BACK IN ACTION

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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

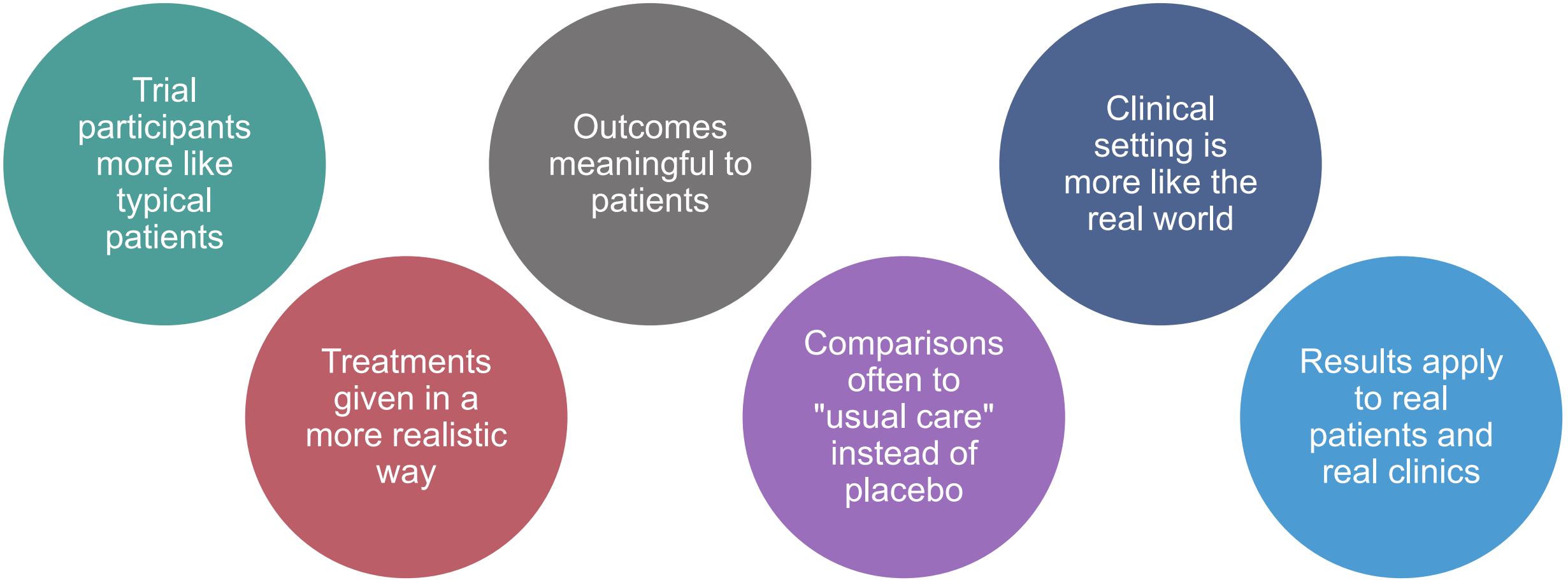
The Traditional Research Model

- 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



Traditional vs. Pragmatic

A Tale of Two Studies

Acupuncture for chronic low back pain

The "SPINE Study"

ORIGINAL INVESTIGATION

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**

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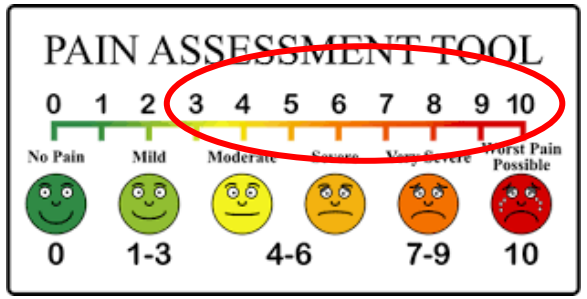
Pragmatic Randomized Controlled Trial of Acupuncture for Chronic Low Back Pain in Older Adults

Who is in the study?

Patients

- ≥ 65 years of age

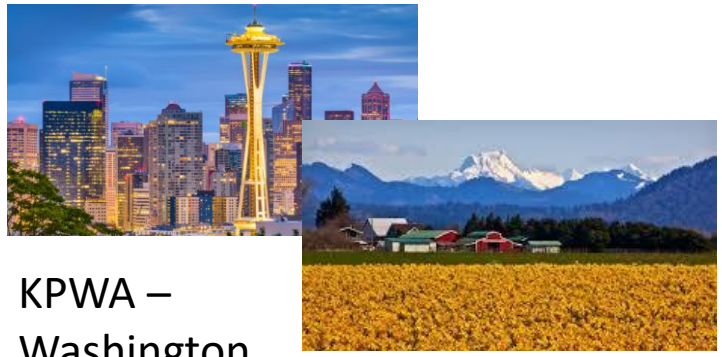
- with low back pain (LBP) for ≥ 3 months in the prior year



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

- who had primary care at one of the four health systems

Design



KPWA – Washington

KPWA

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KPNC

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DIVISION OF RESEARCH
Northern California

SUTTER

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IFH

THE INSTITUTE FOR FAMILY HEALTH

Recruited N=807

Usual Care

Standard Acupuncture

Enhanced Acupuncture

KPNC and Sutter Health – Northern Californian

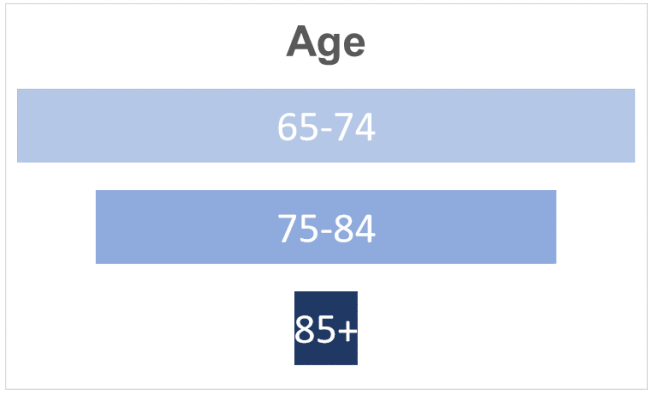
IFH – New York City

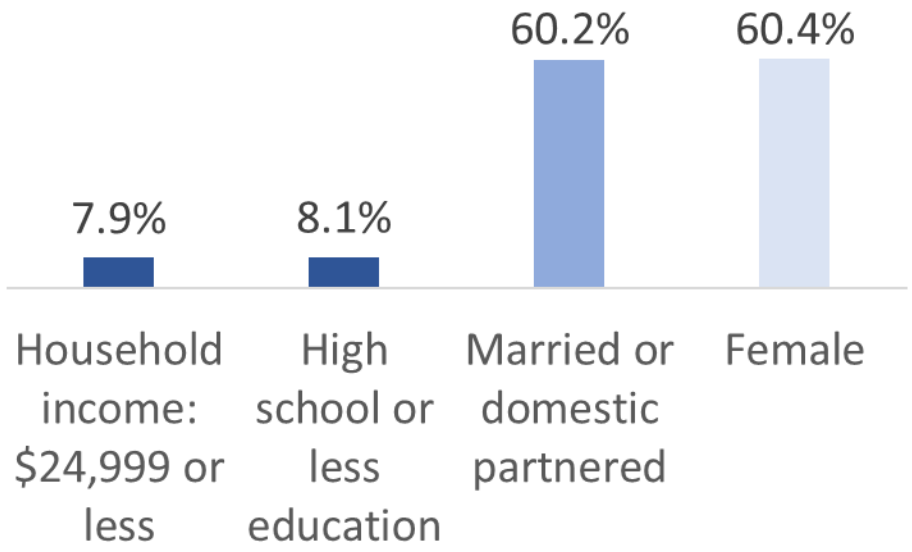
Treatment Arms

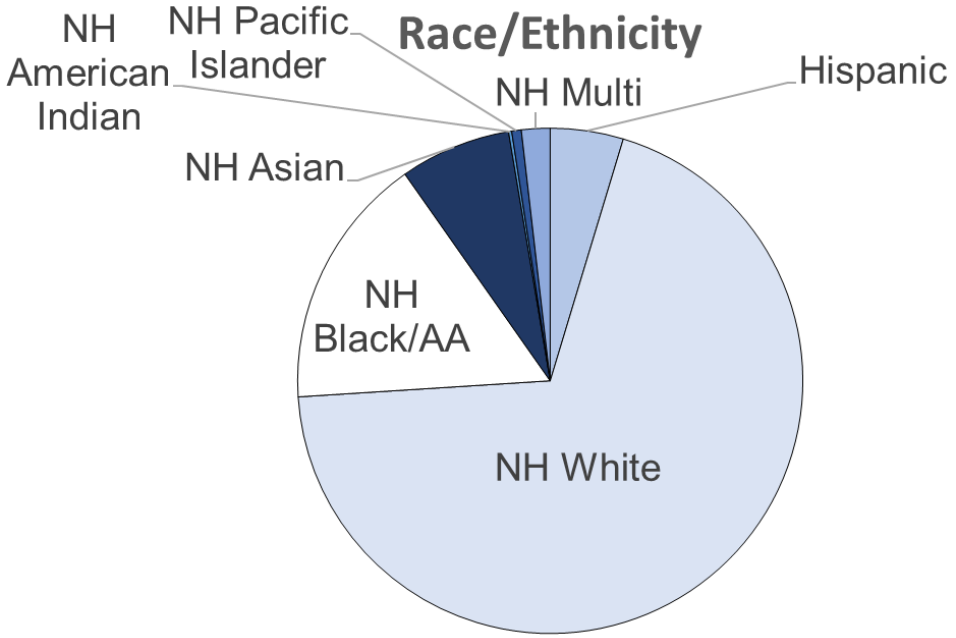
Standard acupuncture: 8-15 treatment sessions over 12 weeks

Enhanced acupuncture: Standard plus up to 6 extra

California Participants: baseline demographic characteristics







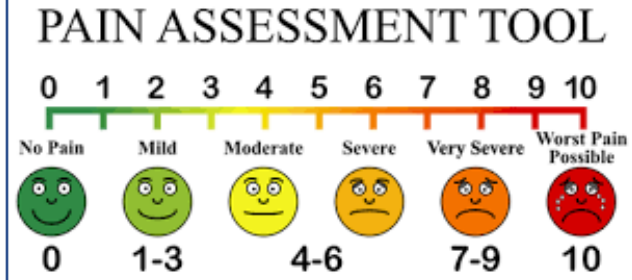
California Participants: baseline clinical characteristics

Primary outcome

Back-Related Disability
Roland Morris Disability
Questionnaire range 0-24

Kaiser 12.6±5.3
Sutter 12.5±5.2

Secondary outcomes



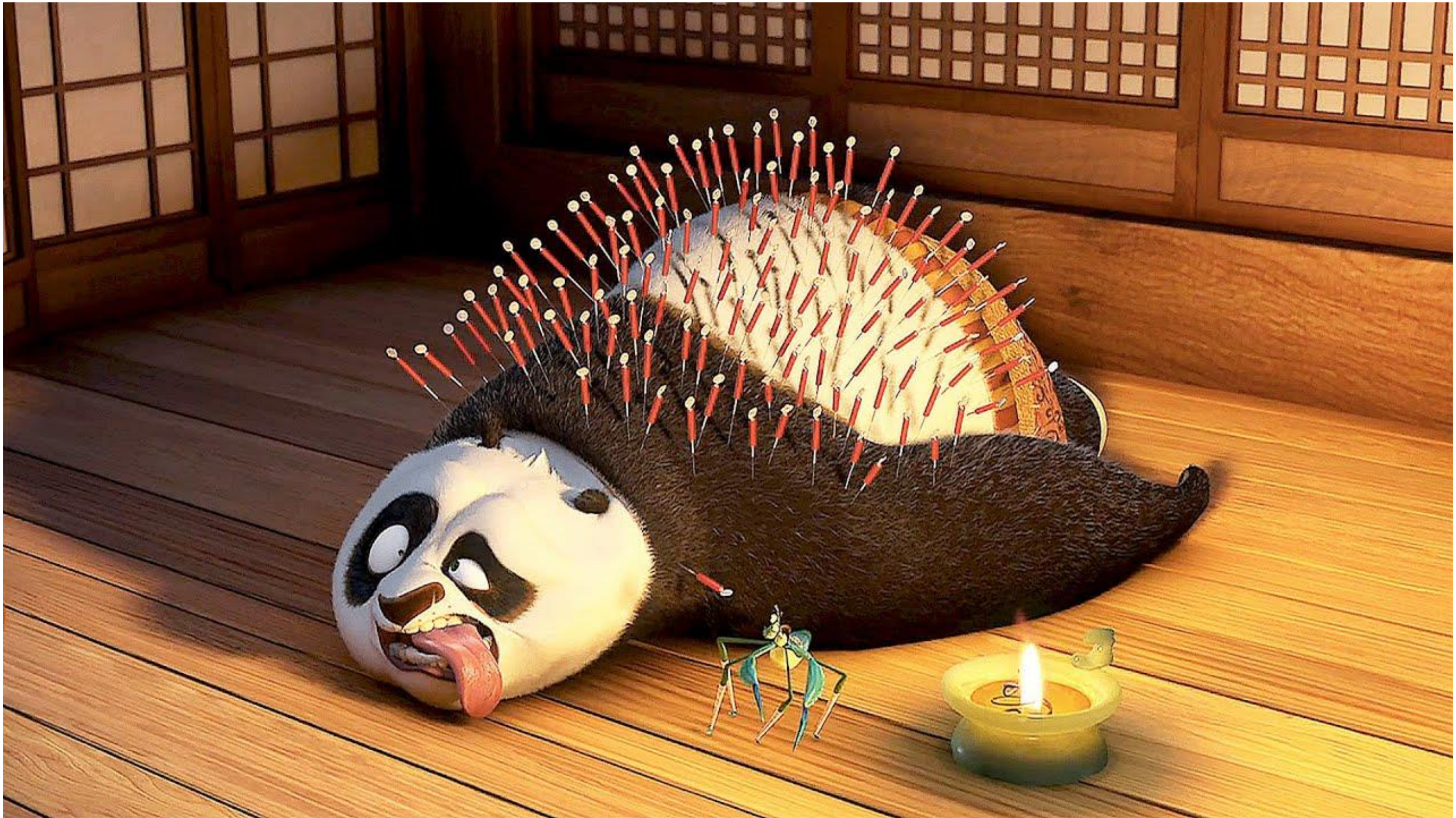
Pain range PEG 0-10

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