Innovation & Integration in Acupuncture Research in the Underserved

Embedding research in an FQHC

The Study

- HEAL* funded Back in Action (BIA) Trial
 - Multicenter: Institute for Family Health (IFH), Kaiser Permanente and Sutter (WA, No. CA)
 - Pragmatic trial, re: acupuncture effectiveness and safety in adults \geq 65 years old
 - Chronic lower back pain (cLBP) diagnosis
- 3-arm trial
 - Standard acupuncture (SA) up to 15 sessions over 90-day period
 - Enhanced acupuncture (EA) adds 6 more sessions in second 90-day period
 - Control group of Usual Care (UC)

The Background

- Prevalence of low back pain increases with age, accounts for 1/3 of 65+
- Acupuncture demonstrated to be effective for cLBP, but research has not focused specifically on 65+
- Need for non-pharm therapies in treatment of pain: 65+ generally multi-morbidities, polypharmacy
- Under-represented populations carry significant pain burden but often have less access to pain intervention
- IFH is a Federally Qualified Health Center (FQHC)
 - Serving under-represented community
 - Recruitment & Intervention through urban clinical sites in Brooklyn, Manhattan & Bronx
 - 2 family medicine residencies
 - 8 Recruitment sites included
 - 3 intervention sites by region

The Problem(s)

- Under-representation in clinical research
 - Historic violations in human subjects research
 - Interest and Access
- Research participation entails:
 - Recruitment
 - Ethics and Education
 - Promotion
 - Intervention
 - Feasibility, Acceptability, Accessibility
 - Research Design
 - Retention
 - Control group dilemma
 - Follow-up assessments participation



Recruitment as Referral

- Recruitment to Research through Patient's Clinician
 - In "real time" with research prompts concurrent to patient appointment, via email and EMR
 - EPIC inbasket: same-day reminders to clinicians
 - Research parameters
 - Patient eligibility
 - Best Practice Alerts (BPA) set up as second reminder
 - One click = referral to Clinical Research Coordinator (CRC)
 - CRC has EPIC access and makes outreach call
 - IT built report to identify all eligible patients per day throughout institution → roughly 10-20 per day
 - CRC can circle back to clinician to let them know if not eligible or other issues via EPIC

Intervention

Acupuncture appointments scheduled in EPIC

- Separate department to avoid scheduling and billing issues
- Arrivals through normal clinical operations

Acupuncture offered at or in proximity to Patient Participant's Home Medical Clinic

"Pop up" clinic set up in conference rooms with massage tables for affordability

Acupuncture intervention documented in EMR

- Specific template built by IT, within research guidelines
- Data capture seamlessly exported for collection with Research Coordinating Center
- Intervention transparency: notes viewable in patient's chart

Follow Up, Post Randomization Assessments



Done by KP Wa Coordinating Center



Challenges: Acknowledgement and Education to participants

Time Difference and Different Area Code Relevance to Research



Scheduling of assessments

Reminders to patients helpful
Financial incentives via refillable Clincards®

IFH Participant demographics

Sex (assigned at birth)			
Female	89	72%	
Male	34	28%	
Primary language			
English	87	71%	
Spanish	36	29%	
Ethnicity			
Hispanic or Latino	46	37%	
Not Hispanic or Latino	51	41%	
Other	25	20%	

IFH Participant demographics

	Race (can choose multiple)	
Black or African American	49	38%
White	30	23%
Other	41	32%

IFH Participant demographics

Income				
Less than \$10,000	28	23%		
\$10,000 \$24,999	29	24%		
\$25,000 \$34,999	12	10%		
\$35,000 \$49,999	10	8%		
\$50,000 \$74,999	8	7%		
Don't know	28	23%		
Insurance				
Medicaid	63	52%		
Medicare	23	19%		
Private	31	25%		

Successes!



Research embedded in Electronic Medical Record

BPA's and reminders for recruitment accepted by colleagues

Rate of recruitment of eligible participants variable but roughly 10-20%



Met recruitment goal of 123 by projected date

Good diversity

Spanish speaking participants 30%



Low no show rate for intervention

Appointments and Attendance within standard clinical flow

Good relationship around physical plant
Low impact on clinical operations

<u>Data sharing</u> with CC fine

Conclusions

- Integration: Access and Acceptability
 - Research embedded within clinical milieu
 - Referrals leveraged clinicians aim of advocacy to validate research
 - Organic referral process decreased knowledge gap
 - Acupuncture care delivered in Healthcare Clinic
 - Validated and normalized acupuncture as viable pain intervention
 - FQHC in multisite trial

Next Steps

- Examine data measures
- Integration of non-pharmacological therapy for pain by referral and/or within Healthcare Clinics
 - Acupuncture as affordable and acceptable in our FQHC setting
- Research design and access for broader representation of US demographics
- From Feasible to Sustainable