Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (Acu OA) aka “Back in Action”

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Multiple PI’s
Why Acupuncture in Older Adults with cLBP?

• Acupuncture for cLBP in younger adults: “moderate evidence of effectiveness for improving pain and function compared to usual care” 2017 ACP practice guideline

• Seeking effectiveness information for older adults

• In midst of National Coverage Determination
Why Acupuncture for Older Adults with cLBP?

• Pain medications often riskier for older adults (more side effects, polypharmacy)

• High LBP prevalence

• Incidental imaging findings ➔ unneeded invasive treatment

• Increasing costs of care

• More openness to acupuncture than in past

*Need more safe and effective treatment options for older adults with cLBP*
Study Aims

- **UG3 Aim 1:** Preliminary work to demonstrate our capacity to do the trial
  
  ... Hopefully transition to **UH3**

- **UH3 Aim 1:** Pragmatic RCT evaluating standard acupuncture and maintenance acupuncture for older adults with cLBP in 4 health care systems (HCSs).

- **UH3 Aim 2:** Conduct a C-E analysis of both types of acupuncture compared to usual medical care.

- **UH3 Aim 3:** Conduct formative and summative evaluations to understand barriers and facilitators to adoption, implementation, and sustainability of acupuncture treatment for older adults.
Overview of Main Trial Design

Recruit, screen, consent and baseline assessment

- Enhanced Acupuncture (Standard Acupuncture plus Maintenance) (n = 263)
- Standard Acupuncture (n = 263)
- Usual Medical Care (n = 263)

Participant Assessment
- 3 months, 6 months, and 12 months post baseline
- Short monthly surveys

Automated Records Assessment
- Health care utilization
- Pharmacy fill data
- Acupuncture treatment visits & visit content
Back In Action Trial Sites

- Washington
- N California
- New York

- 55,000 older adults with back pain visits (2017)
- Multiple types of HCSs (integrated care, FFS, FQHC)
### Proposed Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Inclusions (from EHR)</th>
<th>Exclusions</th>
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</thead>
<tbody>
<tr>
<td>• Primary care received at Participating HCS</td>
<td>• LBP less than 3 months in duration</td>
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<tr>
<td>• LBP diagnosis received in past 12 months</td>
<td>• Mild symptoms (general activity question from BPI &lt; 3)</td>
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<tr>
<td>• ≥ 65 years of age</td>
<td>• LBP caused by specific disease</td>
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<tr>
<td>• Uncomplicated back pain (with or without radiculopathy)</td>
<td>• Back surgery within past 3 months</td>
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<td></td>
<td>• Lawsuit or worker’s comp related to LBP</td>
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<td></td>
<td>• Acupuncture within last 6 months</td>
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<td></td>
<td>• Conditions making consent and treatment difficult (e.g. Non-English speaker, dementia)</td>
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<td></td>
<td>• Inappropriate medical condition</td>
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<td>• Living in nursing home, on Hospice, receiving palliative care</td>
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<td></td>
<td>• PCP declines patient participation</td>
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</tbody>
</table>
Study Interventions

- Standard Acupuncture: *12 weeks of acupuncture needling*
- Enhanced Acupuncture: *Standard Acupuncture plus 12 weeks of Maintenance*
- Usual Medical Care (UMC)

- **CMS Constraint**: acupuncture needling only
- Standard Acupuncture: up to 15 visits over 12 weeks
- Enhanced Acupuncture: Standard Acupuncture plus up to 6 visits over 12 additional weeks
- Everyone has access to usual medical care
- Considering a resource guide for UMC patients
# Outcome Measures

<table>
<thead>
<tr>
<th>Domains</th>
<th>Baseline</th>
<th>Monthly FU</th>
<th>3, 6, 12 Month FU</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic &amp; Clinical Characteristics</strong></td>
<td></td>
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<tr>
<td>Patient Characteristics</td>
<td>√</td>
<td></td>
<td></td>
<td>EHR / PRO</td>
</tr>
<tr>
<td>Medical &amp; Back Pain History</td>
<td>√</td>
<td></td>
<td></td>
<td>EHR / PRO</td>
</tr>
<tr>
<td>Acupuncture Expectations</td>
<td>√</td>
<td></td>
<td></td>
<td>PRO</td>
</tr>
<tr>
<td><strong>Primary and Secondary Measures</strong></td>
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<tr>
<td><em>Back Pain-related Dysfunction (RMDQ – Primary Outcome)</em></td>
<td>√</td>
<td></td>
<td>√</td>
<td>PRO</td>
</tr>
<tr>
<td>Low Back Pain Intensity</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>PRO</td>
</tr>
<tr>
<td>Pain Interference</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>PRO</td>
</tr>
<tr>
<td>Physical Function</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td>PRO</td>
</tr>
<tr>
<td>Depression &amp; Anxiety</td>
<td>√</td>
<td></td>
<td></td>
<td>PRO</td>
</tr>
<tr>
<td>Sleep Disturbance</td>
<td>√</td>
<td></td>
<td></td>
<td>PRO</td>
</tr>
<tr>
<td>Other PROMISE-29 (Fatigue, Ability to Participate in Social Roles) &amp; Patient Global Impression of Change</td>
<td>√</td>
<td></td>
<td>√</td>
<td>PRO</td>
</tr>
<tr>
<td>Euro-QOL-5D (12 month only)</td>
<td>√</td>
<td></td>
<td></td>
<td>PRO</td>
</tr>
<tr>
<td><strong>Treatment-Related Information</strong></td>
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<tr>
<td>Adverse Events</td>
<td></td>
<td></td>
<td></td>
<td>PRO / EHR / Tx records</td>
</tr>
<tr>
<td>Adherence to Assigned Treatment</td>
<td></td>
<td></td>
<td></td>
<td>Tx records</td>
</tr>
<tr>
<td><strong>Health Care Utilization</strong></td>
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<tr>
<td>Health Care Utilization and Costs (pulled annually – pre &amp; post)</td>
<td>√</td>
<td></td>
<td></td>
<td>EHR / PRO / Medicare Claims</td>
</tr>
<tr>
<td>Green measures recommended by NIH Task Force (RTF)</td>
<td></td>
<td></td>
<td></td>
<td>PROMIS-29 profile V 2.0</td>
</tr>
</tbody>
</table>
Aim 1: Effectiveness of Acupuncture

- Evaluate effectiveness of SA and EA compared to UMC at 3, 6 and 12 months
- **Primary outcome measured at 6 month follow-up**
- Hypothesize both SA and EA are better than UMC
  - Longitudinal analysis with GEE
  - Control for multiple comparisons
  - Will use multiple imputation if needed
  - Other analyses of pain intensity, pain interference, physical function
  - Pre-planned subgroup analyses
Aim 2: Cost Effectiveness

- Cost-effectiveness of Standard and Enhanced Acupuncture compared to Usual Medical Care over a year
- Quality-adjusted life-years (QALYs) using EQ-5D

Costs from Medicare perspective
- Medicare claims based (UG3 exploring optimal methods)
- Costs adjusted on prior year health care utilization costs per patient
- Actual acupuncture visit costs

Costs from the health care sector perspective
- Payer costs plus patient out-of-pocket co-pays
- Exploring whether claims data includes these, otherwise estimated based on usual co-pay amounts in each HCS
## Aim 3: Formative & Summative Evaluation

Health plan, patient, & acupuncturist input on adoption, implementation, & sustainability of acupuncture for older adults

<table>
<thead>
<tr>
<th>Trial Year / Phase</th>
<th>Evaluation Focus</th>
<th>Goals</th>
<th>Data / Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>UG3 / Planning</td>
<td>Formative: Trial preparation</td>
<td>Identify participation barriers &amp; facilitators</td>
<td>Patient focus groups; debrief w/pilot patients</td>
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<tr>
<td></td>
<td></td>
<td>Finalize acupuncturist approach &amp; data forms</td>
<td>Acupuncturist Advisory Panel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Align approach with CMS needs*</td>
<td>Ongoing discussions with CMS &amp; health plan leadership</td>
</tr>
<tr>
<td>UH3 / Years 1 &amp; 2</td>
<td>Formative: Implementation</td>
<td>Identify local adaptations &amp; emerging barriers / facilitators</td>
<td>Interviews with patients, acupuncturists &amp; health plan leaders</td>
</tr>
<tr>
<td>UH3 / Year 3</td>
<td>Summative: RE-AIM, spread &amp; sustainment</td>
<td>Identify elements critical for integrating care into a variety of settings</td>
<td>Interviews with: PCPs, stakeholders external to participating HCSs</td>
</tr>
</tbody>
</table>

* UH3 ongoing activity
Acupuncture Advisory Panel (AAP)

• 8 acupuncturists
• All experienced with treating cLPB
• UG3 Tasks: intervention protocol, inform study acupuncturist qualifications, feedback on data collection forms, input into training of study acupuncturists
• We provided information on treatment parameters from high quality RCTs
• Polled AAP members about their tx of older adults with cLBP
• Delphi panel process for intervention protocol
Acupuncture Advisory Panel: current recommendations

- Back and distal acupuncture points, with recommended points
- 6-20 needles
- Needle retention times: none to 20 minutes for back and front treatments, 25-40 minutes if back only
- De qi at discretion of practitioner
- Visit sessions typically 45-60 minutes
- Prefer uncoated needles
- Can alter treatment if appropriate and provide rationale
Back In Action Leadership Team

CORE EXECUTIVE LEADERSHIP TEAM

Karen Sherman
Co-PI (KPWHRI)

Lynn DeBar
Co-PI (KPWHRI)

Andrew Avins
Co-I (KPNCAL)

Alice Pressman
Co-I (SHR)

Ray Teets
Co-I (IFH)

ADVISORY INVESTIGATORS AND SCIENTIFIC CONSULTANTS
Yu-Ru Su, PhD and Clarissa Hsu, PhD (KPWHRI)
Elizabeth Phalen, MD, MS (UW)
Patricia Herman, ND, PhD, MS (RAND)
Debra Weiner, MD; Harley Goldberg, DO; Arya Nielsen, PhD; Mark Nolting, LAc, ND
## UH3 Data Sharing

<table>
<thead>
<tr>
<th>Type of Data</th>
<th>What We Can Access</th>
<th>Needed for Analysis</th>
<th>What We Can Share</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Electronic Health Record Data</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient ID</td>
<td>MHRN, name, and contact information</td>
<td>Unique patient ID linked to MHRN</td>
<td>Anonymous patient ID</td>
</tr>
<tr>
<td>Demographic Info</td>
<td>✓</td>
<td>✓</td>
<td>In some cases windsorized / tabular form</td>
</tr>
<tr>
<td>Clinical Characteristics</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Health Care Utilization</td>
<td>Detailed service information by date</td>
<td>Detailed service information by date</td>
<td>Rolled up summary variables</td>
</tr>
<tr>
<td>Medication use (including pain OTCs collected PRO)</td>
<td>Detailed information by date and agent</td>
<td>Detailed information by date and agent</td>
<td>Rolled up summary variables</td>
</tr>
<tr>
<td>Patient PCP</td>
<td>✓</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Patient Health plan / clinic</td>
<td>✓</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Patient and Acupuncturist reported (outcomes)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back-related pain &amp; functioning</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Comorbid symptoms(PROMIS)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>QOL (EQ5D, etc)</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>PGIC</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Treatment Records</strong></td>
<td></td>
<td></td>
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<tr>
<td>Adverse Events</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient adherence to treatment</td>
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<td>✓</td>
</tr>
<tr>
<td>LAc reported treatment</td>
<td>✓</td>
<td>✓</td>
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## Back In Action Barriers Scorecard

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty*</th>
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<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>1</td>
</tr>
<tr>
<td>Engagement of clinicians and health systems</td>
<td>✓</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td>✓</td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>✓</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>✓</td>
</tr>
<tr>
<td>Implementing/delivering intervention across healthcare organizations</td>
<td>✓</td>
</tr>
</tbody>
</table>

*Your best guess!  
1 = little difficulty  
5 = extreme difficulty