Pragmatic Trial of **Acu**puncture for Chronic Low Back Pain in **O**lder **A**dults (Acu OA) aka "Back in Action"

Karen Sherman, PhD, MPH
Lynn DeBar, PhD, MPH
Multiple PI's

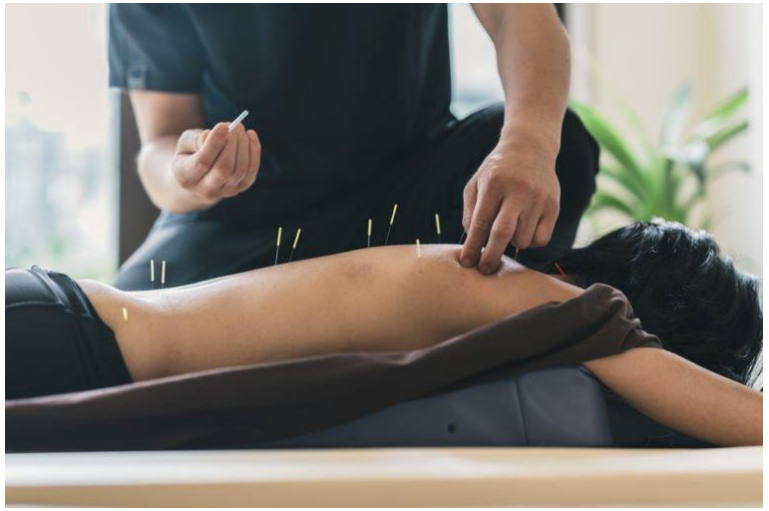
BACK IN ACTION

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*

CMS.gov | Centers for Medicare & Medicaid Services

- 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

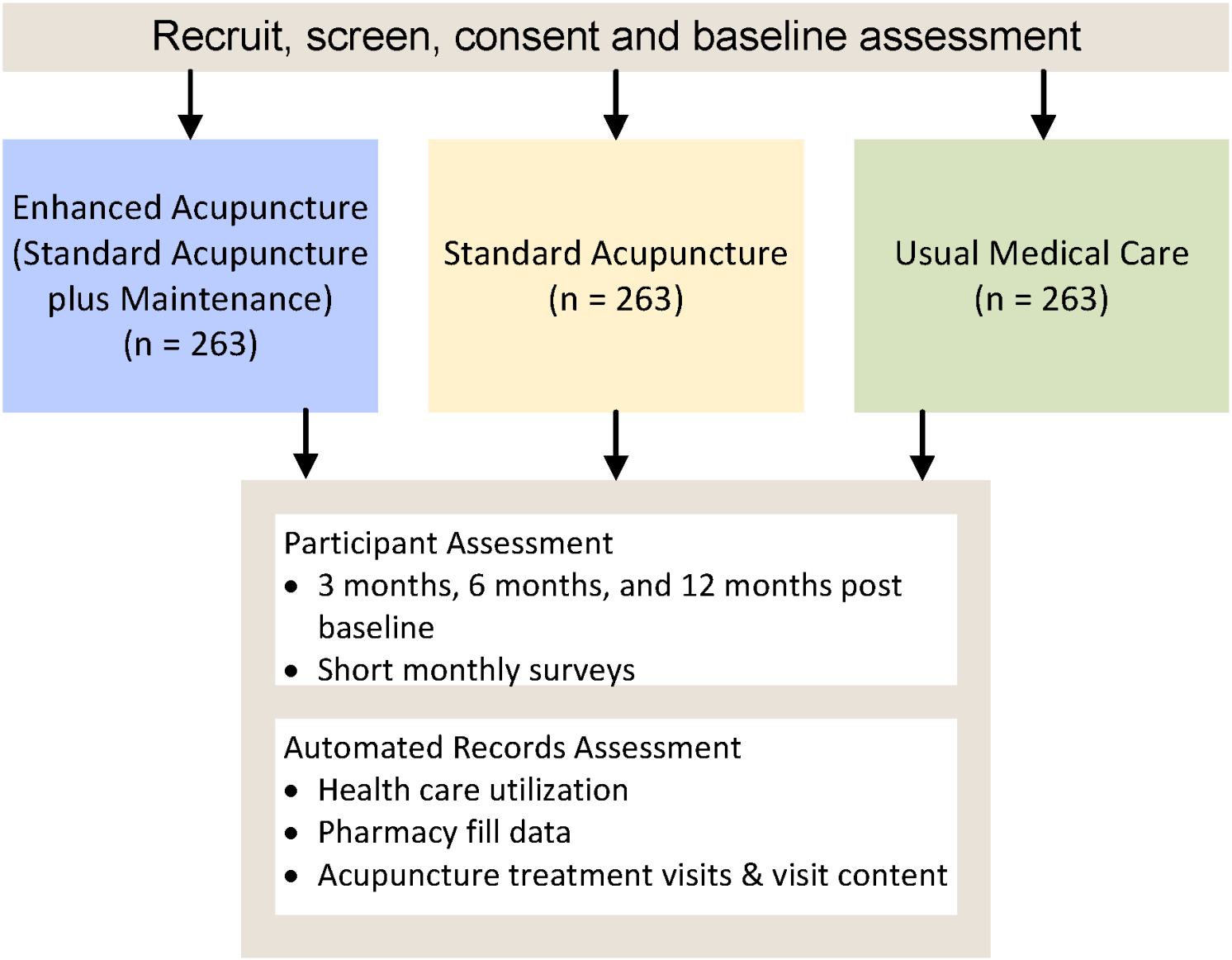
Study Aims

- **UG3 Aim 1: Preliminary work to demonstrate our capacity to do the trial**

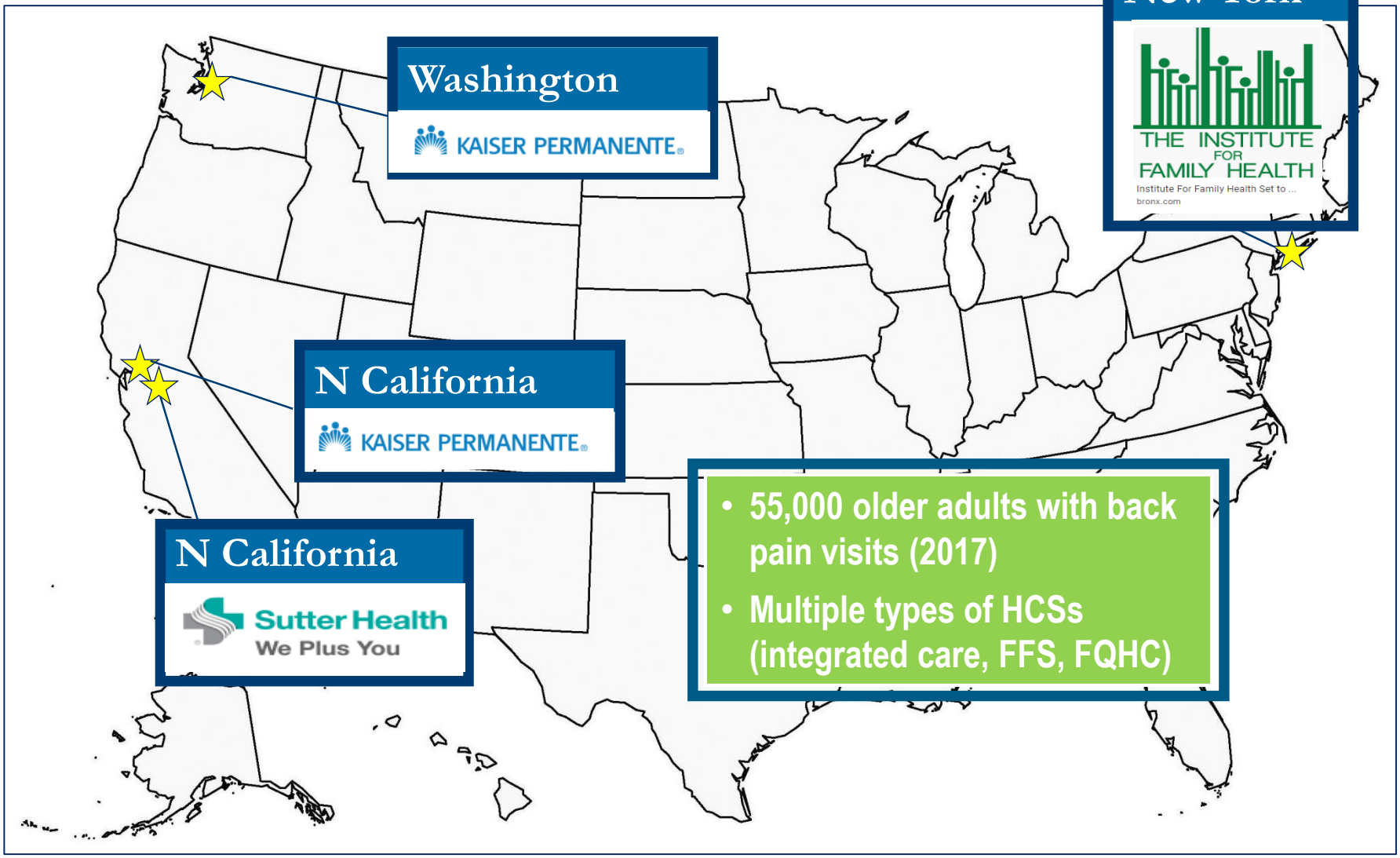
  … Hopefully transition to UH3

- **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



Back In Action Trial Sites



Proposed Inclusion and Exclusion Criteria

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

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

Domains	Baseline	Monthly FU	3, 6, 12 Month FU	Data Source
Demographic & Clinical Characteristics				
Patient Characteristics	√			EHR / PRO
Medical & Back Pain History	√			EHR / PRO
Acupuncture Expectations	√			PRO
Primary and Secondary Measures				
Back Pain-related Dysfunction (RMDQ – Primary Outcome)*	√		√	PRO
Low Back Pain Intensity	√	√	√	PRO
Pain Interference	√	√	√	PRO
Physical Function	√	√	√	PRO
Depression & Anxiety	√		√	PRO
Sleep Disturbance	√		√	PRO
Other PROMISE-29 (Fatigue, Ability to Participate in Social Roles) & Patient Global Impression of Change	√		√	PRO
Euro-QOL-5D (12 month only)	√		√	PRO
Treatment-Related Information				
Adverse Events			√	PRO / EHR / Tx records
Adherence to Assigned Treatment			√	Tx records
Health Care Utilization				
Health Care Utilization and Costs (pulled annually – pre & post)	√		√	EHR / PRO / Medicare Claims

Green measures recommended by NIH Task Force (RTF) PROMIS-29 profile V 2.0

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

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

*** UH3 ongoing activity**

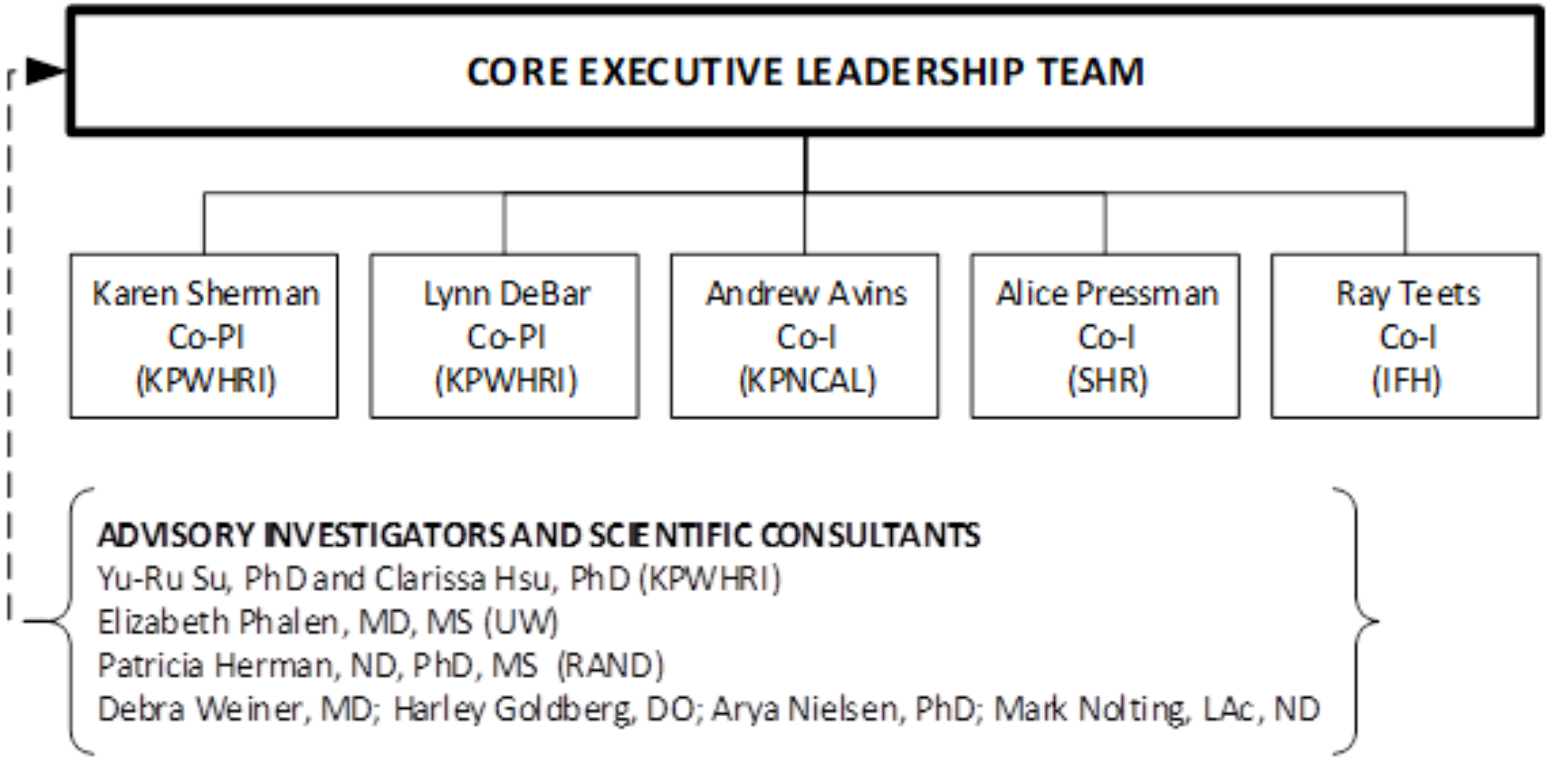
Acupuncture Advisory Panel (AAP)

- 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



UH3 Data Sharing

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

Back In Action Barriers Scorecard

Barrier	Level of Difficulty*				
	1	2	3	4	5
Enrollment and engagement of patients/subjects			✓		
Engagement of clinicians and health systems	✓				
Data collection and merging datasets		✓			
Regulatory issues (IRBs and consent)		✓			
Stability of control intervention		✓			
Implementing/delivering intervention across healthcare organizations				✓	

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