Diversity in Clinical Trial Research (DCTR)

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Pragmatic Trial Supplement NIH PA20-272, (HEAL/BiA Pragmatic Trial)
Disclosures

NO RELEVANT DISCLOSURES
Background

- Lower engagement of patients of color in research participation has resulted in historical trends of underrepresentation in clinical trials.
- Among those who do select to engage in research, there is a higher risk of loss-to-follow-up by Black and Hispanic/Latino participants.
- Solutions offered to address the barriers to participation engagement by Black and Hispanic/Latino patients apply a patient-centered approach that considers cultural, social, and environmental differences include:
  - Understanding cultural norms and personal interactions
  - Providing general respect and quality care for participants
  - Establishing trust to build relationships
  - Assuring culturally sensitive patient facing material and project terminology
  - Providing Q&A sessions throughout the research process
This is an NIH funded Supplementary diversity and inclusion study running ancillary to the currently funded BIA study; a Pragmatic, three-arm parallel groups multi-site randomized controlled trial: standard acupuncture, extended acupuncture, and usual care

Objectives:

► To enhance diversity and inclusion in the recruitment of patients
► To assess and reduce patient opt-out rates
► To assure retention of a diverse patient sample
► To understand diversity and inclusion in patient participation in an Integrative Medicine clinical trial
Approach

- In-depth Interviews with Patients
- Advisory Board Recommendations
- Recruitment & Retention Specialist
- Implementation changes to BIA/HEAL study team
Lessons Learned: Recruitment

Challenges

• Hispanic patients highly valued input from their clinicians

• Recruitment from the clinician led to some confusion particularly around the EHR integrated “Interested” option.

• Most patients do not understand the meaning of the term “research”

Solutions

• Adding clinician script in Spanish

• Change the language on the clinical EHR recruitment from “interested” (suggesting interested in being in the study) to “interested in learning more”

• Emphasis on the term “study” rather than “research”
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<tr>
<th>Challenges</th>
<th>Solutions</th>
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<td>• Patients feeling discomfort or experiencing no benefits from the treatment but are not discussing these with researchers/clinicians</td>
<td>• Enhanced training to those providing the clinical intervention to initiate discussions about discomfort and response.</td>
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<td>• Patients’ family demands take precedence</td>
<td>• Enhanced training for outreach to include culturally appropriate, patient-centered language to empathize and support patient through these demands.</td>
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Lessons Learned: Dissemination

Challenges

- Participants are interested in knowing the findings.
- Dissemination beyond participants could be a tool to support future recruitment.

Solutions

- Develop a visually simple but informative dissemination image that participants would be able to share with others.
Segments from our DCTR Advisory Board
Next Steps