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

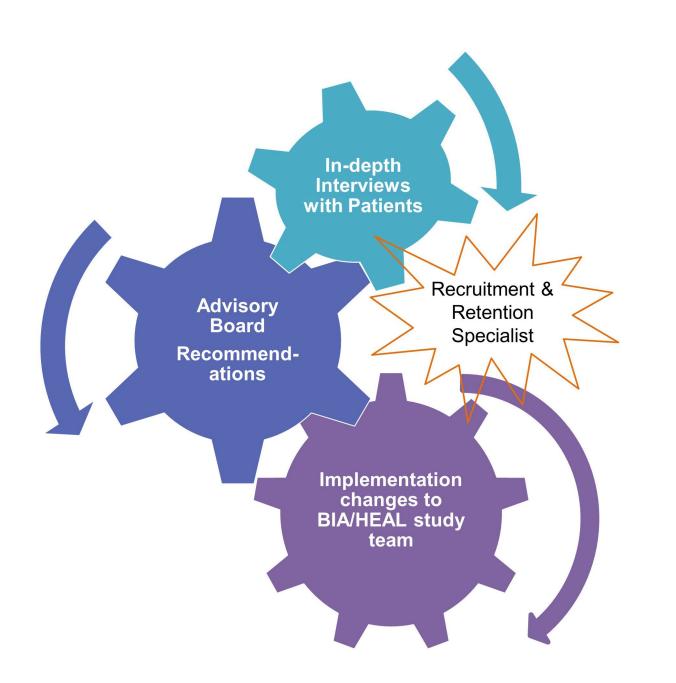
- Lower engagement of patients of color in research participation has resulted in historical trends of underrepresentation in clinical trials.
- Among those who do select to engage in research, there is a higher risk of loss-to-follow-up by Black and Hispanic/Latino participants.
- Solutions offered 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

Diversity Supplement for: BackinAction (BIA) HEAL Study

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

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"

Lessons Learned: Retention

Challenges

- Patients feeling discomfort or experiencing no benefits from the treatment but are not discussing these with researchers/clinicians
- Patients' family demands take precedence

Solutions

- Enhanced training to those providing the clinical intervention to initiate discussions about discomfort and response.
- Enhanced training for outreach to include culturally appropriate, patient-centered language to empathize and support patient through these demands.

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

Conceptualization

Sampling Plan

Measurement

Analysis

Dissemination



- Do the research questions/hypotheses/objec tives address racial and ethnic disparities?
- Is the research team racially and ethnically diverse?
- Is a Patient Advisory Board including racial and ethnic minorities being utilized?



- Are inclusion criteria's responsive to barriers experienced by racial and ethnic minorities?
- Are there recruitment effort to enhance interest in racial and ethnic minorities?*
- Are retention efforts in place to address continuity challenges experienced by racial and ethnic minorities?*

*Interventional Research Only



- Are measures of risk factors sensitive to racial and ethnic cultural differences?
- Are measures of outcomes sensitive to racial and ethnic cultural differences?
- Is there a plan to address data incongruities related to race and ethnicity?



- Is power sufficient to stratify by racial and ethnic sub populations?
- Will associations be stratified by race and ethnicity?
- Does the analysis consider additional social determinants associate with race and ethnicity?



- Is there a culturally sensitive dissemination plan to share findings with participants?
- Is there a culturally sensitive dissemination plan to share findings with communities from which the sample was drawn?

Next Steps