CLINICAL TRIALS: BARRIERS, FACILITATORS & MEDIATORS

Boston Team: Candace Feldman, MD, ScD; Jessica Williams, MD, MPH; Elmer Freeman (CCHERS), Kreager Taber, BA
Chicago Team: Rosalind Ramsey-Goldman, MD, DrPH, Patricia Canessa, PhD, Karen Mancera-Cuevas MS, MPH, CHES, Holly Milaeger, MPH

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Objectives

- Discuss the **barriers, facilitators and mediators** in clinical trials enrollment

- We will be sharing examples that were discussed during our Lupus Conversations focus groups
Definitions

❖ Barriers
  ❖ Things that make it more difficult for eligible participants to enroll or participate in a clinical trial
  ❖ Decrease the chance that an eligible participant will want to enroll

❖ Facilitators
  ❖ Make it easier for participants to enroll or participate in a clinical trial
  ❖ Increase the chance that an eligible participant will want to enroll
  ❖ Facilitators are helpers that increase the likelihood of enrollment
Facilitators to Clinical Trials Enrollment

- **Family, peer or partner support**
  - Inclusion of patient’s support network as part of the clinical trial recruitment process and allow time to address their questions

- **Supportive relationship with Healthcare Provider**
  - Patients and Providers should be able to discuss the risks and benefits of a clinical trial, both before the patient is enrolled and during the study

- Include discussion with participants to share clinical trials study findings

- **Comments:** The patient motivation or compelling stage of the disease that leads into finding “other” treatment solutions.
Facilitators for Clinical Trials Enrollment II

- **Clear Explanation of the Study’s Purpose and Goals**
  - Participants should understand why the study is being conducted and why they are eligible

- **Allowing Time for Informed Consent**
  - Patients should be given enough information about the risks and benefits of enrolling in a study to make the decision that is **right for them**

- **Open Communication Between Patients, PI, and Study Staff**
  - Patients should feel comfortable asking the study staff and PI questions, which will most likely be answered with **multiple conversations**

- **Telling Patients the Study’s Results**
  - Study Staff should share the results of the Trial with the Patients in an understandable way
Barriers to Clinical Trials Enrollment

- **Health Status**
  - Patient may be too sick.
  - Patient may not have a confirmed diagnosis of lupus.
  - Patient may have a history of prior withdrawal due to medical complications through the course of prior clinical trials.

- **Confusing Research Materials**
  - Unclear and lengthy consent forms.
  - Inaccessible recruitment documents.
  - Confusing explanations of the study’s protocol.

- **Lack of peer or family support**
  - Family and friends seeing clinical trials as “unsafe”.
  - Confusion about what a clinical trial is and what enrollment will mean.

- **Historical Injustice and Racism**
  - Past and present experiences of discrimination and racism in healthcare and everyday life may contribute to mistrust and limit participation.
Barriers to Clinical Trials Enrollment II

- **Health Literacy Challenges**
  - Descriptions of study drug or study protocol in overly-medical terms.
  - Meeting the participant at their literacy level.
  - Linguistically-competent translation and adaptation to culturally-related concepts.

- **Financial and Time Constraints**
  - Patients may not be able to take time off of work to go to study visits or have competing obligations.
  - Financial burden of paying for childcare, transportation, or parking to attend study visits
QUESTIONS?
THANK YOU!
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