Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults (Back in Action)

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BACK IN ACTION

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 care) pragmatic trial *(807 patients)*

SETTINGS: KP Washington, KP Northern California, Sutter Health, Institute of Family Health (NYC FQHC Network) – combination of integrative care FFS, FQHC Health Systems

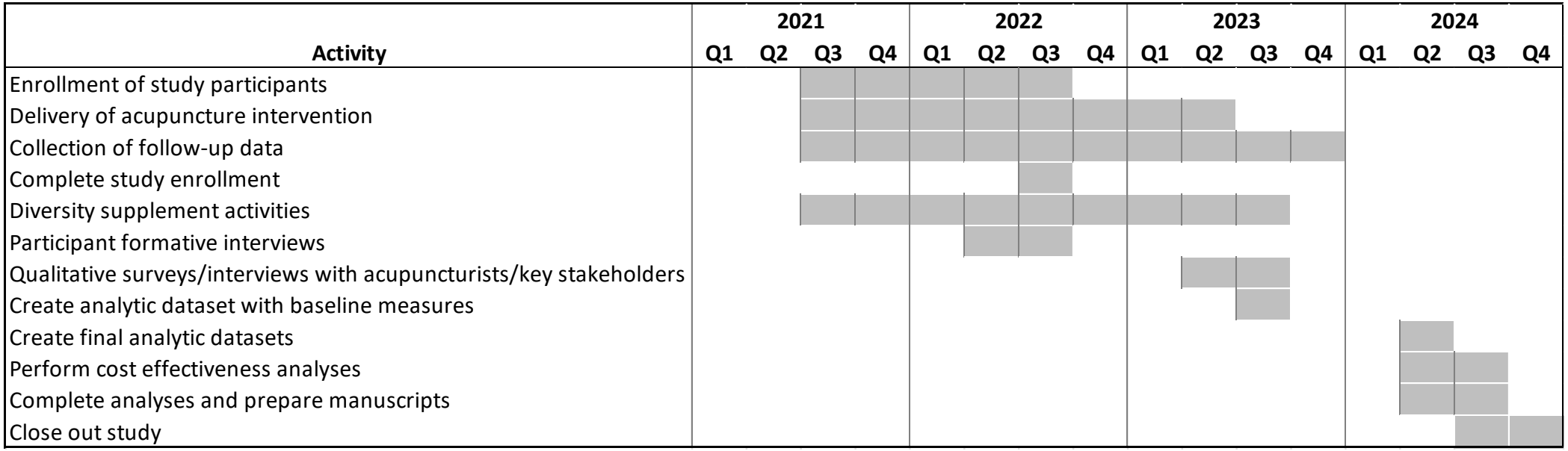
ELIGIBILITY: ≥ 65 years of age with EHR diagnosis consistent with uncomplicated chronic low back pain meeting threshold of pain-related general activity interference (≥ 3 on PE**G**)

INTERVENTION: Standard (15 treatment sessions across 12 weeks) or enhanced (up to 6 additional maintenance sessions across 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.

Status Updates

- Completed Enrollment October 2023
  - N = 807, 62% Female, Age (M=74, SD=6), Race/ethnicity: 65% White, 17% Black, 5% Asian, other 11.7%; 11% Hispanic
- Qualitative Survey/Interviews with study acupuncturists/key health plan & national stakeholders Q2/Q3 of this year
- Preparing for Baseline data papers / healthcare utilization data pulls to support economic analyses



BackInAction: Barriers Scorecard

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

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

Top Barriers and Challenges (1)

- Clinical / Demographic heterogeneity across clinical sites
  - IFH (FQHC sample): younger, lower education, more HICP, more baseline disability (RMDQ) and pain (PEG), higher expectations for acupuncture

Patient Characteristics	Total	IFH	KPNC	KPWA	Sutter
Total, N (row %)	807(100.0)	124(15.4)	288(35.7)	185(22.9)	210(26.0)
Age, mean (SD)	74(6.0)	71.6(5.8)	73.7(5.7)	73.8(5.8)	76(6.0)
Female, N (%)	497(61.6)	88(71.0)	173(60.1)	108(58.4)	128(61.0)
Education, N (%)					
Less than HS	31(3.8)	23(18.5)	4(1.4)	2(1.1)	2(1.0)
HS Graduate	91(11.3)	31(25.0)	30(10.4)	21(11.4)	9(4.3)
Some College	214(26.5)	36(29.0)	75(26.0)	58(31.4)	45(21.4)
College Grad	468(58.0)	33(26.6)	177(61.5)	104(56.2)	154(73.3)
Unreported	3(0.4)	1(0.8)	2(0.7)	0(0.0)	0(0.0)
Back Pain Characteristics, N(%)					
High Impact Chronic Pain	377(46.7)	74(59.7)	126(43.8)	73(39.5)	104(49.5)
Sciatica	549(68.0)	95(76.6)	186(64.6)	127(68.6)	141(67.1)
Acupuncture expectations*, Mean (SD)	6.4(2.4)	7.9(2.3)	6.1(2.3)	6(2.4)	6.3(2.4)
Baseline outcome variables					
Roland Morris Disability Questionnaire, Mean(SD)	15.2(7.3)	20.1(7.6)	14.2(6.9)	13.5(6.0)	15.1(7.3)
Roland LT 5, N (%)	39(4.8)	1(0.8)	16(5.6)	11(5.9)	11(5.2)
Roland GT 18, N (%)	249(30.9)	79(63.7)	73(25.3)	34(18.4)	63(30.0)
PEG, Mean(SD)	5.8(3.7)	8(5.7)	5.3(2.1)	5.1(2.9)	5.8(3.9)

*Expectations of acupuncture is on a 0 to 10 scale.

Top Barriers and Challenges (2)

- Clinical / Demographic heterogeneity across clinical sites and over time analytic implications
  - Missing outcome data: incorporating site interactions for pattern mixture imputation model when missing data is mostly in one smaller site (Flexible yet parsimonious models)
  - Subgroup analyses and Changes in recruitment over time:
    - **Examples:** KPWA enrolled earlier but then over-recruited certain racial and ethnic groups later to increase diversity; IFH enrolled later and then added Spanish language even later;
    - COVID 19 pandemic with new variants and major calendar time changes (Potential implications on participant outcomes, adherence, and intervention effect)
    - Analytically we need to flexibly control for time in subgroup analyses potentially with interactions with intervention effect
  - Subgroup analyses and interpretation: with certain subgroups largely from certain sites, is adjustment for site enough?

Top Barriers and Challenges (3)

- Clinical / Demographic heterogeneity across clinical sites

- CMS Data availability lags precluded use (incomplete [ambulatory care only] health service use data for FQHC site/participants)

- Barriers to Sustained Implementation / Acupuncture availability
  - Lack of congruence of CMS/Medicare payment provision with organization of acupuncture services (not allowed to bill through FQHCs, community acupuncturists not under supervision of qualifying healthcare provider not reimbursable)

American Society of Acupuncturists™

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For Immediate Release!

Acupuncture for Our Seniors Act of 2023

WASHINGTON, May 09, 2023 (GLOBE NEWSWIRE) -- The American Society of Acupuncturists (ASA) and the National Certification Commission for Acupuncture and Oriental Medicine (NCCAOM) commend U.S. Representatives Judy Chu (D-CA) and Brian Fitzpatrick (R-PA) for introducing [Bill Number pending], *the Acupuncture for Our Seniors Act. The Acupuncture for our Seniors Act* would authorize the U.S. Centers for Medicare and Medicaid Services to recognize qualified acupuncturists as healthcare providers. Medicare recognition would enable qualified acupuncturists to provide covered services to Medicare beneficiaries, which will soon surpass 80-million Americans.

Recent Generalizable Lesson Learned (1)

- Importance of Additional Outreach/Support for Retention at IFH/FQHC site
  - Efforts to increase 6-month follow-up rates implemented 2/16/23: Reminder letter with $5 pre-incentive and reminder call from local sites

	TOTAL		IFH		KPNC		KPWA		SH	
	W/Outcome	(%)	W/Outcome	(%)	W/Outcome	(%)	W/Outcome	(%)	W/Outcome	(%)
Overall* (N=748)	664	(88.8)	84	(77.8)	231	(88.5)	166	(92.7)	183	(91.5)
Before 2/16 (N=604)	535	(88.6)	58	(76.3)	179	(87.3)	162	(93.1)	136	(91.3)
2/16 to 4/24 (N=144)	129	(89.6)	26	(81.3)	52	(92.9)	4	(80.0)	47	(92.2)

*Overall is amongst those past 6 months window (IFH=108/124; KPNC=261/288 ; KPWA= 179/185 ; SH=200/210)

Recent Generalizable Lesson Learned (2)

- Acupuncture was popular with older adults outreached (despite COVID-related risks [vulnerable population, in-person/hi touch tx])
  - Modified consent process – exploring/discouraging enrollment for those exclusively focused on desire for acupuncture treatment (explaining usual care importance for study)
  - May have helped to have usual care+ condition ("wellness" offering as component of usual care control)
    - UH2 formative data suggested "altruism" primary motivator for participation (were our PCT enrollees less comparable to pilot focus group participants than we anticipated?)
    - Support for online wellness offerings/aids to self-care? (didn't pursue due to concerns about potential confounding of contemporaneous "wellness" offering)
    - Make delayed acupuncture available? (not feasible within timeframe and study resources)

Data Sharing Plans

- Older Adult Participants / Health Plans: lay language summary
- With Researchers / HEAL:
  - Data set with HEAL required Common Data Elements (but without participant race/ethnicity or site identifier in publicly available project data set)
  - PRISM still considering how stewarded/hosted
- Other important constituencies for data sharing to enhance broader uptake if positive study outcomes
  - CMS: communicating findings but logistic limitations of widespread availability given reimbursement constraints
  - PCP referrers: understanding potential clinical impact (more than just a “safe” placebo?)
  - Organizations supporting NPT availability and championing older adult needs and complementary and integrative health offerings (e.g., AARP, ACPA, AIPM)