Back In Action
Randomized Controlled Trial of Acupuncture for Chronic Low Back Pain in Older Adults

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Low Back Pain In Older Adults (the What)

• Leading cause of disability worldwide
• High cost-burden (>100B/yr in the U.S.)
• Older adults at higher risk for complications
  • Opioids and other pain medications
  • Back imaging is unreliable
  • Effect of other common health conditions
4 Main Study Goals

To test the effectiveness of acupuncture needling among older adults with chronic low back pain to:

1. Improve back pain-related disability
2. Learn how many acupuncture sessions are needed
3. Help CMS to plan for coverage
4. Determine the cost of acupuncture
Acupuncture for Low Back Pain In Older Adults (the Why)

- Safe and effective
- Also helps with other pain conditions
  - sleep problems,
  - fatigue,
  - emotional well-being
- Personalized treatment
- Medicare coverage
The Traditional Research Model

- Designed to answer scientific question
- Usually in academic centers
- Highly selected participants
- Placebo/sham-controlled
- Treatment best for research
- NOT "real-world" clinical settings
Problems with the Traditional Research Model

- Study participants unlike typical patients
- Treatments unlike what real patients might expect
- Placebo/sham controls are problematic
- Treatment outcome measurements often good for research but not what patients care most about
The "Pragmatic Trial" Model

- Trial participants more like typical patients
- Treatments given in a more realistic way
- Outcomes meaningful to patients
- Comparisons often to "usual care" instead of placebo
- Clinical setting is more like the real world
- Results apply to real patients and real clinics
Traditional vs. Pragmatic
A Tale of Two Studies

Acupuncture for chronic low back pain
The "SPINE Study"

A Randomized Trial Comparing Acupuncture, Simulated Acupuncture, and Usual Care for Chronic Low Back Pain

Daniel C. Cherkin, PhD; Karen J. Sherman, PhD; Andrew L. Avins, MD, MPH; Janet H. Erro, RN, MN; Laura Ichikawa, MS; William E. Barlow, PhD; Kristin Delaney, MPH; Rene Hawkes, BA; Luisa Hamilton, MD; Alice Pressman, MS; Partap S. Khalsa, DC, PhD; Richard A. Deyo, MD, MPH

• JAMA Internal Medicine 2009; 169:858-866
Characteristics of the SPINE study

- Unique participants
- Sham-acupuncture control group
  - Fake needles were toothpicks!
- Separated "diagnosing" practitioner from "treating" practitioner
- Participants (literally) blinded to treatment
- No communication allowed between participant and practitioner
- **Not a real-life acupuncture experience**
Back In Action
Pragmatic Randomized Controlled Trial of Acupuncture for Chronic Low Back Pain in Older Adults
Who is in the study?

Patients

• ≥ 65 years of age

• with low back pain (LBP) for ≥ 3 months in the prior year

• with pain-related general activity interference (≥ 3 on PEG)

• who had primary care at one of the four health systems
Eligible Older Adults

Design

KPWA – Washington

KPNC – Kaiser Permanente Northern California

SUTTER – Sutter Health

IFH – The Institute for Family Health

Recruited N=807

Usual Care

Standard Acupuncture

Enhanced Acupuncture

KPNC and Sutter Health – Northern Californian

IFH – New York City
Treatment Arms

**Standard acupuncture:** 8-15 treatment sessions over 12 weeks

**Enhanced acupuncture:** Standard plus up to 6 extra
California Participants: baseline demographic characteristics

**Age**
- 65-74
- 75-84
- 85+

**Race/Ethnicity**
- NH White
- NH Multi
- NH Black/AA
- NH Pacific Islander
- NH American Indian
- Hispanic

**Other Characteristics**
- Household income: $24,999 or less: 7.9%
- High school or less education: 8.1%
- Married or domestic partnered: 60.2%
- Female: 60.4%
California Participants: baseline clinical characteristics

**Primary outcome**
Back-Related Disability
Roland Morris Disability Questionnaire range 0-24
Kaiser 12.6±5.3
Sutter 12.5±5.2

**Secondary outcomes**
Pain range PEG 0-10
Kaiser 5.3±2.1
Sutter 5.4±2.2

PROMIS physical function range 0-100
Kaiser 40.2±6.4
Sutter 38.0±6.6
What is Acupuncture?
Chinese Medicine Philosophy
Bliss...
Questions and Discussion