

Justice and equity in pragmatic clinical trials: Challenges & recommendations

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NPTs for pain management: an opportunity and challenge

- Dynamic interaction of factors within and across the biological, psychological and social domains of pain
- Experiences under any one domain (e.g., history of racial or sexual harassment and discrimination) can have broad biological, psychological, and social effects
- Non-pharmacological treatments (NPTs) for pain often seek to address pain in an integrated way, acknowledging its multiple influences
- Negative experiences with health systems can interfere with some groups' participation in pain PCTs, the delivery of NPTs, and pain recovery

Challenge #1: Study Context & Design

- Example Challenge:
 - Potential for biases, prejudices, and inequities to transfer from health systems to PCTs
- Example Mitigation Strategies:
 - Understand, prospectively, community attitudes and beliefs regarding a health system and how these might transfer to aspects of trial implementation (e.g., experiences with pain treatment in VA, sexual harassment in VA)
 - Develop, share, and enforce standards for equity and inclusion across the study team and supporting personnel

Challenge #2: Participant Recruitment and Retention

- Example Mitigation Strategies:
 - Choose settings where potentially excluded populations are represented
 - Racial/ethnic minoritized patients concentrated in certain healthcare facilities
 - Identify potential barriers to trial participation prospectively
 - Create and include patient engagement groups as part of the research team who can review and offer feedback on recruitment methods and materials
 - Include within recruitment materials culturally sensitive and specific images and language that include populations experiencing lower access to care or other known disparities within the study's health system
 - Consider proactive outreach: systems-level strategy of identifying and reaching out to patients with tailored materials, to connect them to treatment
 - Can address barriers of awareness, engagement, interest, knowledge, mistrust

Challenge #3: Study Interventions

- Example Challenge:
 - Interventions that do not align well with contextual needs or strong preference of certain patient populations
- Example Mitigation Strategies:
 - Identify multiple strategies (e.g., individual and group-delivered interventions, condensed treatment schedules, multi-lingual therapy) to facilitate intervention delivery for different types of patient populations.

Challenge #4: Stakeholder Engagement

- Example Challenge:
 - Limited racial, ethnic, and ability diversity among providers, investigators, and study staff
- Example Mitigation Strategies:
 - Use known strategies to attract and engage investigators from underrepresented groups
 - Engage with diverse patient groups who can review and offer feedback on study design and implementation choices
 - Invite patients who represent a study population formally to be members of the research team
 - Offer structural competency and cultural sensitivity training for research and healthcare staff involved in PCTs

Example: LAMP – PCT of two approaches for delivering mindfulness-based interventions to VA patients with chronic pain

- Focus on addressing needs of women Veterans
 - Experience higher rates of pain and conditions that contribute to pain (e.g., anxiety, depression, PTSD, sleep disorders, history of past trauma)
 - 24% of female Veterans experienced sexual harassment in VA
 - 15%-40% experienced military sexual trauma
- Women Veterans reported feeling uncomfortable with group mindfulness format (Martinez, 2015)

Strategies used by LAMP



- Ongoing input from diverse Veteran and Stakeholder Engagement Panel & input from PMC Patient Resource Group
- Choose sites with higher percentage of minoritized patients (also more likely to be younger and female)
- Proactive recruitment; reached out to patients through EHR using tailored materials

Adaptations to intervention

- Included MBI without group component; pivoted to online group sessions
- Guided meditations recorded in female voice
- Interventions trauma-informed (e.g., shorter guided meditations, participants encouraged to do what felt safe, 2nd facilitator trained to monitor and provide support)

More Work Needed

- To develop measures and evidence related to understanding the impact of various inequities on PCTs
- To develop and test interventional strategies that address some of the psychological and social factors bridging both the experience of pain and the experience of inequity