

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

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**NIH PRAGMATIC TRIALS
COLLABORATORY**

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Objective

- Evaluate the effectiveness of guided relaxation and acupuncture to improve pain control
- Determine the most appropriate and effective treatment sequence for any given patient based on their unique characteristics
- Describe the processes and structure required to implement guided relaxation and acupuncture within healthcare systems

Study design

- Pragmatic trial that follows a quantitative adaptive design that responds to patients' characteristics and evolving pain status
- Randomized to 3 arms (guided relaxation, acupuncture, and usual care)
- 3 healthcare systems (soon adding 2 more)

Participating healthcare systems

- Duke Health
- University of Florida Health
- University of Illinois Hospital and Health Sciences System
- **New**: Johns Hopkins University
- **New**: Emory University



Outcomes

- **Aim 1**: Determine the effectiveness of guided relaxation and acupuncture as compared to usual care in decreasing pain and opioid use for SCD patients. **Hypothesis**: At 6 weeks, SCD patients randomized to either CIH intervention will have a greater decrease in pain, opioid use, sleep, anxiety, depressive symptoms, and pain catastrophizing compared to SCD patients randomized to usual care.
- **Aim 2**: Identify the best adaptive intervention for improved outcomes by documenting outcomes among adaptive intervention sequences: (1) initiate guided relaxation and switch to acupuncture for non-responders at midpoint; (2) initiate guided relaxation and continue with guided relaxation for non-responders at midpoint; (3) initiate acupuncture and switch to guided relaxation for non-responders at midpoint or (4) initiate acupuncture and continue with acupuncture for non-responders at midpoint.
- **Aim 3**: Explore differences in response to the adaptive interventions by age and sex.
- **Aim 4**: Identify implementation facilitators, challenges, and solutions for structures and processes that contribute to the seamless integration of CIH therapies into the health systems by conducting individual interviews with participants in the intervention group who responded to the intervention and those who did not. We will also conduct focus groups with hospital personnel at 4 timepoints.

Barriers/challenges

- Recruitment
 - Overall: 72% of current expected number of participants
 - Duke: 82%
 - UIC: 93%
 - UF: 45%
- Adherence
 - Each site has struggled with completing a ‘full dose’ of each intervention to varying degrees

Solutions/lessons learned

- Recruitment responses

- Team worked with animators at Duke to create videos that explain acupuncture, guided relaxation, and the study overall

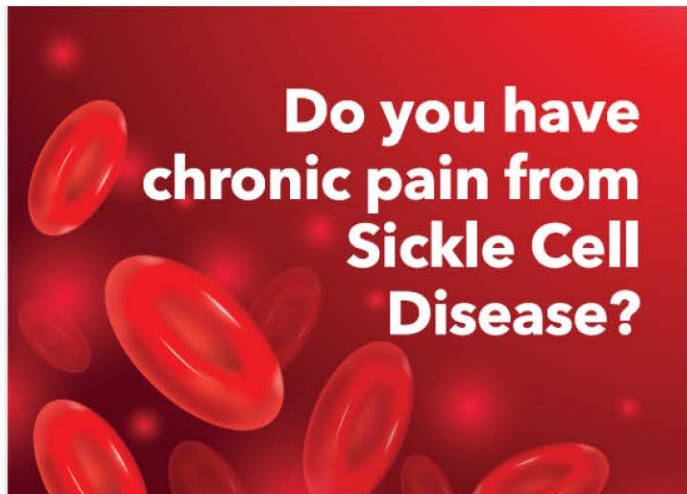
- Duke sent videos through MyChart
 - UIC and UF showed these in clinic/texted links to interested patients



Solutions/lessons learned

■ Recruitment responses

- UIC ran an ad on Chicago public transportation, and posted new flyers in clinic spaces



We are looking for people with chronic pain from Sickle Cell Disease (SCD) for a research study to see if acupuncture or guided relaxation might help reduce their pain.

WHO CAN PARTICIPATE?

- Diagnosed with SCD
- Aged 18 or older
- English-speaking
- Living with chronic pain

WHAT WILL HAPPEN?

If you join, you might either receive acupuncture treatments at the UIC College of Nursing or use a web-based app that will guide you through the process of relaxing. You will be enrolled for 24 weeks and will be compensated for your participation.

WHO RUNS THE STUDY?

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For more info visit the study website at gracestudy.uic.edu (773) 636-9564



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Solutions/lessons learned

- Recruitment responses
 - UIC and UF sent letters to sickle cell patients about the study
 - Patients were given the opportunity to ‘opt out’ of the study
 - Research staff are contacting those who did not opt out

Solutions/lessons learned

- Recruitment responses
 - Adding additional recruitment sites
 - Emory University in Atlanta
 - Johns Hopkins in Baltimore

Solutions/lessons learned

- Adherence
 - Set up automatic weekly text reminders to guided relaxation participants
 - Increased travel compensation for those in the acupuncture arm
 - UIC hired racially concordant acupuncturists