

# Additional Considerations When Conducting ePCTs: A Framework for Achieving Health Equity in Pragmatic Trials

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# Learning goals

- Understand the meaning and importance of health equity in embedded pragmatic clinical trials (ePCTs)
- Recognize common barriers to ePCT equity using the PRECIS-2 framework

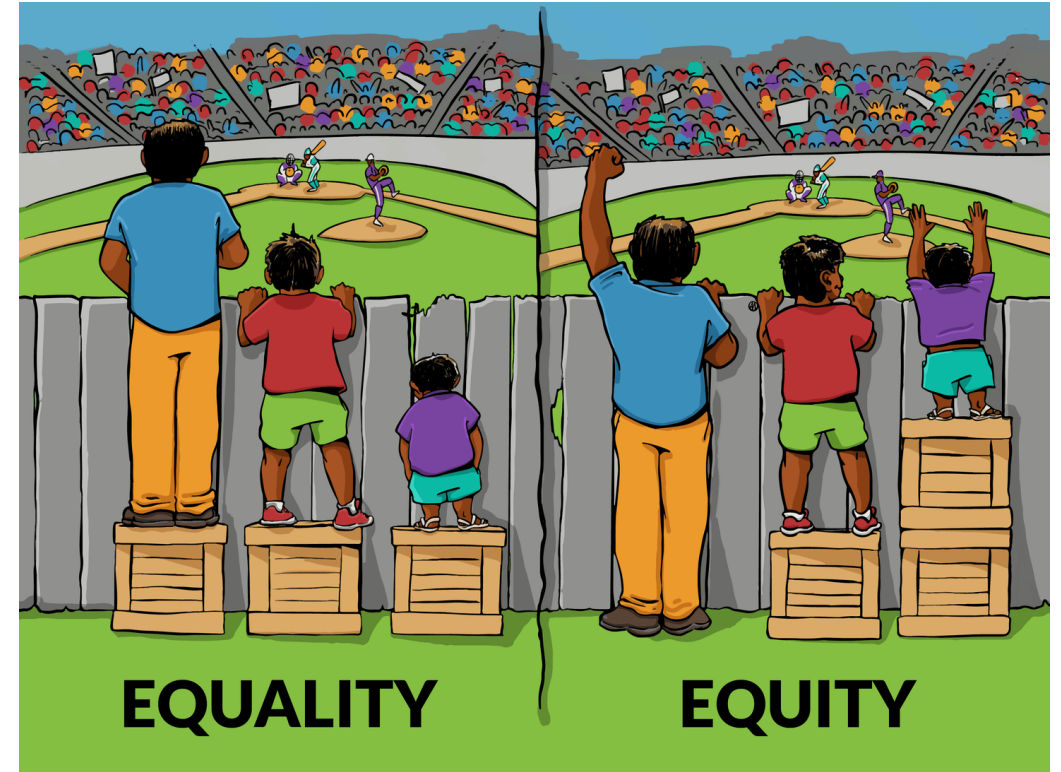


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# The Necessity of Health Equity in Research

- Helps us “level up” the health of individuals, groups, and communities with greatest need
- Must be front and center as we design and implement studies
- Without health equity, access may be undermined and effectiveness could be misrepresented

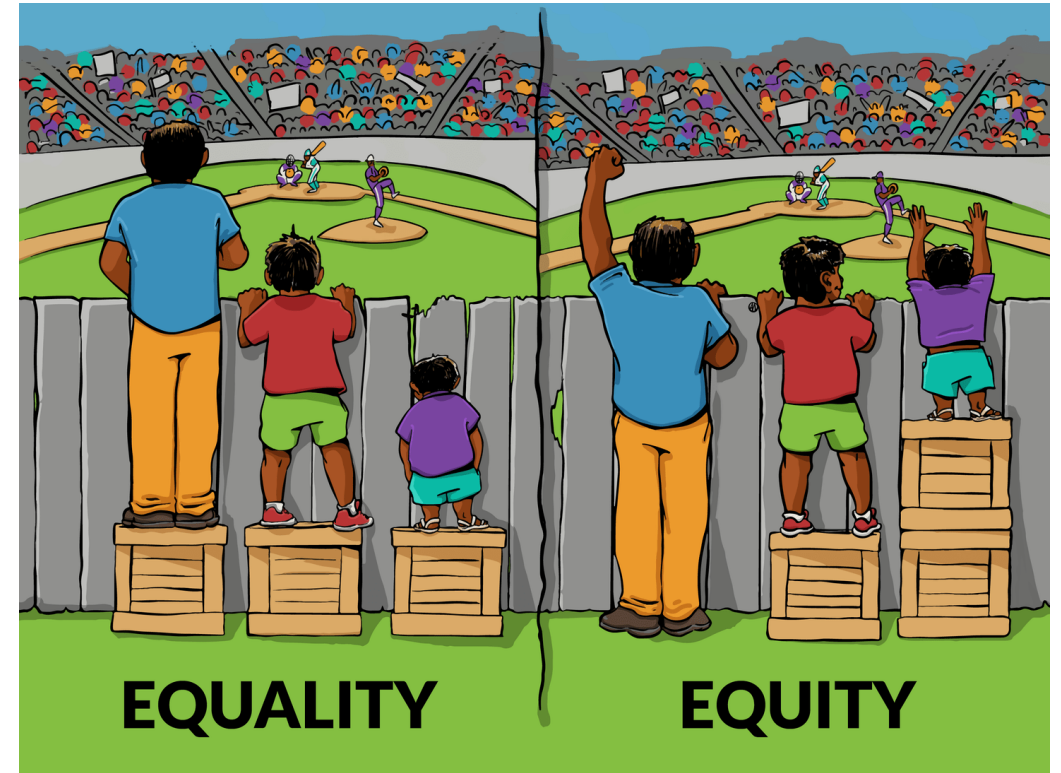
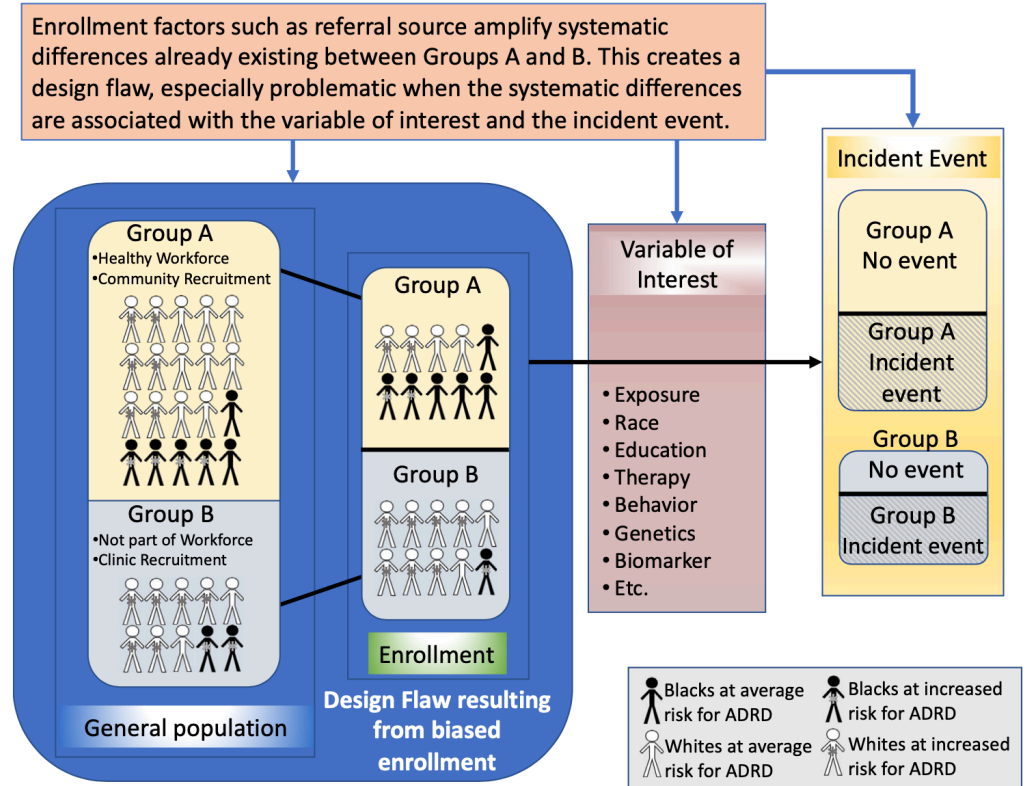
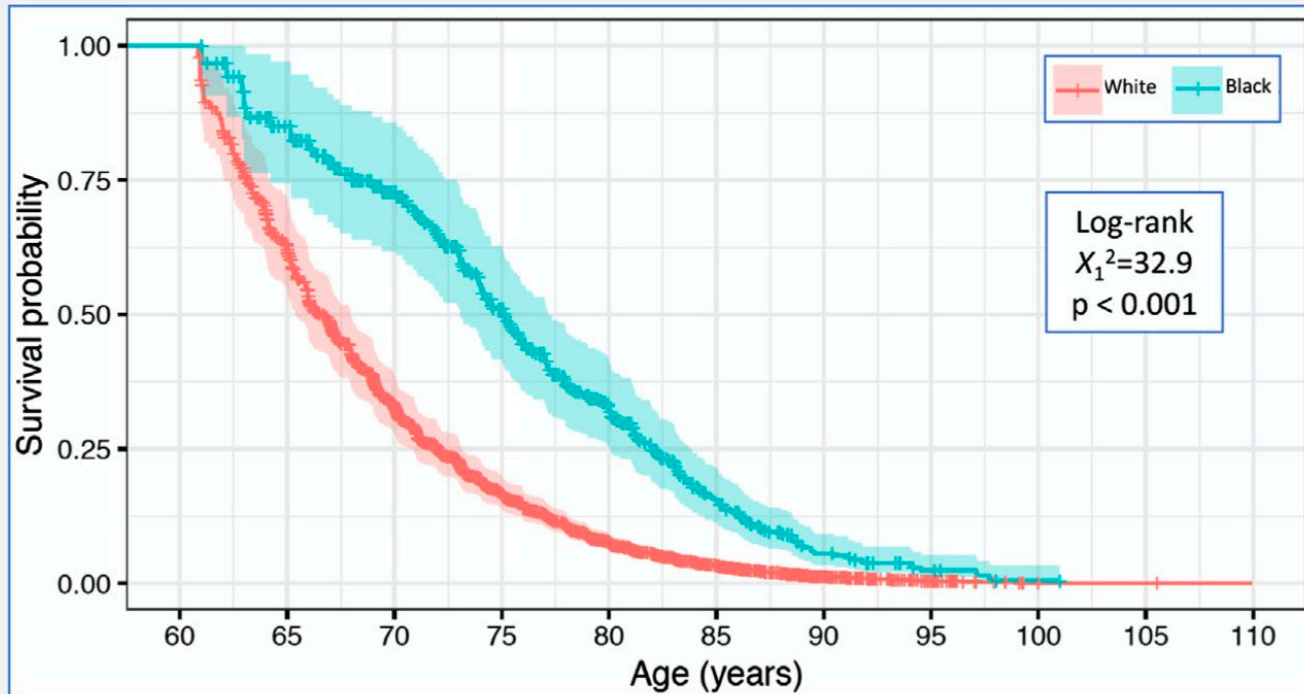


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# The Necessity of Health Equity in Research

Kaplan-Meier Curves for non-Hispanic Whites and Blacks diagnosed with MCI at Baseline

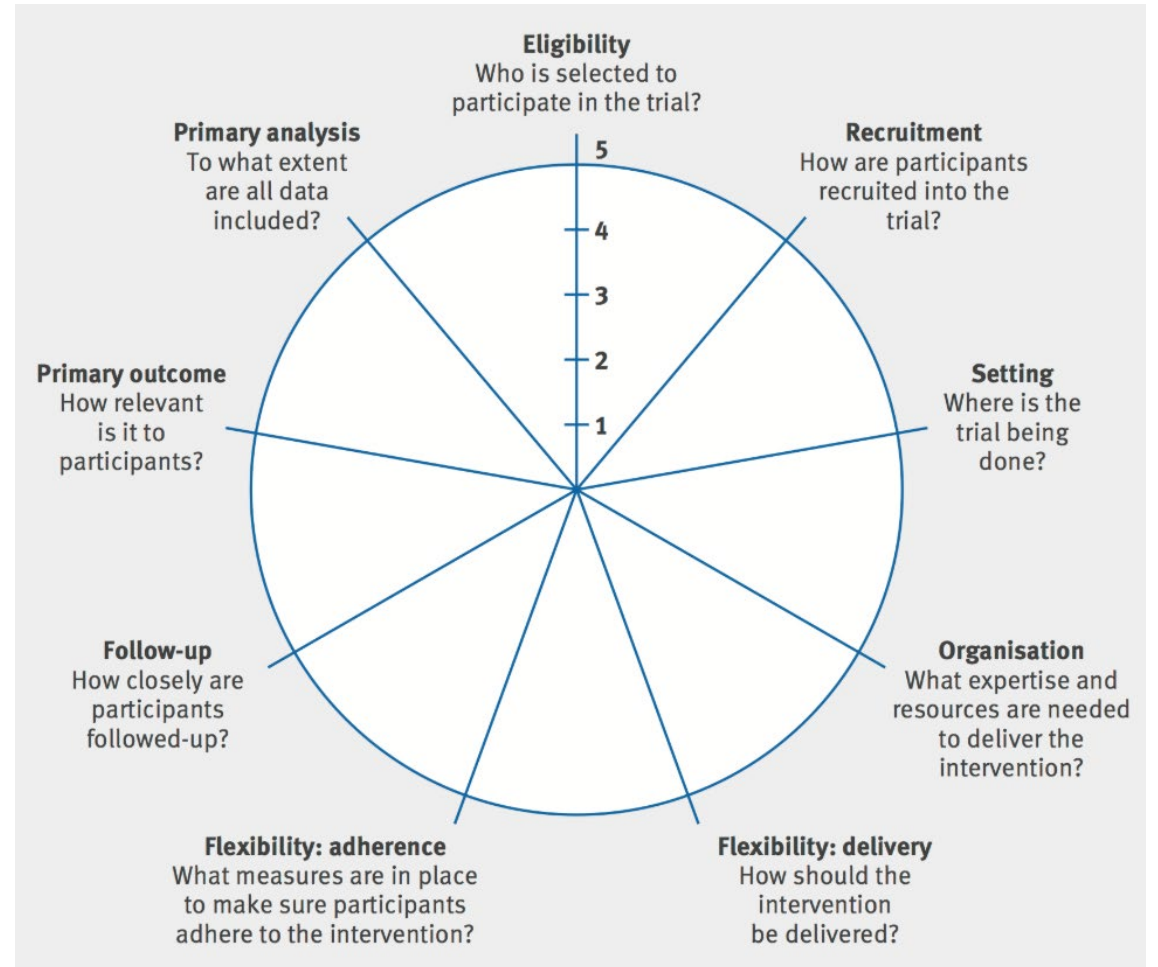


# Develop and Disseminate Guidance

Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2): <http://www.precis-2.org/>

Enrollment bias occurs at every level of selection

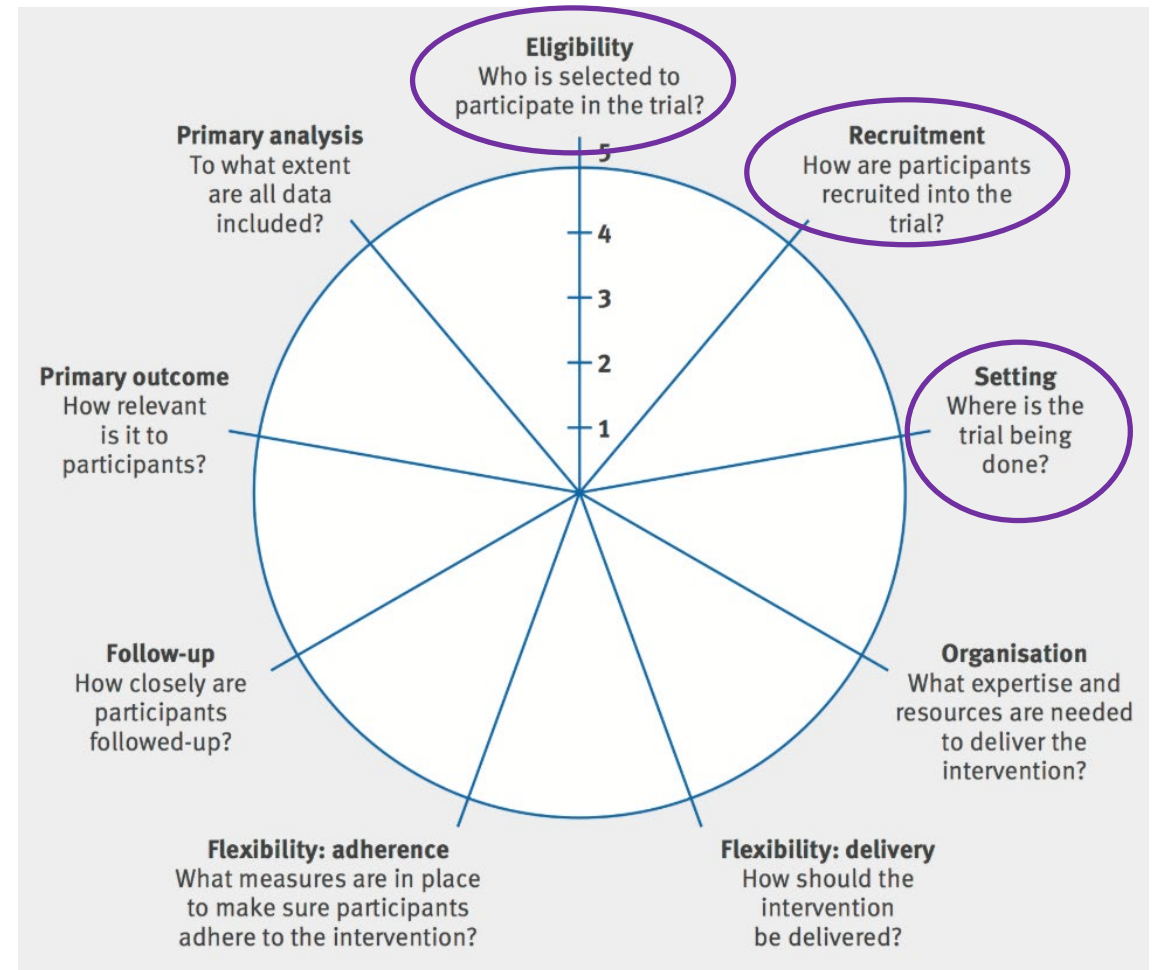
- Not merely at participant level
- “Healthy worker bias” can occur at the level of the HCS too
- ePCT does not sidestep this issue



# Health Equity Considerations Using PRECIS-2

Several selection factors in determining who will be involved in an ePCT

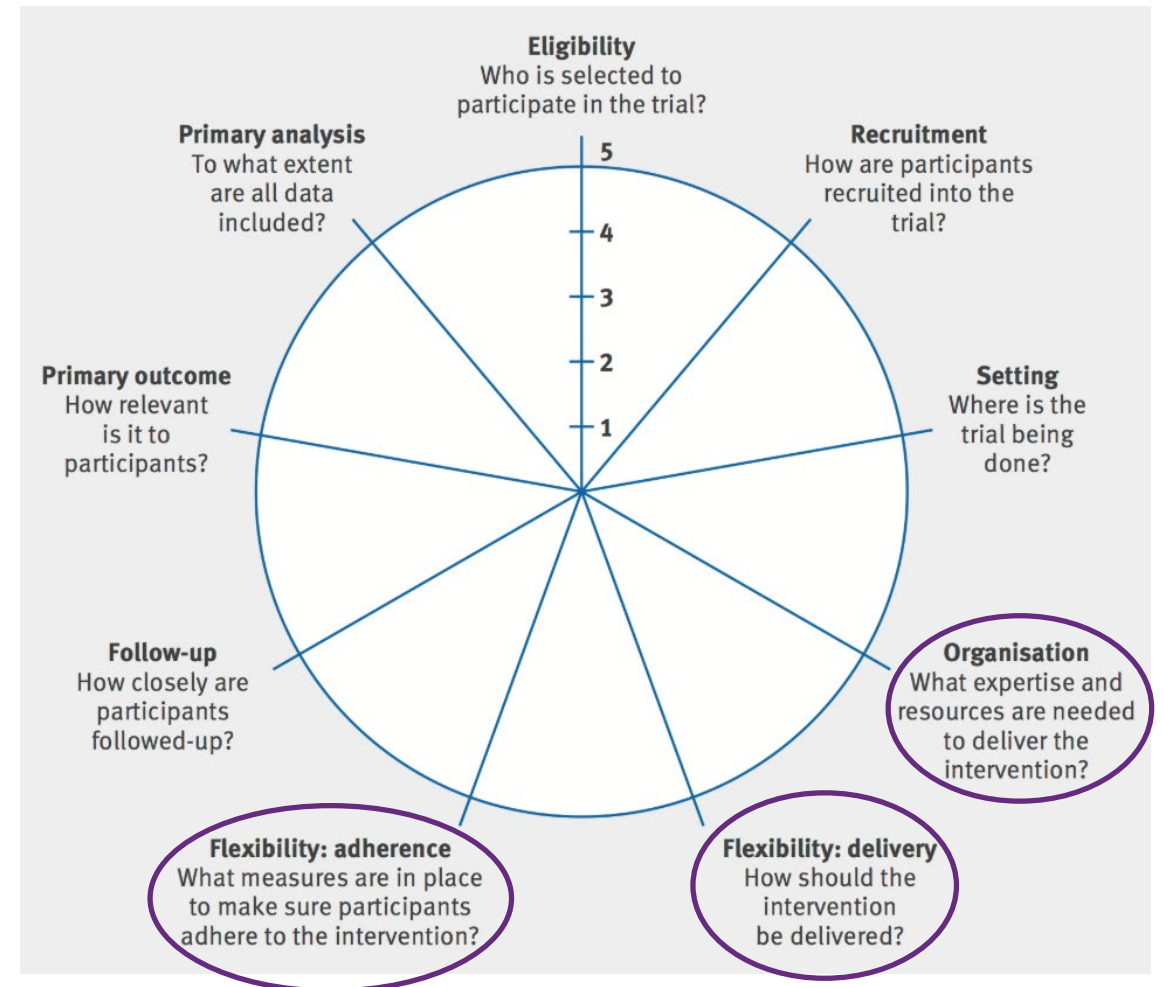
- Many healthcare systems (HCS) are segregated
- Willingness to participate may influence HCS selection, particularly HCSs serving minority populations
- Difficult to maintain accurate and complete identification of demographic characteristics in electronic health record (EHRs)



# Health Equity Considerations Using PRECIS-2

We may inadvertently perpetuate biases and disparities

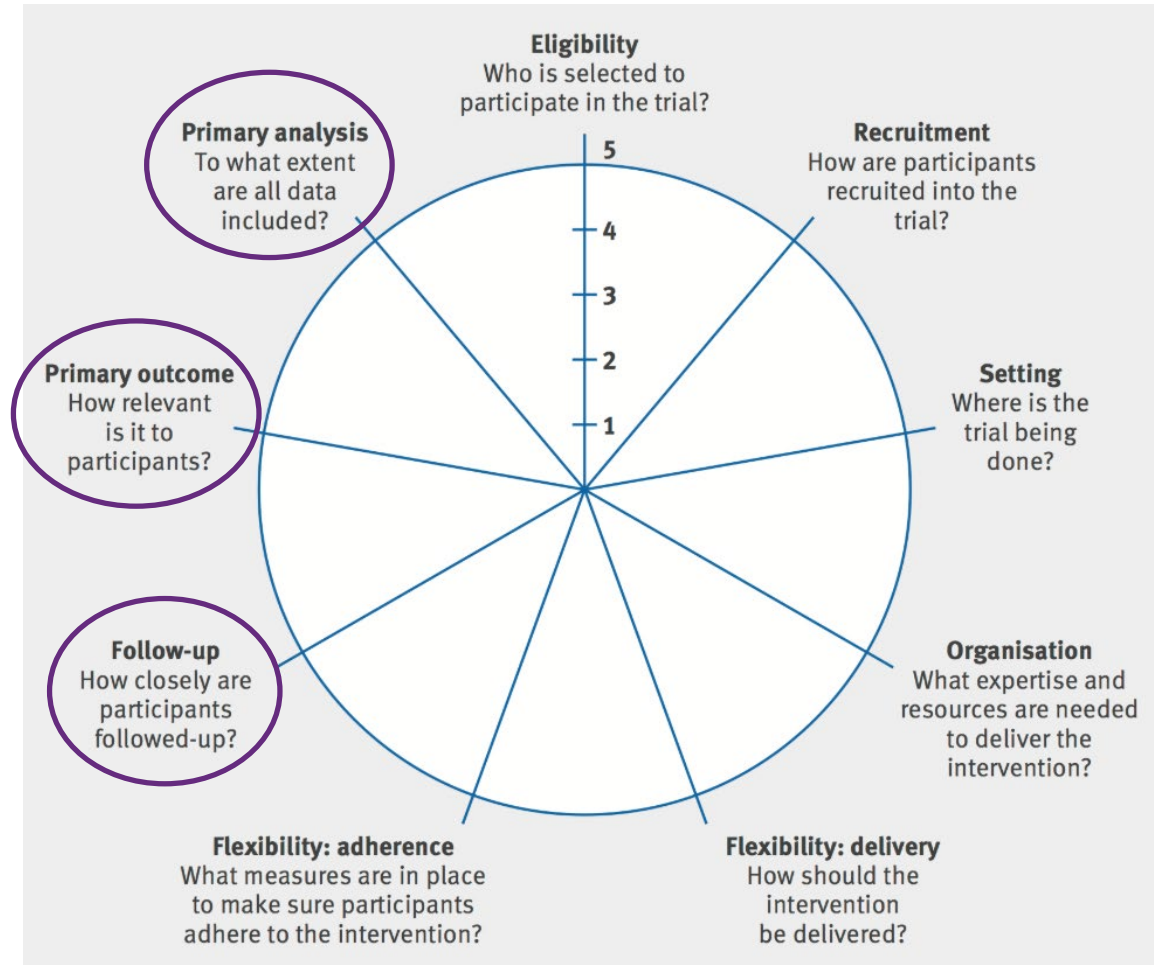
- Background and training of providers may impact delivery
- Limitations due to existing language or health literacy barriers
- Flexibly adapting of evidence-based interventions to diverse populations may be ad hoc or may not occur at all
- Adherence to intervention may be uneven or inequitable as a result



# Develop and Disseminate Guidance

Outcomes must be relevant and important to minoritized populations

- Instruments to assess outcomes may not be translated or validated for linguistically and culturally diverse groups
- High risk of differential rates of attrition/retention in standard/usual follow-up care
- Subgroup analyses require sufficient minority participants to enable comparisons, or may falsely suggest lower effectiveness for minorities if there is differential delivery or implementation





# Measures of Equity in Designing ePCTs

## HEALTH CARE SYSTEMS

Demography  
(within/among  
HCS)

Diversity  
(relative to HCS  
census, disease  
burden,  
community)



## DATA SOURCES

Missing-ness &  
gaps in data  
sources

Stakeholder  
outcomes

Data burden



## ETHICS/ REG

Engagement  
metrics for  
vulnerable  
populations

Consent  
language &  
format



## OUTCOMES

Triangulation  
and alignment  
of outcomes  
across all  
stakeholder  
groups



## DESIGN/ STATS

DAGs

Quantitative  
bias analyses  
(modified E-  
value)

Floating  
catchment area  
metrics



## IMPLEMENT

GOI Score

CFIR analyses

Favorable /  
unfavorable  
adaptation



# Summary

- **Health equity is a crucial and unique aspect of ePCTs**
  - Only way to ensure effective and generalizable research
  - Vital to implement PRECIS-2 domains with health equity lens
- **A health equity lens implies limitations in the current use of PRECIS-2 to develop ePCTs**
  - PRECIS-2 only helps us see how *pragmatic* a trial design is
  - Does not inform about study biases

# Key Takeaways

**Health equity considerations may be examined by reviewing**

- Which HCSes are included
- Bioethical elements of consent
- Data burden
- Calculations to identify selection biases, at multiple levels
- Implementation adaptations

# Resources

Visit the Living Textbook of Pragmatic Clinical Trials at

[www.rethinkingclinicaltrials.org](http://www.rethinkingclinicaltrials.org)

IMPACT Training Modules ePCT Video Learning Library

[www.impactcollaboratory.org](http://www.impactcollaboratory.org)



## Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials



WATCH THE VIDEO

Welcome to the Living Textbook of pragmatic clinical trials, a collection of knowledge from the NIH Health Care Systems Research Collaboratory. Pragmatic clinical trials present an opportunity to efficiently generate high-quality evidence to inform medical decision-making. However, these trials pose different challenges than traditional clinical trials. The Living Textbook reflects a collection of special considerations and best practices in the design, conduct, and reporting of pragmatic clinical trials.

### GET STARTED

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Training Videos

## Learn more about how to conduct ePCTs for people living with dementia

The NIA IMPACT Training Modules are short videos designed to introduce the important components and considerations related to embedded pragmatic clinical trials (ePCTs) for people living with dementia and their care partners. These videos are appropriate for investigators, health systems leaders, research staff and others who want to learn about the design and conduct of ePCTs.

Training modules are organized by topics/cores. Each tile below opens up into a series of relevant modules. [Sign up here](#) to be included on the mailing list to be informed about new and upcoming training content and opportunities.

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