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 ≥ 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)

*HEAL = Helping Ease Addiction Long-Term, NIH funded initiative
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
The Answer

Embed research activity parallel to clinical milieu
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

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<table>
<thead>
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<tbody>
<tr>
<td><strong>Sex (assigned at birth)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>89</td>
<td>72%</td>
</tr>
<tr>
<td>Male</td>
<td>34</td>
<td>28%</td>
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<tr>
<td><strong>Primary language</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English</td>
<td>87</td>
<td>71%</td>
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<tr>
<td>Spanish</td>
<td>36</td>
<td>29%</td>
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<tr>
<td><strong>Ethnicity</strong></td>
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<tr>
<td>Hispanic or Latino</td>
<td>46</td>
<td>37%</td>
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<tr>
<td>Not Hispanic or Latino</td>
<td>51</td>
<td>41%</td>
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<tr>
<td>Other</td>
<td>25</td>
<td>20%</td>
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### IFH Participant demographics

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<thead>
<tr>
<th>Race (can choose multiple)</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Black or African American</td>
<td>49</td>
<td>38%</td>
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<tr>
<td>White</td>
<td>30</td>
<td>23%</td>
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<tr>
<td>Other</td>
<td>41</td>
<td>32%</td>
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### IFH Participant demographics

<table>
<thead>
<tr>
<th>Income</th>
<th>Count</th>
<th>Percentage</th>
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<tr>
<td>Less than $10,000</td>
<td>28</td>
<td>23%</td>
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<tr>
<td>$10,000--- $24,999</td>
<td>29</td>
<td>24%</td>
</tr>
<tr>
<td>$25,000--- $34,999</td>
<td>12</td>
<td>10%</td>
</tr>
<tr>
<td>$35,000--- $49,999</td>
<td>10</td>
<td>8%</td>
</tr>
<tr>
<td>$50,000--- $74,999</td>
<td>8</td>
<td>7%</td>
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<tr>
<td>Don’t know</td>
<td>28</td>
<td>23%</td>
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<tr>
<th>Insurance</th>
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<tr>
<td>Medicaid</td>
<td>63</td>
<td>52%</td>
</tr>
<tr>
<td>Medicare</td>
<td>23</td>
<td>19%</td>
</tr>
<tr>
<td>Private</td>
<td>31</td>
<td>25%</td>
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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
Data sharing 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