



NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer's Disease (AD) and AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)

Why is Health Equity Important in Pragmatic Clinical Trials?

Instructor: Jonathan Jackson, PhD

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

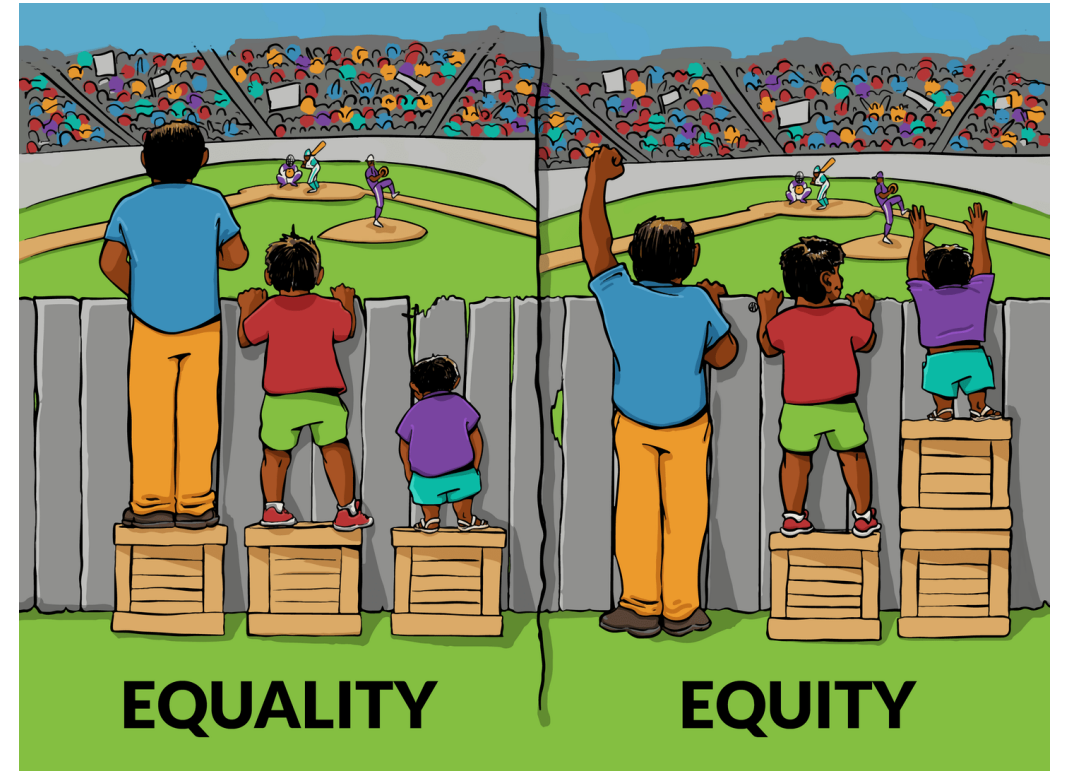
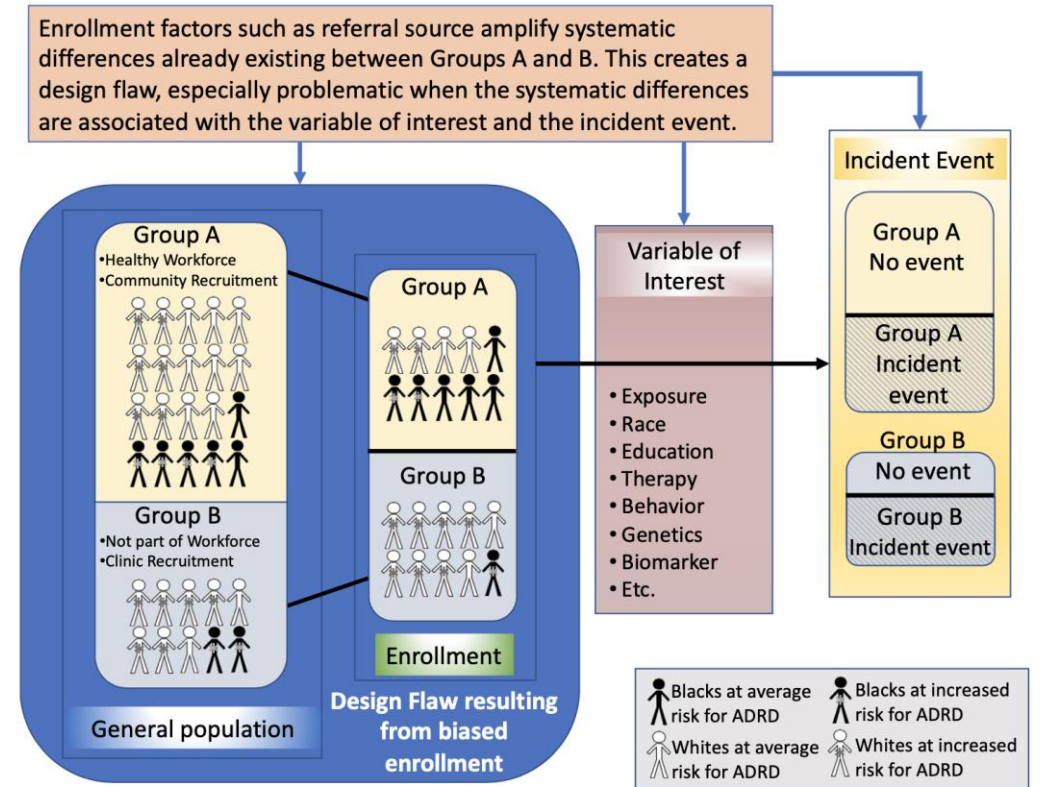
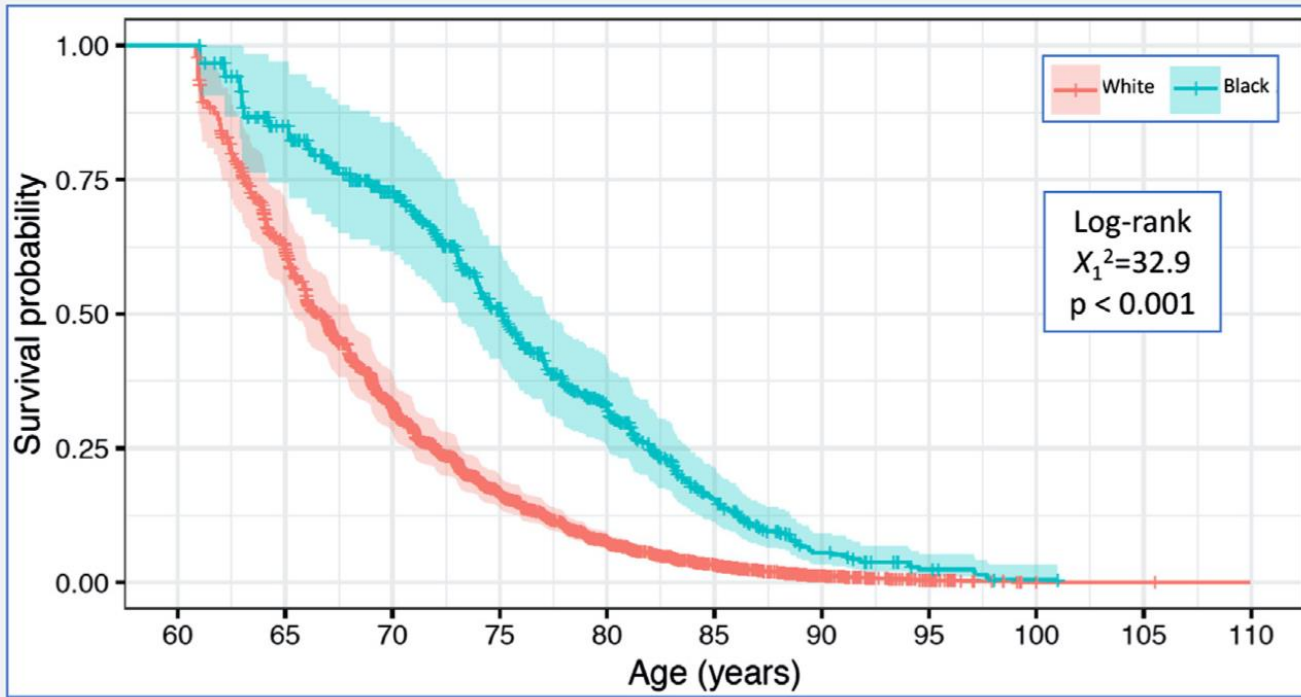


Image attribution: Interaction Institute for Social Change, by artist Angus Maguire
<https://interactioninstitute.org/illustrating-equality-vs-equity/> &
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The Necessity of Health Equity in Research

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

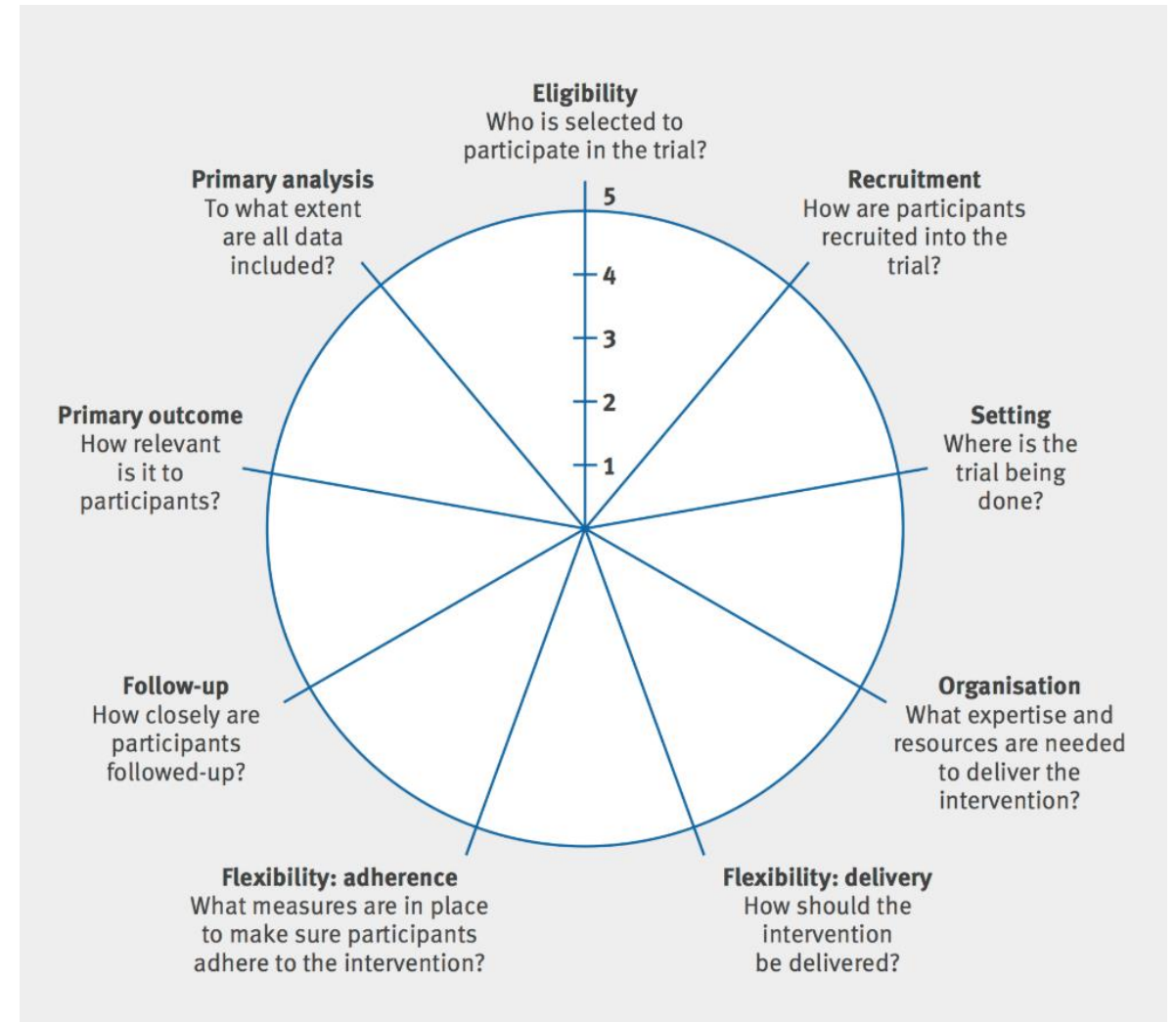


Develop and disseminate guidance

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

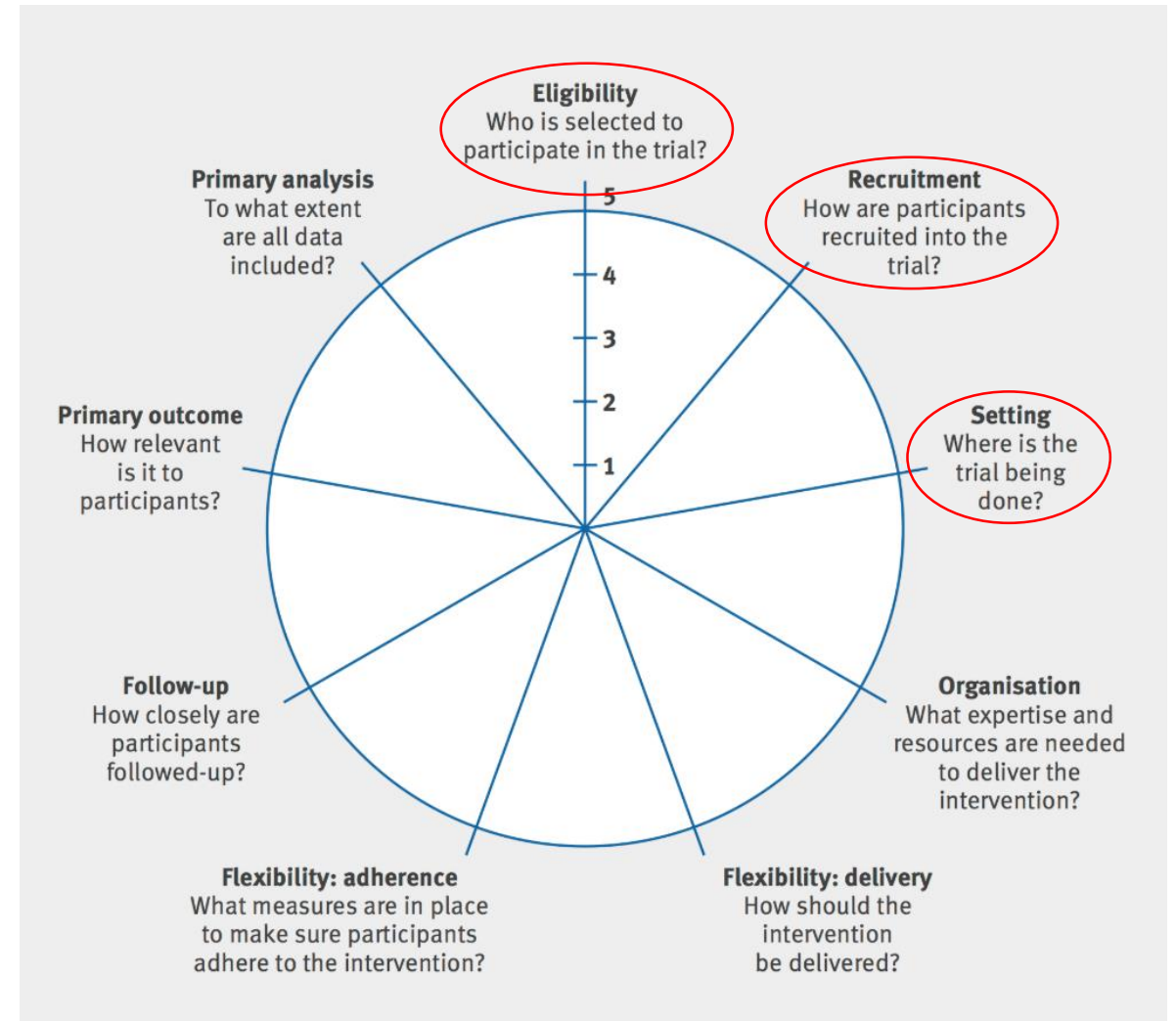
Enrollment bias occurs at every level of selection

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



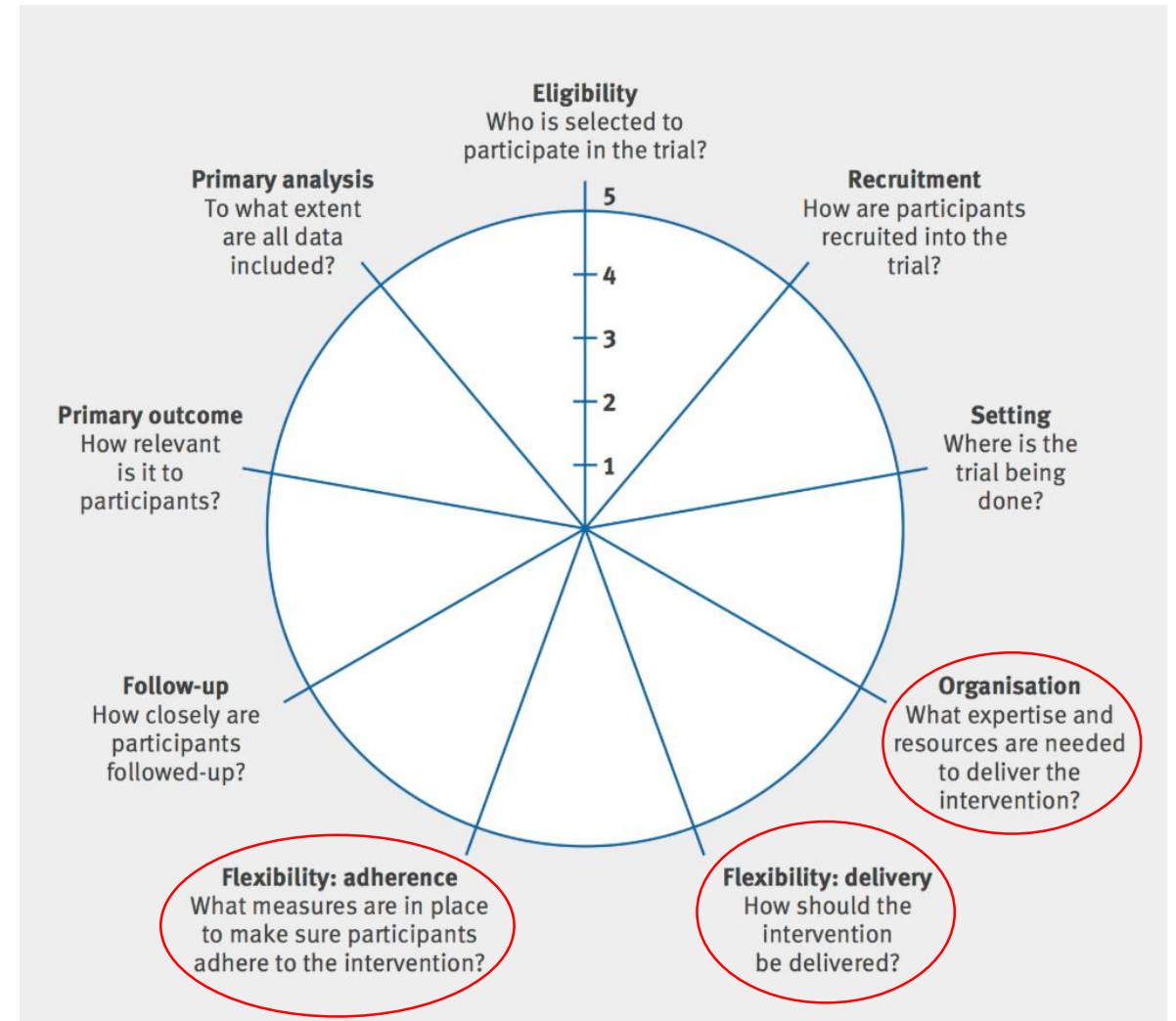
Health Equity Considerations Using PRECIS-2

- Several selection factors in determining who will be involved in an ePCT
 - Many HCSs 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



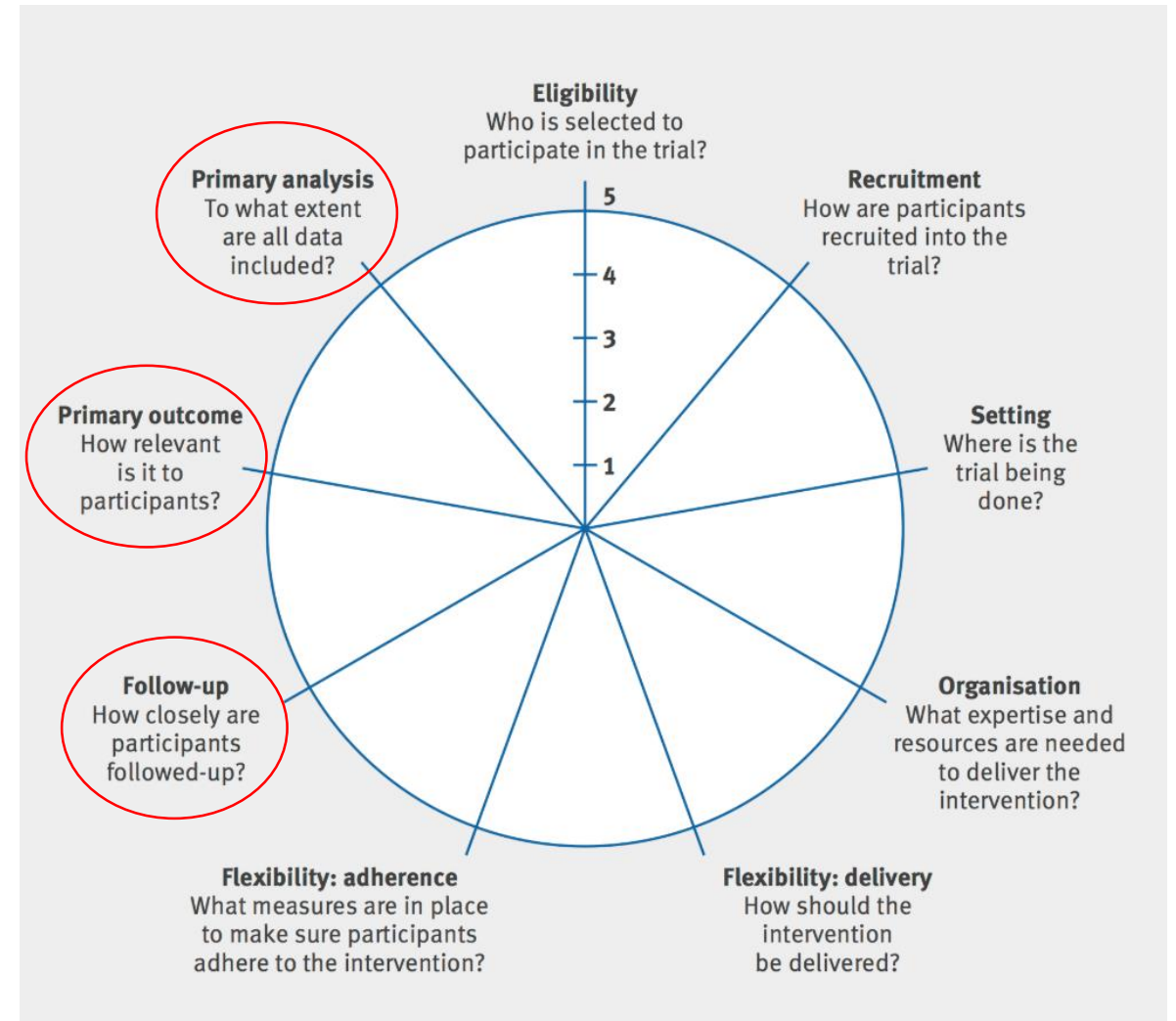
Health Equity Considerations Using PRECIS-2

- 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

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.** If we are to ensure that our research is truly effective and generalizable, it is vital to implement PRECIS-2 domains with this lens to design for equity.
- **A health equity lens implies limitations in the current use of PRECIS-2 to develop ePCTs.** The PRECIS-2 domain helps us understand how *pragmatic* a trial design is but doesn't inherently inform us about its *biases*. Robust reports about implementation, return of value, and selection / exchangeability, all framed via equity, may help clarify this dimension.



Guiding Good Choices → Guidando Buenas Decisiones

A supplement pilot to explore the feasibility of implementing a universal prevention curriculum for the Spanish-speaking families of young adolescents

Stacy Sterling, DrPH, MSW

Grand Rounds Diversity Workshop Series: Inclusion of Diverse Participants in Pragmatic Clinical Trials: Meeting participants where they are: outreach, trust and consent to maximize diversity

June 25, 2021

MULTISITE PARTNERSHIP TO IMPLEMENT GUIDING GOOD CHOICES IN 3 HEALTHCARE SYSTEMS

3 large “learning” healthcare systems:

Kaiser Permanente Northern California

Henry Ford Health System

Kaiser Permanente Colorado

Social Development Research Group, School of Social Work, University of Washington, the developers of Guiding Good Choices

Guiding Good Choices for Health (GGC4H)

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Funders

NCCIH
NIDA
ODP
OBSSR

MANY BEHAVIORAL HEALTH PROBLEMS BEGIN OR RISE SHARPLY DURING ADOLESCENCE

By the time they leave high school:

- 50% of adolescents will have used some form of illicit drugs
- 20-25% will have met diagnostic criteria for depression
- Many will engage in delinquency or violence
- Other common behavioral health problems: Anxiety, Sexual risk behavior, academic and school problems

MANY ADVANTAGES TO PROVIDING PARENTING PROGRAMS IN PEDIATRIC PRIMARY CARE

- Behavioral health problems in adolescence influence later health.
- Pediatricians have high credibility and are trusted by parents.
- Most children in U.S. have access to pediatric primary care.
- Care provided in a pediatric setting is less stigmatizing than specialty care.

GUIDING GOOD CHOICES

Universal prevention program for **parents of early adolescents** ages 9 - 14

Theoretically grounded: **Social Development Model**

2 RCTs demonstrated behavioral health impact:

- ✓ Affects **Parenting Behavior** regardless of family risk (Spoth et al., 1998)
- ✓ Reduced Growth in **Substance Use** (Mason et al., 2003)
- ✓ Reduced Growth in **Delinquency** (Mason et al., 2003)
- ✓ Reduced **Depressive symptoms** (Mason et al., 2007)
- ✓ **Cost-beneficial: Benefit-Cost Ratio: \$2.77** (WSIPP, 2018)



6 SESSIONS, ONE INCLUDING ADOLESCENTS - **VIRTUAL**

Orientation & Tech Check

Session 1. Getting Started: How to Promote Health and Wellbeing During the Teen Years

Session 2. Setting Guidelines: How to Develop Healthy Beliefs and Clear Standards

Session 3. Avoiding Trouble: How to Say No, Keep Your Friends, and Still Have Fun

Session 4. Managing Conflict: How to Deal With Your Anger in a Positive Way

Session 5. Involving Everyone: How to Strengthen Family Bonds

Sessions emphasize parenting skills

Build **family bonding**

Establish and reinforce **clear and consistent guidelines** for children's behavior

Teach children **skills to resist negative peer influence**

Improve **family management** practices

Reduce family conflict

KPNC Oakland Pediatrics - Diverse Patient Population

- Hispanic/Latino 17%
 - Asian 17%
 - Black/African-American 16%
 - White 31%
 - Hawaiian/Pacific Islander 1%
 - Native American 1%
 - Multi-racial 6%
 - Unknown 11%
-
- Spanish as primary language in EHR 6%
 - Many require a translator
 - Many more feel more comfortable in Spanish

Supplement Aims

Aim 1.

- (a) Semi-structured interviews with Spanish-speaking/preferring families
- (b) Semi-structured interviews with pediatricians with large proportions of children of Spanish-speaking/preferring families
- (c) Content analysis of interviews to identify themes that can guide tailoring of GGC referral, enrollment, engagement, and intervention processes and activities for uses with the target population.

Aim 2.

- (a) Hire and train 2-3 Spanish-speaking interventionists; Rigorous 3-day training with curriculum experts.
- (b) Orient pediatricians in the KPNC Oakland Pediatrics Clinic, including any tailoring to messaging identified in Aim 1.
- (c) Develop and disseminate Spanish language versions of all enrollment tools and materials (e.g., referral scripts and talking points describing GBD).

Aim 3. Deliver GBD to 2 groups of parents.

Data Type	Content
Pediatrician interviews	Priorities, services needs, concerns, perceptions of prevention programs, perceptions of behavioral health services, anticipated barriers to and facilitators of participation, suggestions for GGC recruitment. Organizational support and resources for prevention programs, bilingual/bicultural family services.
Parent/guardian interviews	Understanding of families' priorities, service needs, concerns, perceptions of prevention programs, perceptions of behavioral health services, anticipated barriers to and facilitators of participation.
Attendance Logs	Families' GGC participation
Intervention fidelity checklist	Coverage of Core GGC components, Parent engagement, Dosage
Satisfaction surveys	Families' GGC satisfaction
Pre-post GGC knowledge	Parent GGC knowledge

Pediatricians:

“Not just the language it’s the culture. There’s a difference. Different culture from Mexico than from Spain, than from Peru. You need to be sensitive to that”

*“Very important for those leading the class to be **bicultural**, not just bilingual”*

“Immigrant intergenerational stress - 1st generation children walk a “cultural tightrope” - they negotiate between their world at home and the outside world (school, neighborhood) – so GGC (curriculum-content) needs to include this aspect for Spanish preferring families.”

“Disconnect parents have” – they need help understanding the experiences and pressures of their children. Parents can only understand the world from their reality/experiences and compare their kids’ experiences to theirs. They need help to understand the social forces that impact their kids.”

“Working multiple jobs, physical separation of families (due to immigration status), language barriers, racism, housing, food deserts, looming fears (immigration status/deportation even if here legally), health insurance status.”

“Parents want to talk about mental health but are afraid to discuss in front of their kids because of their children’s trauma.”

“A little bit of stigma about mental health – stereotype – especially among fathers.”

Pediatrician Interviews

“Curriculum of GGC is great, marketing should be different – start with provider, but depend more on personal phone recruitment.”

*“**Help your teen succeed – helping you helping your child succeed in relationships**’. Success in general appeals; they all think they’re bonded already”*

“Focus on effective family relationships, on how the class can help the kids do better in school, on sexual activity (that is a concern)”

*“Any outreach should highlight **tools**, to help guide parents on how to communicate with their kids”*

“GGC should be open to grandparents and siblings who are guardians. Families can also be split – ex. dad is in Mexico, going back and forth and parent acts as single parent”

“Use all types of outreach include phone calls, text messages (especially), emails. Provider referrals, phone calls and text messages are viewed as most effective”

“In-person. It’s cultural – they prefer face-to face – eye contact. Even a phone appt is not too popular. Her patients’ parents don’t know how to navigate online”

“Not as many resources or opportunities for monolingual Spanish-speaking parents”

Parent Interviews

“The thing is I have two little kids, so, childcare during the class. The schedule, it has to be flexible. I’m not very keen on technology, but now I’m learning because classes are online, with all this going on, I’m learning how to deal with the computer, I would like video calls.”

Q: “What would be the best way to get to parents to inform them about the programs?”

A: “Texting. And phone calls.”

“It is important to learn more regarding what’s going on with teenagers, to deal with deeper topics about what’s going on currently.”

“I think that social media worries me the most right now. I’m not scared of her being bullied, I’m scared of what people post. Many people are sending messages like, “Send me a picture of you and I’ll pay for it. Show me your feet. People want to give you money for doing this and that. Many things on the internet aren’t good.”

“Kids grow up faster here. That’s why I need to talk to somebody about it. I want someone to help my daughter and me. I want my husband to listen to that conversation too.”

“Many Latinos understand English, but some don’t know how to speak it yet. I do understand what they say, but it’s harder for me to talk in English. I still don’t manage to talk fluently English, so I would appreciate it if it was a bilingual group.”



✓ ¿Tiene un hijo/a pre-adolescente entre 10 y 13 años?

✓ ¿Está interesado en cómo promover la salud, la salud mental y el bienestar durante la adolescencia?

Programa gratuito para padres

“Guiando buenas decisiones”

El programa virtual, conducido en español, consiste en 6 talleres con otros padres de adolescentes jóvenes. Incluye una sesión introductoria para orientar a los padres sobre cómo acceder a los talleres en línea usando el Zoom.

Temas:

- Cómo desarrollar creencias saludables y estándares claros
- Cómo fortalecer los vínculos familiares
- Cómo enseñarle a su hijo/a a decir “no” a sus amigos (sin perder la amistad ni la diversión)
- Cómo ayudar a su hijo/a a tener éxito en la escuela y en la vida

Para más información llame al
(408) 728-0089

 KAISER PERMANENTE.



GUIANDO
BUENAS DECISIONES

¿Qué es guiando buenas decisiones?

GBD es un programa para padres de jóvenes de 9 a 14 años, que se ofrece en cinco talleres de 2 horas cada uno, durante cinco semanas consecutivas. Cuando se ofrece virtualmente (vía internet), se añade una sesión introductoria para orientar a los padres al entorno virtual y a las herramientas necesarias para participar desde casa.

Actividad 3: Deseos para nuestros/as hijos/as

15 minutos

EN ESTA ACTIVIDAD:

- 4 min: Organización y tiempo individual para escribir.
- 11 min: Debate con el grupo completo, complementado con notas en el chat.

OBJETIVO: Que los/as participantes sean capaces de describir la importancia de prevenir el consumo de drogas en sus familias.

POR QUÉ: Para motivarlos/as para que continúen asistiendo a las sesiones de OBD restantes.



Para desarrollar creencias saludables y estándares claros

1. Establezca pautas.
 - Sea claro y específico; conozca el por qué.
 - *“No usar ni poseer nicotina. Es decir, no se permiten cigarrillos, cigarrillos electrónicos, cigarros, tabaco de mascar, etc. porque...”*
2. Monitoree.
3. Explique las consecuencias.
 - Positivas: apoye, reconozca y celebre.
 - Negativas: deben ser consistentes, adecuadas y moderadas.



GUIANDO

Sesión 2 | Diapositiva 7

¡Bienvenidos!

En el chat de Zoom, comparta una cosa que haya causado estrés familiar últimamente.

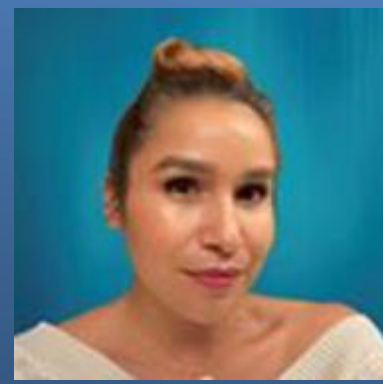




Christina Grijalva



Esti Iturralde



Nancy Charvat-Aguilar



Georgina Berrios

Bilingual, bicultural outreach and intervention team

Sueños



Kick-off of first cycle of GBD was June 9th

Recruited 20 families in < a week

Multi-generational, grandparents, moms and dads

Very engaged

Lessons so far:

- Tailored, personalized outreach, community connections
- Bilingual, bicultural staff
- Balancing fidelity with feasibility and relatability
- Emphasis on strengths, tools, success
- Cultural and linguistic adaptation
- Careful attention to inter-generational challenges: issues, experiences and language
- Virtual modality not a barrier, may be a facilitator, increasing convenience and access
- Scheduling flexibility
- Communities eager for services

Thank you!

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**Hybrid Effectiveness-Implementation Trial of
Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain**

GRACE Trial

HEAL Initiative

Grand Rounds Session 2: Meeting Participants Where They Are:
Outreach Trust and Consent to Maximize Diversity

Judith Schlaeger, PhD, CNM, LAc, FAAN

Associate Professor, University of Illinois Chicago

College of Nursing

MPI



GRACE Trial – UG3/UH3

- Pragmatic effectiveness-implementation trial
 - 3-armed SMART design of guided relaxation, acupuncture, and usual care
- 3 Sickle Cell Disease Clinics at 3 medical centers:
 - UI Health
 - Duke Health
 - UF Health
- UG3 Planning Phase
 - Human-centered design based on principles of community-based participatory research (CBPR)
 - Pilot studies completed to inform proposal development
 - Qualitative approach being used to inform
 - Implementation of study procedures
 - Recruitment and retention
 - Dissemination

Practices Inspired by Community-based Participatory Research

Patient variation

- Very few exclusion criteria. We will rarely exclude a patient who is interested in participating. For example:
 - Co-morbidities: except for mental incapacitation with an inability to understand the study, none will be excluded
 - E.g., blood thinners or participating in other study
 - Race: >90% will be Black/African American, but could include Latinx patients or patients of other races/ethnicities attending SCD clinics
 - SES: University medical centers tend to serve lower resourced communities, proxy for reaching the underserved

Sustained Engagement

- Sustained Engagement
 - Formative Research
 - Inclusion of concerns before the study was developed
 - Pilot Studies
 - Barriers and Facilitators
 - Effectiveness-Implementation Study
 - Collaborative decision-making
 - Pre-Implementation (UG3)
 - Implementation (UH3)
 - Dissemination



Formative Research

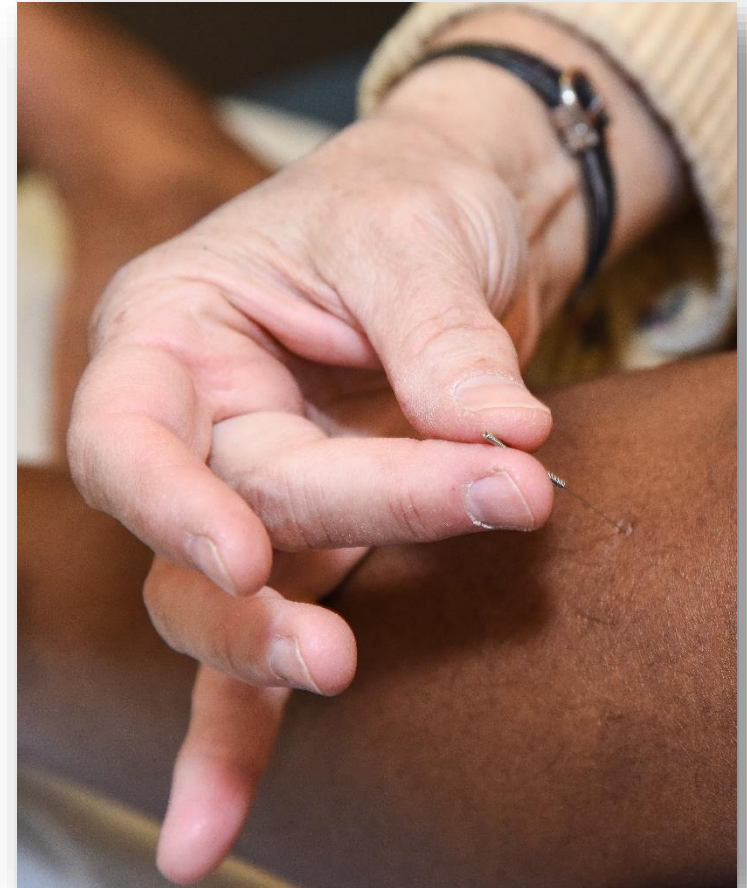
- To obtain patient perspectives on complementary and integrative health
 - Pilot survey: All (n=57) used some form complementary and integrated health
 - Adult Sickle Cell patients desired
 - Relaxation/meditation
 - Acupuncture

Guided Relaxation (GR) Pilot Study

- Twelve participants who accessed GR video clips daily for 2 weeks reported a reduction in chronic pain.
- Barriers
 - Initially, newness of GR made one participant feel uncomfortable; they reported feeling embarrassed
 - Images were too repetitive, and they wanted more options
 - One said, they wanted video clips that were ‘more modern and wanted the ability to view full screen’
 - Reliant on visuals
 - One said, they wanted the GR to be ‘more geared towards listen[ing] to relax and not watching to relax.’
- Facilitators
 - Experience with GR, reduced “embarrassment”, especially because participants noted that the intervention worked
 - Using tablets was easy and portable

Acupuncture Pilot Study

- The five who completed a series of 10 acupuncture treatments reported reductions in chronic pain, sleep disturbance, depression, anxiety, anger, and constipation.
- Barriers
 - transportation difficulties
 - a need to have their visits rescheduled because they experienced unpredictable and frequent pain at home
 - Feeling sore or achy post-acupuncture
- Facilitators
 - Paying transportation costs
 - convenient parking
 - ensuring an accessible study location
 - prioritizing flexibility in rescheduling acupuncture sessions



UG3 Interviews: Patient Willingness

- Willing to try guided relaxation and acupuncture reflects dissatisfaction with current pain control
 - Wanting alternatives to pain medications as “these do not really work but also affect memory, thinking, and quality of life”.

“It’s supposed to like relax your body or something to where they include like needles in your body or something. It’s worth a try...I mean. Like I said, I’ll try to see anything that would help with pain. I have sickle cell, sometimes the pain can be like... excruciating. I could barely talk, that’s how much pain. So, to introduce it as another way to relieve your pain, basically.”

- male, age 28

UG3 Interviews: Provider Willingness

- Short-term: Support the study of guided relaxation and acupuncture to reduce patients' pain
- Long-term: Willing to prescribe non-pharmacologic alternatives if effective

“My sense is that patients are really interested in nonopioid approaches to managing chronic pain and non-pharmacologic approaches, so I think a substantial proportion would be open to trying this approach.”

- Nurse, 5 years of experience at the SCD Clinic

UG3 Interviews: Implementation Barriers

- Acupuncture
 - Same structural concerns as pilot study
 - transportation, scheduling, time constraints [10 sessions over 5 weeks]
 - Fear of needles, and concerns about leg ulcers with needle placement
 - Requests to learn more about acupuncture, what is it, and how it works
- Guided Relaxation
 - Technology and Data
 - Concerns about access to smart devices and data were not born out.

“Okay I'm not tech friendly...I do have a smartphone...a tablet that I'm trying to figure out. So, I don't think it to be an issue. I pay my WIFI every day, but far as my phone. I don't pay for extra for the data. I just do the unlimited, but at times it's not unlimited.” – Female, age 39

– Focus

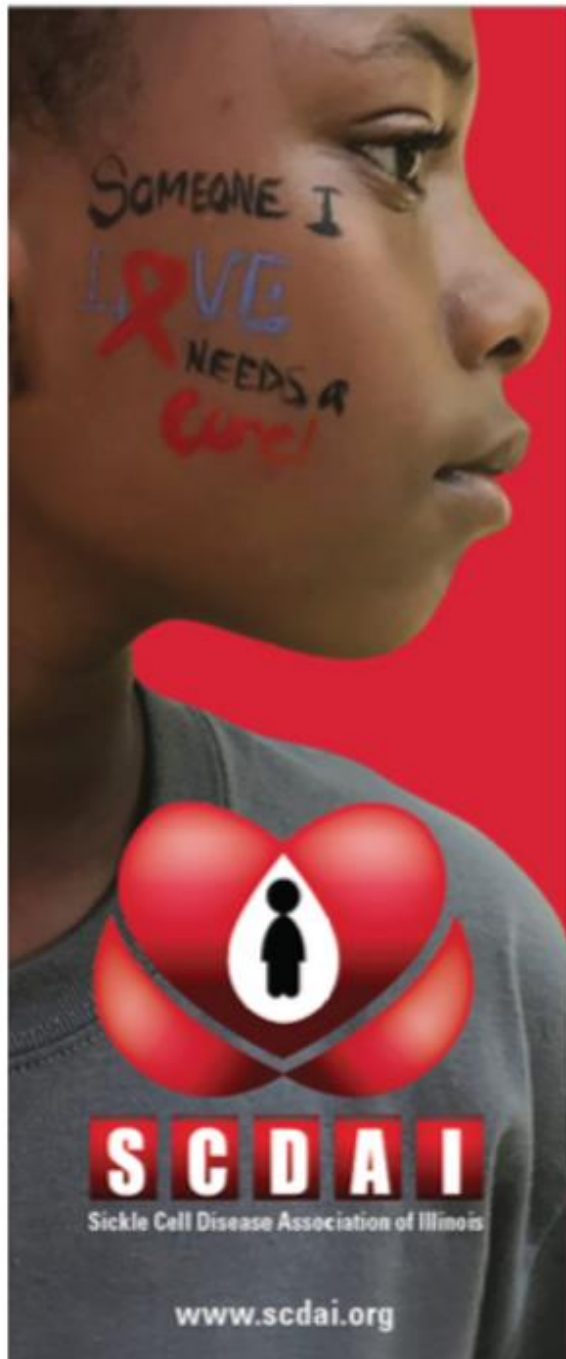
“Ma'am I have ADD, I can't do that. Like empty your mind? No” - Female, age 20

Pilot Studies/UG3

Interviews: Suggestions

- Provide education about the study and what to expect
 - **Patients:** recommended providing short videos, brochures, and/or in-person demonstrations
 - **Providers:** explain inclusion/exclusion criteria and provide summary of scientific evidence supporting Guided Relaxation and Acupuncture
- Address fear of needle concerns by having recruiters show a picture comparing needle sizes to potential participants
- Address accommodating leg ulcers and scars
- Address soreness/achiness post acupuncture
- Modernize GR videoclips, provide more options, and emphasize listening more





Building Trust in Our Communities

- Long history of engagement with **Sickle Cell Disease Community Based Organizations**
 - Sickle Cell Disease Association of Illinois (SCDAI)
 - Patient members interviewed who then shared information with support group members
 - Invited to present an overview of study at one of their monthly meetings
 - Asked to about acupuncture at a future meeting
 - Sickle Cell Disease Association of North Central Florida
 - Expressing interest
 - Bridges Pointe, Durham North Carolina
 - Expressing interest

