of BackInAction (formerly known as AcuOA) will consist of a 3-arm trial of 789 adults ≥65 years of age with cLBP to compare a standard 12-week course of acupuncture, an enhanced course of acupuncture, and usual medical care. The primary outcome will be back-related function at 26 weeks. The expectation is that back-related function in older adults with cLBP will be most improved among participants in the enhanced acupuncture arm, followed by the standard acupuncture arm, and least improved among those receiving only usual care.

The large study sample will be recruited from 4 diverse health plans to represent the ethnic and racial composition of Medicare enrollees as well as the most common ways acupuncture is incorporated in insurance-based care for chronic pain. If successful, this pragmatic randomized clinical trial will offer clear guidance about the value of acupuncture for improving functional status and reducing pain intensity and pain interference for older adults with cLBP. This evidence also will provide important information to Medicare about the value of acupuncture for their beneficiaries and for individual physicians and patients deciding on a course of treatment.

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Completing all aspects of the single IRB oversight process took longer than expected.	The study team worked closely with leadership of the IRB to address delays and barriers. It was important to allow sufficient time to assemble study materials (such as consent forms, data collection forms, recruitment materials) in order to move forward with IRB approval.
The requirement to use the HEAL Initiative's Common Domain Elements (CDEs) increased redundancy in our proposed questionnaire and was not completely pertinent to our population of older adults.	The team modified some CDEs and dropped some PROMIS-29 secondary and tertiary outcomes and other questions in order to reduce redundancies.
The Centers for Medicare and Medicaid Services (CMS) decided to move forward with reimbursing for acupuncture treatment for older adults with low back pain, which may have an impact on the community acupuncturists treating these patients.	The study team considers this to be an ongoing process and is closely monitoring CMS decisions. The team anticipates a potential need to tailor the study and to understand the impact on real-world care and ramifications for the generalizability of the trial's approach and findings.

"A pragmatic trial allows us to ask questions that are valuable to the older adult population."

SELECTED PUBLICATIONS & PRESENTATIONS

- Presentation: Presentation to the NIH Pragmatic Trials Collaboratory Steering Committee (2023)

- Article (Study Design): Acupuncture for Chronic Low Back Pain in Older Adults: Design and Protocol for the BackInAction Pragmatic Clinical Trial (2023)

- Poster: Who Says Older Folks Aren't Tech-Savvy? Experience With a Fully Electronic Consent Procedure in a Trial With Older Adults (2023)

Access the complete set of BackInAction resources.