

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



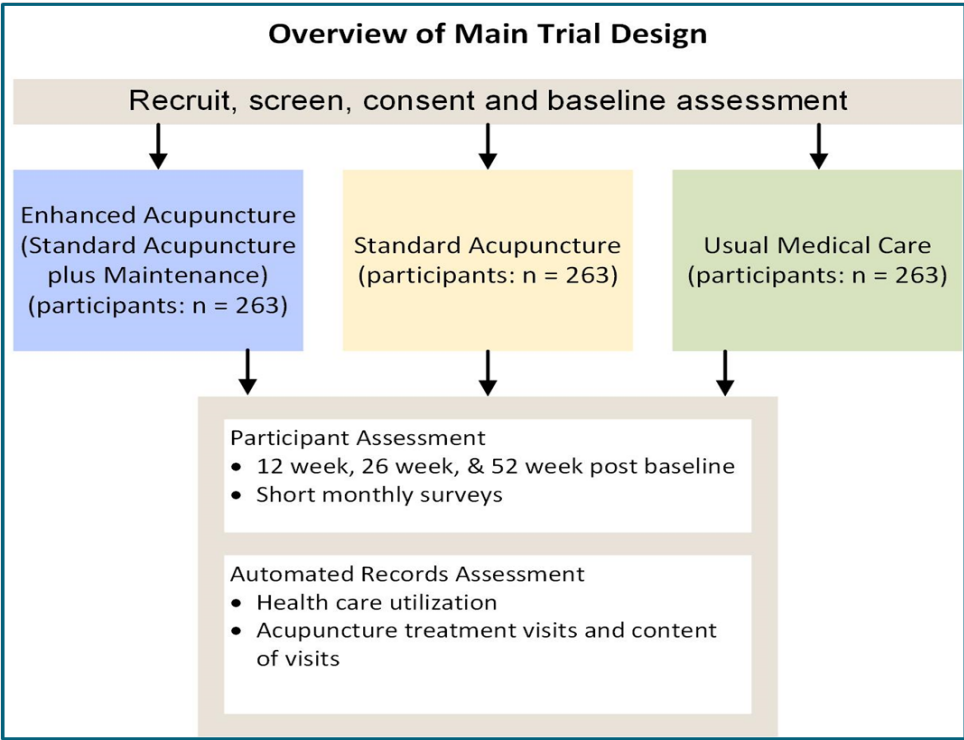
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## INTRODUCTION

- Acupuncture is effective for improving pain and function in adults with chronic low back pain.
- Little data exist for older adults who need safer, more effective treatment options.
- The US Centers for Medicare and Medicaid wanted more information on older adults to support a coverage decision
- This pragmatic trial was designed to assess the value of acupuncture for older adults with chronic low back pain to assist Medicare with coverage decisions.

## METHODS

- The study is part of NIH HEAL(Helping to End Addiction Long-term) initiative and the HEAL PRISM (Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing) research program.
- It is also part of the NIH Health Care Systems Research Collaboratory, which is a NIH program designed to facilitate the conduct of large pragmatic trials in health care systems. The trial design is shown below.



## STUDY POPULATION

- Collectively, the 4 trial sites were selected to represent the age, sex, and racial/ethnic distribution of community-dwelling older adults who are Medicare insured
- Older adults with chronic low back pain who meet the following:

Inclusions	Exclusions
<ul style="list-style-type: none"><li>• Primary care received at participating Health Care System</li><li>• ≥ 65 years of age</li><li>• Uncomplicated back pain (with or without radicular pain)</li><li>• LBP ≥ 3 months</li><li>• Visited a health care provider for low back pain within the past 12 months</li><li>• At least moderate disability (General activity question from PEG ≥3)</li></ul>	<ul style="list-style-type: none"><li>• Specific cause of LBP (e.g., fractures)</li><li>• Back surgery within past 3 months</li><li>• Lawsuit or workers comp related to LBP</li><li>• Acupuncture within last 6 months</li><li>• Conditions making consent &amp; difficult (e.g., Non-English or Spanish speaker, dementia)</li><li>• Inappropriate medical condition</li><li>• Living in nursing home, on Hospice, receiving palliative care</li></ul>

- Electronic health records (EHR) are used to identify potentially eligible patients at the 3 Health Care Systems on the West Coast.
- Letters are mailed to inform patients about the study & study staff call them to ascertain interest
- Physician referrals are used to identify potentially eligible patients at the New York Health Care System. Phase II recruitment efforts also involve EHR data pulls and subsequent outreach via mail and electronic media.

- Interested patients are screened and then those eligible are consented to the study via oral, written, or e-consent.

- Baseline interviews are conducted by phone and patients are randomized

## WHAT ARE THE ACUPUNCTURE INTERVENTIONS?

- Standard Acupuncture: up to 15 acupuncture needle only treatments over 90 days
- Enhanced Acupuncture: Standard acupuncture + an additional up to 6 acupuncture needle treatments over the next 90 days
- Over 40 licensed acupuncturists providing the treatments

## WHAT IS THE COMPARISON GROUP?

- Usual medical care
- Participants can access any treatment that is available as part of their insurance coverage, and we ask them to refrain from acupuncture

## WHAT ARE THE OUTCOME MEASURES?

Data will be collected by telephone or online questionnaire at 3-, 6-, and 12-months post-randomization.

**Primary Outcome:** Roland Morris Disability Questionnaire (RMDQ).

**Other Key Outcomes** include the PEG, PROMIS Physical Function. and many NIH Back Pain Research Task Force, outcomes of special value to older adults and required Common Data Elements” found in all HEAL trials.

## HOW WILL WE ANALYZE THE DATA?

- **Primary analysis** a longitudinal analysis including the continuous outcome, change in RMDQ, from baseline (primary outcome) measured at all follow-up times, in one model estimated using generalized estimating equations (GEE).
- **Secondary analyses** will be conducted using a similar framework.

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