Acupuncture for Chronic Low Back Pain in Older Adults: Main Outcomes from the BackInAction Pragmatic Clinical Trial

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BACK IN ACTION

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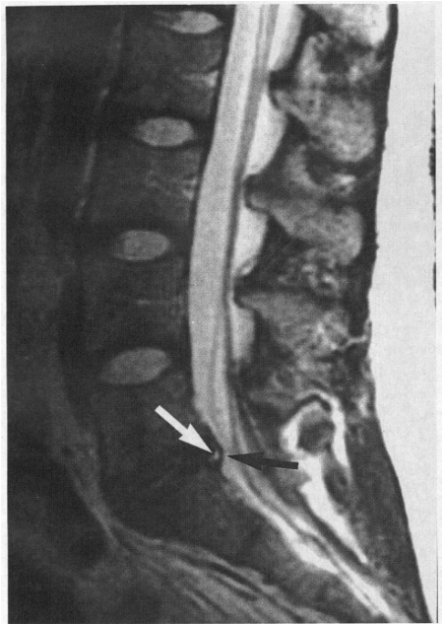
Low Back Pain In Older Adults (the What)

- Leading cause of disability worldwide
- High cost-burden (>$100B/year 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



Acupuncture for Low Back Pain In Older Adults (the Why)

- Safe and effective
- Treats other pain-related conditions
  - Sleep problems
  - Fatigue
  - Emotional well-being
- Personalized treatment
  - Including evaluating the potential impact of maintenance sessions
- Medicare coverage

BackInAction Overview

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

- Improve back pain-related disability
- Evaluate acupuncture needling dose-dependence and safety for older adults
- Inform CMS Medicare Coverage Decision/Impact (outcomes + acupuncturist/key informant interviews)
- Evaluate cost-utility and cost effectiveness of acupuncture intervention

semi-flexible acupuncture protocol and community acupuncturist care provision focus

DESIGN: 3-arm (standard acupuncture/enhanced acupuncture/usual medical care only) pragmatic trial *(800 participants)*

SETTINGS:

- Kaiser Permanente Washington
- Kaiser Permanente Northern California
- Sutter Health Northern California
- Institute of Family Health NYC

ELIGIBILITY: ≥ 65 years of age with EHR diagnosis of uncomplicated chronic low back pain meeting threshold of pain-related general activity interference (≥ 3 on PE**G**)

INTERVENTIONS:

- **Arm 1:** Standard (15 treatment sessions over 12 weeks)
- **Arm 2:** Enhanced (6 additional maintenance sessions over following 12 weeks)

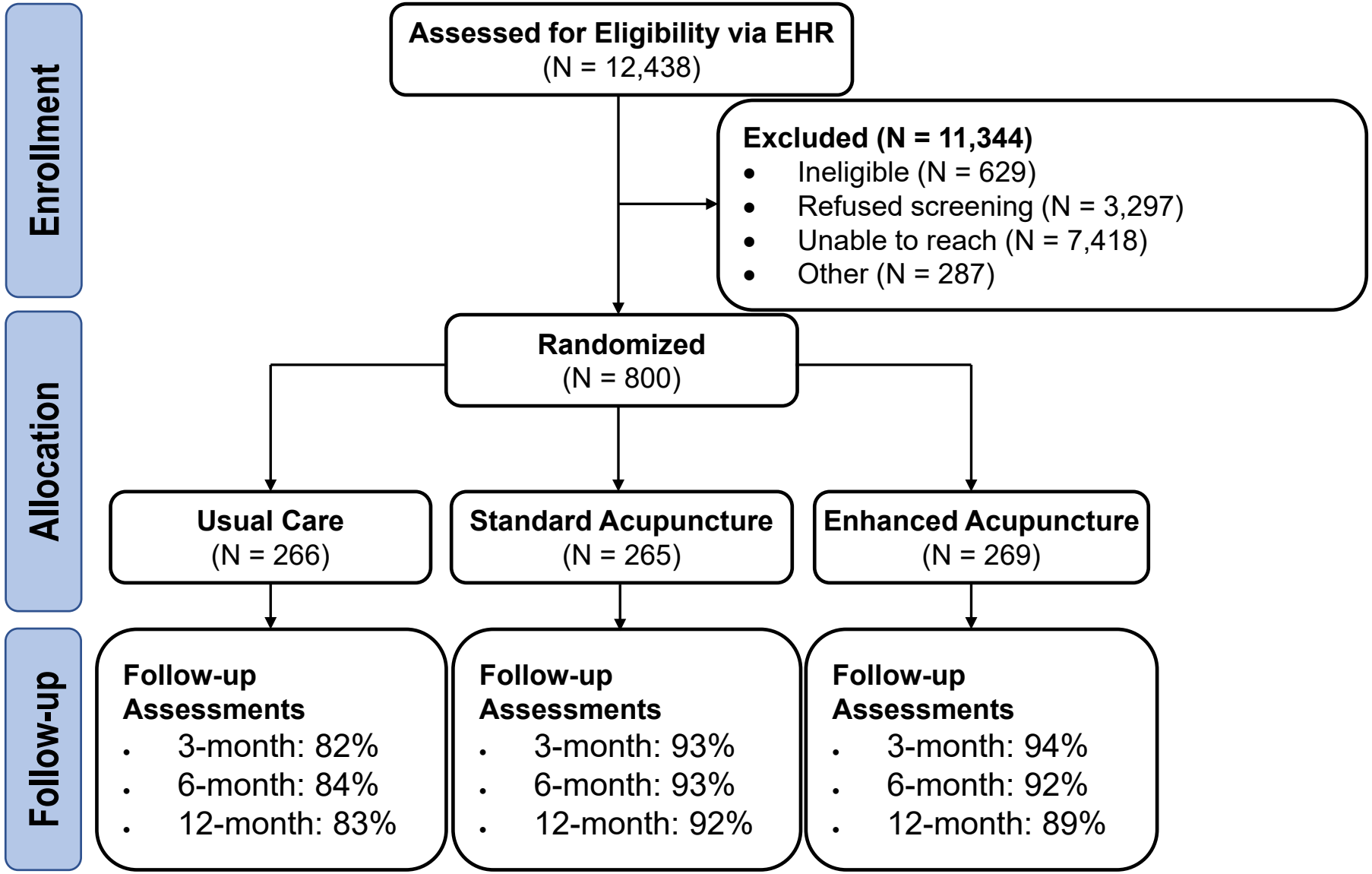
50+ community- (KPNC, KPWA, SH) or primary clinic-based (IFH) acupuncturists delivering intervention

DeBar LL, et al. *Contemporary Clinical Trials*. 2023 March 27.
Nielsen A, et al. *Glob Adv Health Med*. 2021.

BackInAction Outcome Measures

Patient-Reported Outcomes (PROs)		
Roland Morris Disability Questionnaire (RMDQ)	Primary	Study assessment
RMDQ – minimal clinically important difference (MCID)	Secondary	Study assessment
PEG (continuous and MCID)	Secondary	Study assessment
Physical Functioning (PROMIS)	Secondary	Study assessment
Patient Global Impression of Change (PGIC)	Secondary	Study assessment
Sleep Quality and Duration (PROMIS)	Exploratory	Study assessment
Depression and Anxiety (PHQ4)	Exploratory	Study assessment
Fatigue (PROMIS)	Exploratory	Study assessment
Social Role Functioning (PROMIS)	Exploratory	Study assessment
Outcomes Related to Cost Analyses – Quality Adjusted Life Years using:		
EQ-5D-5L	Descriptive (Power N/A)	Study assessment
Health Services Received (ambulatory visits, telephone and email encounters, inpatient care, medications dispensed, procedures)	Descriptive (Power N/A)	EHR

Participant Flow



Baseline Participant Sociodemographic Characteristics*

Participant Characteristics	Total (N=800)	NYC – FQHC Network HCS (N=123)	Northern CA – Integrated HCS (N=286)	Pacific NW – Integrated HCS (N=185)	Northern CA – FFS HCS (N=206)
Age, mean (SD)	73.6 (6.0)	71.2 (5.7)	73.2 (5.6)	73.3 (5.8)	76.1 (6.0)
Female, N (%)	496 (62.0)	89 (72.4)	171 (59.8)	108 (58.4)	128 (62.1)
Education – At least some college	678 (85%)	69 (56%)	252 (89%)	162 (88%)	195 (95%)
Household income					
Less than $50,000	223 (28%)	79 (64%)	55 (19%)	60 (32%)	29 (14%)
$150,000 or more	104 (16%)	- (<5%)	33 (15%)	23 (14%)	46 (27%)
Race & Ethnicity, N (%)					
White Non-Hispanic (NH)	510 (64%)	26 (21%)	179 (63%)	148 (80%)	157 (76%)
Black or African American NH	132 (17%)	42 (34%)	52 (18%)	11 (6%)	27 (13%)
Hispanic	86 (11%)	46 (37%)	21 (7%)	17 (9%)	- (<5%)
Asian	42 (5%)	- (<5%)	20 (7%)	- (<5%)	15 (7%)
Other	30 (4%)	9 (7%)	- (<5%)	- (<5%)	- (<5%)

* FQHC – Federally Qualified Health Center, FFS – Fee for Service, HCS – Health Care System, NH - NonHispanic

Baseline Participant Clinical Characteristics*

Participant Characteristics	Total (N=800)	NYC – FQHC Network HCS (N=123)	Northern CA – Integrated HCS (N=286)	Pacific NW – Integrated HCS (N=185)	Northern CA – FFS HCS (N=206)
Back Pain Characteristics					
High Impact Chronic Pain	375 (47%)	74 (61%)	124 (44%)	73 (40%)	104 (51%)
Number of Pain Conditions	2.9 (1.4)	2.8 (1.5)	3.1 (1.3)	3.3 (1.3)	2.3 (1.4)
Roland Morris Disability Questionnaire (RMDQ)	13.2 (5.5)	17.3 (5.3)	12.6 (5.4)	12.2 (4.9)	12.5 (5.2)
RMDQ ≥ 18	196 (25%)	73 (59%)	59 (21%)	27 (15%)	37 (18%)
PEG Score	5.6 (2.2)	7.3 (2.0)	5.3 (2.1)	5.0 (1.9)	5.4 (2.2)
Medical co-morbidity (Elixhauser)	2.6 (2.0)	2.9 (1.8)	3.0 (2.0)	2.6 (2.3)	1.7 (1.6)
Frail	156 (20%)	48 (41%)	44 (16%)	29 (16%)	35 (18%)
Mental Health Comorbidities					
Depression symptoms (PHQ2≥3)	162 (21%)	49 (41%)	45 (16%)	25 (14%)	43 (21%)
Anxiety symptoms (PHQ2≥3)	173 (22%)	43 (36%)	46 (17%)	35 (19%)	49 (24%)

* FQHC – Federally Qualified Health Center, FFS – Fee for Service, HCS – Health Care System

Acupuncture Treatment Details

Standard acupuncture: 8-15 treatment sessions over 12 weeks

- Sessions completed: Mean = 10.68 (Standard Deviation = 3.96)
- 97% at least one visit
- 82% at least eight visits (considered ‘critical dose’)
- 22% attended all 15 visits allowed

Enhanced acupuncture: Standard plus up to 6 extra over next 12 weeks

- Sessions completed: Mean = 4.64 (Standard Deviation = 2.21)
- 86% at least one visit
- 55% attended all 6 visits allowed

Primary Analysis

Primary Outcome: Change in RMDQ from Baseline

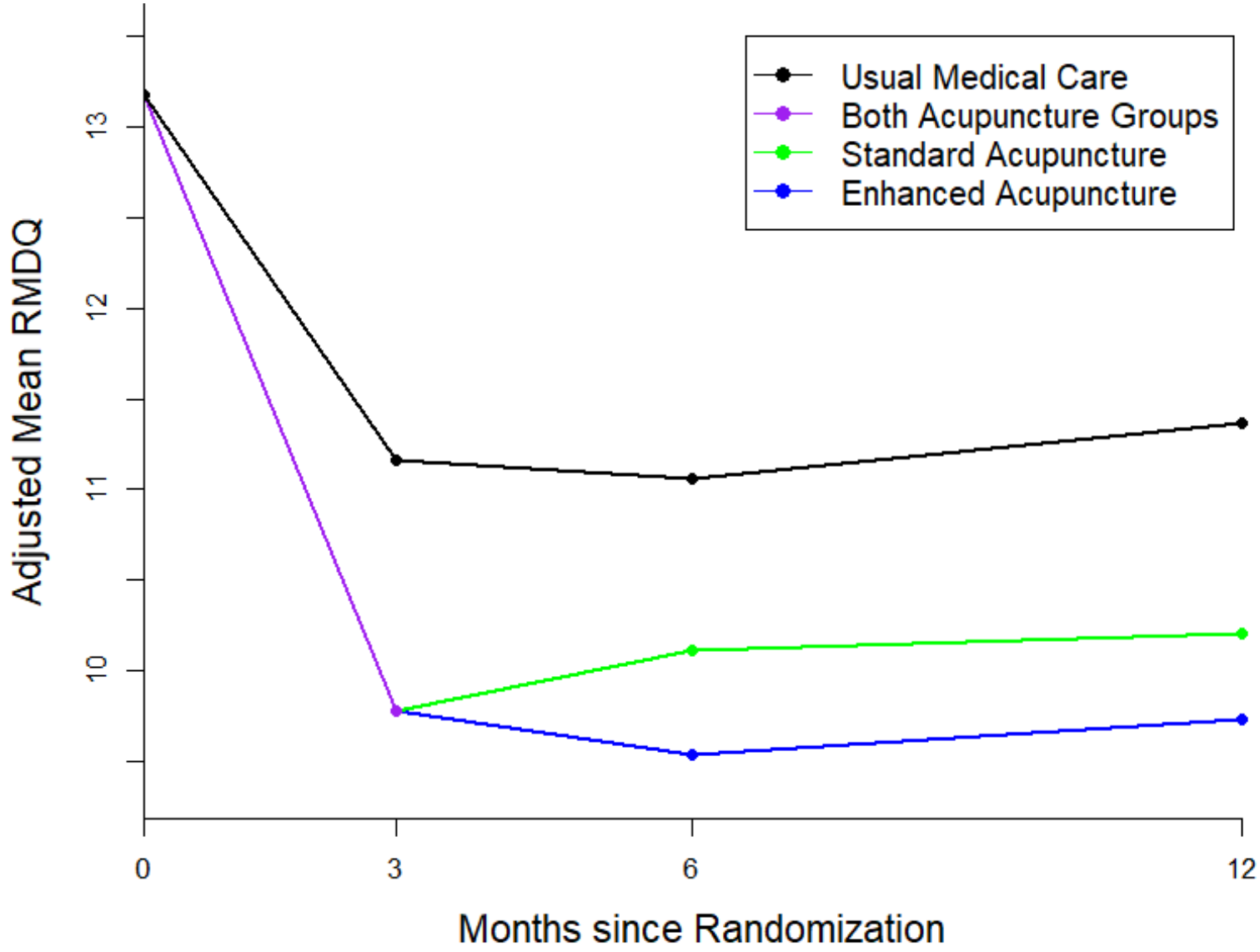
Time Points: 3, 6 (primary), and 12 months

General Framework:

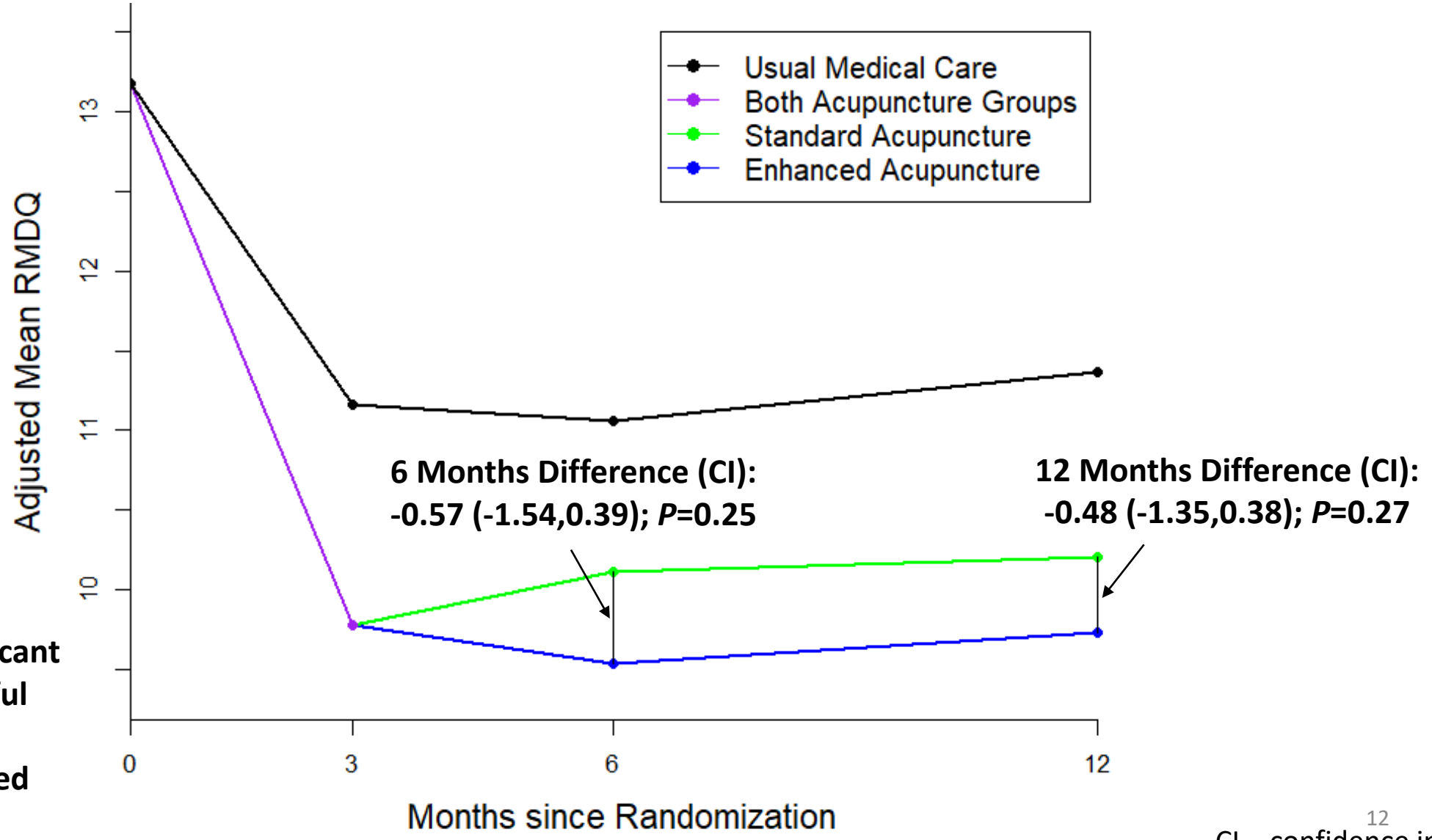
- GEE Analysis with all time points in the same model
- Robust Standard errors to account for correlation within person and acupuncturist
- Adjust for Baseline RMDQ, age, sex, race, and Health Care system
- Multiple Comparisons: Fisher's Least Significant Difference Approach
- Missing Outcome Data: Combination of Pattern Mixture Imputation (missing outcome rates >15% at one site) and inverse weighting for those with no follow-up time points. Added additional covariates that were related to missingness to imputation and weighting models
  - Education, BMI, Number of Pain Conditions, General pain, Substance Use Disorder, PEG, Pain Catastrophizing, and fear avoidance

Adjusted Mean Pain-related Functioning

(Primary Study Outcome)



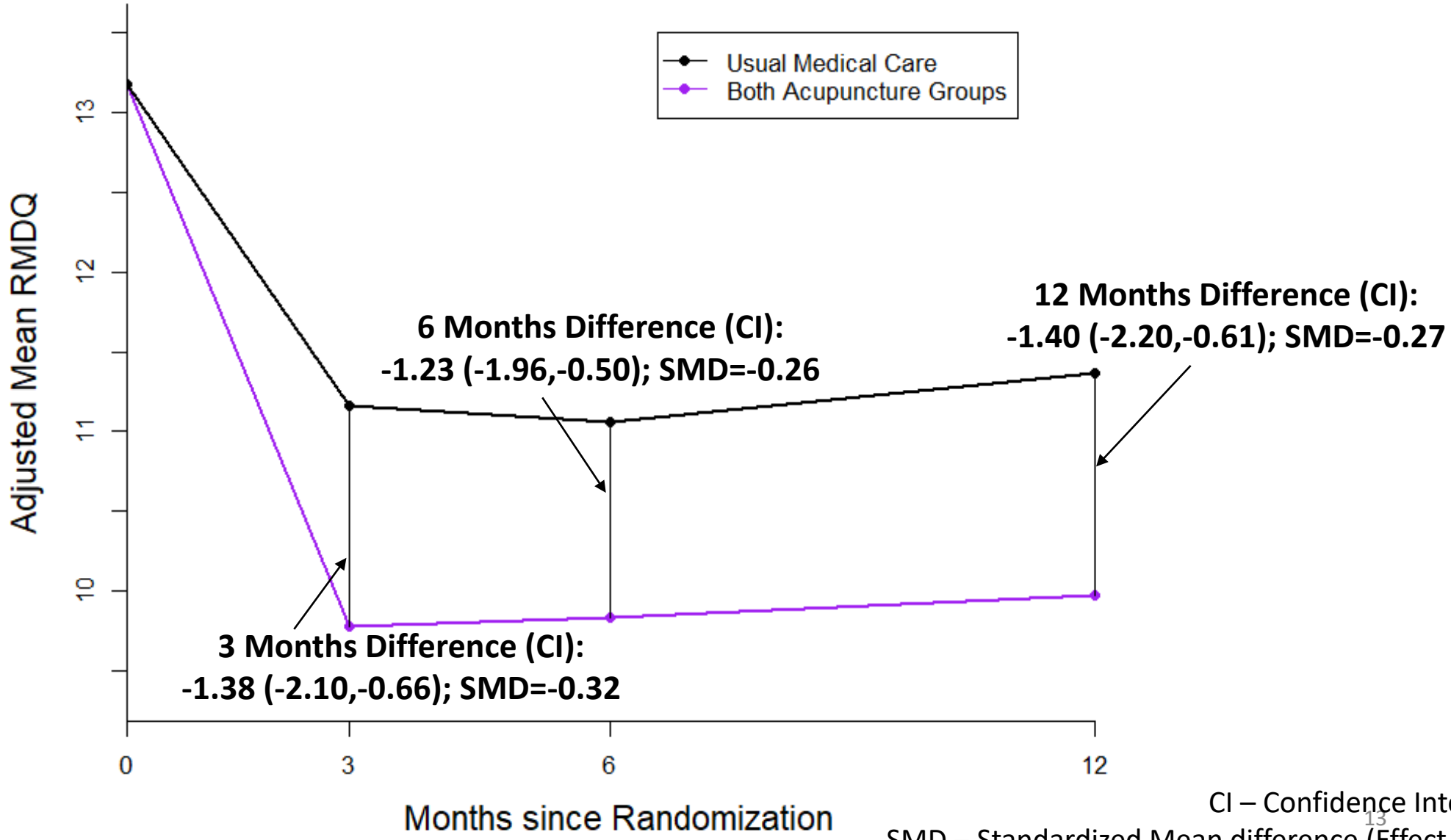
Standard Versus Enhanced Acupuncture



No Statistically Significant or Clinically Meaningful Differences between Standard and Enhanced Acupuncture

CI – confidence interval

Acupuncture versus Usual Care



All P-values < 0.001

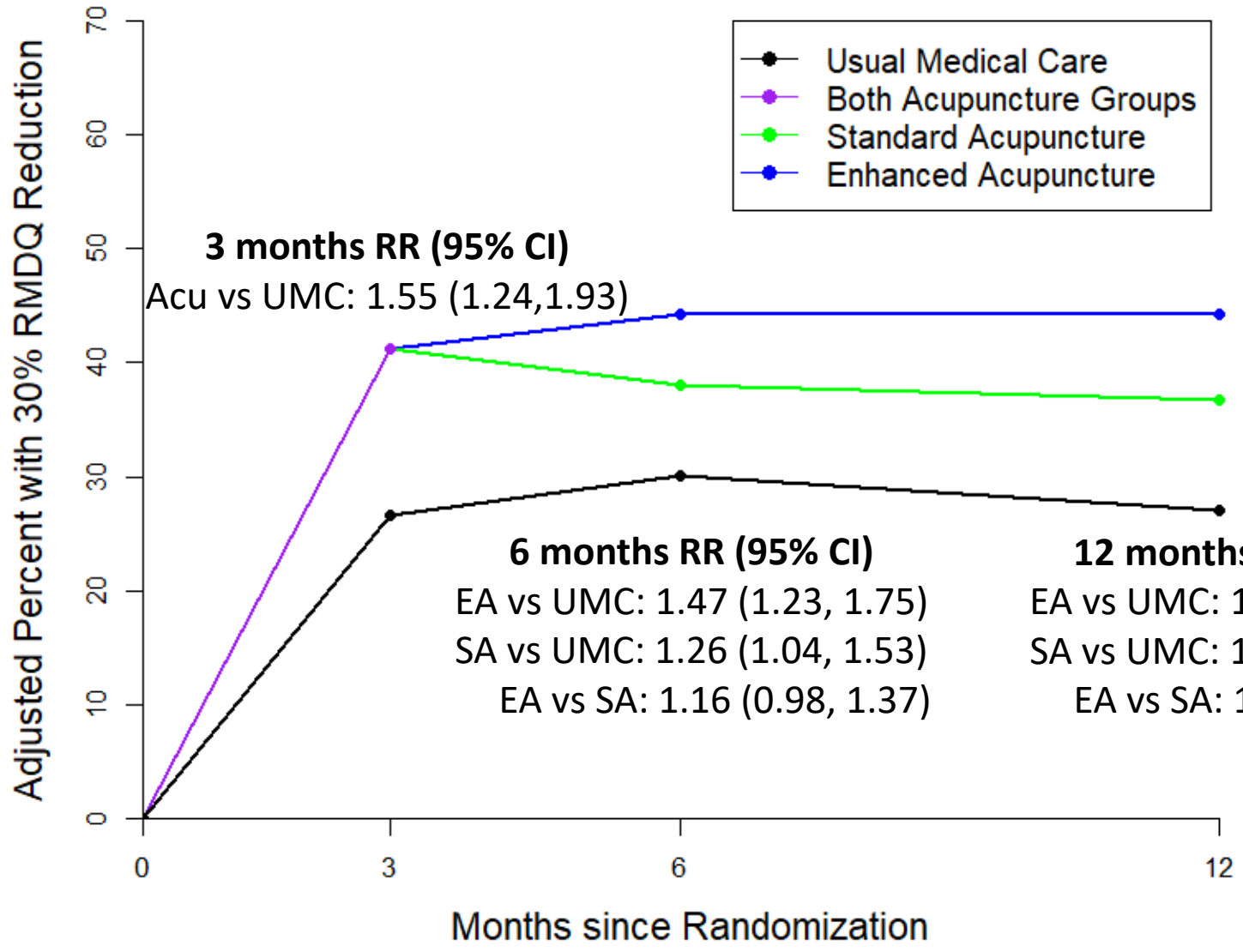
CI – Confidence Interval
SMD – Standardized Mean difference (Effect size)

Adjusted Percent with 30% Reduction (MCID)

	Adjusted Percent with MCID (95% CI)		
Time Point	**Usual Medical Care (UMC)**	**Standardized Acupuncture (SA)**	**Enhanced Acupuncture (EA)**
3 Months	26.6 (19.8, 35.9)	41.2 (35.6, 47.8)	
6 Months	30.1 (24.7, 36.7)	38.1 (31.6, 45.9)	44.2 (37.7, 51.8)
12 Months	27.1 (21.6, 34.1)	36.7 (30.1, 44.8)	44.2 (35.8, 54.7)

CI – Confidence Interval

Adjusted Relative Risk for MCID



3 months RR (95% CI)
Acu vs UMC: 1.55 (1.24,1.93)

6 months RR (95% CI)
EA vs UMC: 1.47 (1.23, 1.75)
SA vs UMC: 1.26 (1.04, 1.53)
EA vs SA: 1.16 (0.98, 1.37)

12 months RR (95% CI)
EA vs UMC: 1.63 (1.36, 1.96)
SA vs UMC: 1.35 (1.12, 1.64)
EA vs SA: 1.21 (1.04, 1.39)

All statistically significant (P-Value<0.05) except for the comparison of EA vs SA at 6 months

RR- Relative Risk
CI – Confidence Interval

(Why) Does It Matter?

Modest effect size of pain-related dysfunction (0.26-0.32) but:

- Comparable effects to those seen in other acupuncture and nonpharmacologic LBP trials
- Focused on older adults – benefit/risk of acupuncture compelling
  - Higher comorbidities and polypharmacy than younger adults
  - Age-related physio changes = more risks associated with common treatments
- Delivered by those best able to provide real world care
  - 50+ acupuncturists (LAc's) practicing in the community
- Effect sustained well past active 3-month standard acupuncture intervention
  - Longer effect duration: compared to opioid & nonopioid medication effects
  - Maintenance sessions appear to boost % with longer term improved functioning
- Favorable safety profile

Next Steps

Study ID: _____ Visit Date: _____/_____/
Visit No (fill in; max of 15 or 21-Enhanced):_____ Visit Start Time: ____:____ Visit End T

Back of the Body						
Left			C			
BL	BL	HTJJ	GV	HTJJ		
	BL 10					
	BL 11	T1	GV 14	T1		
BL 41	BL 12	T2		T2		
BL 42	**BL 13**	T3		T3		
BL 43	BL 14					
BL 44	**BL 15**	T5	GV11	T5		
BL 45		T6		T6		
BL 46	**BL 17**	T7		T7		
BL 47	**BL 18**	T9		T9		
BL 48	**BL19**	T10		T10		
Bl 49	**BL20**	T11		T11		
BL 50	**BL21**	T12		T12		
Pi Gen / BL 51	**BL 22**	L1		L1		
BL 52	**BL 23**	L2	GV4	L2		
	BL 24	L3		L3		
Yao Yan	**BL 25**	L4	GV3	L4		
Huan Zhong						Zhong
	BL 26	L5	SQZX	L5	BL 26	
SI Joint	BL 27				BL 27	SI Joint
BL 53	BL 28				BL 28	BL 53
	BL 29				BL 29	
	BL 30					
GB 29						
GB 30						
	BL 31					
	BL 32					
BL 54	BL 33		GV 2			
	BL 34					
	BL 35				BL 35	

Knee	Knee
Ankle	Ankle

- Further analyses to explore/better understand:
  - role of maintenance acupuncture
  - broader secondary outcomes and moderators of pain-related outcomes
- range of needling approaches utilized (and potential relationship with participant's clinical characteristics)
  - potentially, rapidity of acupuncture-related improvements

Exploring and communicating barriers to CMS reimbursement due to LAc practitioner restrictions

The Acupuncture for Our Seniors Act
H.R. 3133 Fact Sheet

Chu (D-CA) and Brian Fitzpatrick (R-PA) introduced
s Act. H.R. 3133 would allow the U.S. Centers for
recognize qualified acupuncturists as Medicare
le acupuncturists to provide covered services to
) without supervision and bill Medicare directly for

onic lower back pain. H.R. 3133 would enable CMS
ders, so beneficiaries have access to the most
ce.
dicare policy with the acupuncturist licensure laws so
ver 60-million Medicare beneficiaries.
le acupuncturists to directly bill Medicare for covered
e's supervision requirement.
ists' as individuals who are licensed, or certified
, for those in states that do not provide issue licenses

roviders of acupuncture from continuing to provide the

rogram by granting provider status to acupuncturists,
ect access to their services.

are and wellness by:
e beneficiaries access to acupuncturists
sts to provide covered services to Medicare beneficiaries
- Establishing an acupuncture-coverage model for third-party payers.

Patient Benefits

The Acupuncture for our Seniors Act would enable qualified acupuncturists to provide patient-centered care to Medicare beneficiaries.

Access to acupuncturists could improve patient outcomes by:
- Providing non-invasive, evidence-based, cost-effective care to manage pain
  ealthcare
  thin standard healthcare-management plans.

-invasive pain-management intervention that can help
mobility and independence, reduce reliance on
decrease the need for surgeries
ncture service; H.R. 3133 would enable the most
deliver this service to Medicare beneficiaries.

It Takes A Village…

KP Washington
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Carolyn Eng
Jane Grafton
Gabrielle Gunderson
Laurel Hansell
Luesa Healy
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Patricia Herman – RAND
Sam Mann - RAND
Lanay Mudd / Robin Boineau– NCCIH (Project Officers [present/past])
Qilu Yu – NCCIH biostatistical advisor
Study Acupuncturists

QUESTIONS?

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Sample Size / Power Estimates

Primary Outcome: Change in RMDQ from Baseline

Time Point: 6 months

Assumptions:

- MCID: 2 pt difference
- Group Differences: SA and EA each have MCID above UMC
- Power: 90% power to detect a difference between each acupuncture group and usual medical care only (pair-wise comparison power)
- Standard Deviation: 6 points
- Loss to Follow-up: 20%
- Test Statistic: Omnibus F-Test then T-tests between groups

Sample Size: 789 Total Participants (263 per group)

Primary Analysis: Comparisons

3 months: Is Standard Acupuncture superior to Usual Medical Care (UMC) at 3 months?

- Approach: Single Acupuncture Group (SA and EA receive the same intervention over the first 3 months) comparing the combined group to UMC

6 and 12 months: Is standard or enhanced acupuncture superior to UMC at either time point?

- Step 1: Compare SA and EA to each other to assess if acupuncture treatment with additional maintenance is better then standard acupuncture at these study time points
- Step 2:
  - Scenario 1: If SA and EA are different, compare each to UMC and evaluate whether standard and/or enhanced acupuncture is superior to UMC at 6 months
  - Scenario 2: If SA and EA are not different, combine both into a single acupuncture group and compare to UMC evaluating whether acupuncture overall is superior to UMC at these time points

Adjusted Relative Risk comparison of MCID

	Adjusted Relative Risk between Intervention Groups (95% CI)		
Time	**Enhanced vs Standard**	**Standard vs UMC**	**Enhanced vs UMC**
3 Months		**1.55 (1.24, 1.93)**	
6 Months	1.16 (0.98, 1.37)	**1.26 (1.04, 1.53)**	**1.47 (1.23, 1.75)**
12 Months	**1.21 (1.04, 1.39)**	**1.35 (1.12, 1.64)**	**1.63 (1.36, 1.96)**

CI – Confidence Interval