NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

GRACE TRIAL

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

Principal Investigators

Ardith Z. Doorenbos, PhD, RN, FAAN; Judith M. Schlaeger, PhD, CNM, LAc, FAAN; Robert Molokie, MD; Miriam O. Ezenwa, PhD, RN, FAAN; and Nirmish Shah, MD

Sponsoring Institution

University of Illinois Chicago

Collaborators

- University of Illinois Hospital and Health Sciences System
- University of Florida Health
- Duke University Health System

NIH Institute Providing Oversight

National Center for Complementary and Integrative Health (NCCIH)

Program Official

Beda Jean-Francois, PhD (NCCIH)

ClinicalTrials.gov Identifier

NCT04906447

ABSTRACT

Nearly 100 people die every day in the United States from a prescription opioid overdose. This crisis is caused in part by an overreliance on opioids to treat individuals experiencing chronic pain. Acute or chronic pain is a constant companion to more than 100,000 people living with sickle cell disease in the United States and millions more worldwide. Pain is a hallmark of sickle cell disease and results in almost 200,000 annual emergency department admissions and is a leading cause of hospitalization. It is known that the use of complementary and integrative therapies to reduce pain and opioid use has the potential to enable patients with sickle cell disease to better cope with their pain, yet few studies have evaluated the effectiveness of such therapies, and none have assessed how to implement them across multiple healthcare systems and patient populations.

To address this gap, GRACE is a pragmatic trial conducted across 3 large healthcare systems that will assess the effects of guided relaxation and acupuncture treatments for people with sickle cell disease. GRACE has 3 priorities:

- 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 structures required to implement guided relaxation and acupuncture within healthcare systems.

The intervention phase will involve 3 arms (guided relaxation, acupuncture, and usual care) and will follow a quantitative adaptive design that responds to patients' characteristics and evolving pain status. GRACE will use the Consolidated Framework for Implementation Research to plan, execute, and evaluate the associated implementation processes.

WHAT WE'VE LEARNED SO FAR

Challenge	Solution
Potential responses to the Patient Health Questionnaire (PHQ)-9 item about suicidal ideation	The study now makes support available for any patients who may report having suicidal thoughts.
Change in study design due to patient stakeholder input	The study team consulted with the NIH Collaboratory's Biostatistics and Study Design Core Working Group to come up with new design and power considerations.

"If we can better manage pain, we can impact the quality of life and change the possibilities for patients with sickle cell disease. They can have a plan for activities and have a more productive work situation. Pain management can change so many things in their lives." — Dr. Ardith Doorenbos

"I think we will get the most realistic findings of how these therapeutic interventions work, whereas in more classic trials they're going to end up with such a group of selected patients that it may not be as generalizable as a pragmatic clinical trial." — Dr. Robert Molokie

PRESENTATIONS & ABSTRACTS

- Article: Acupuncture for Chronic Pain in Adults With Sickle Cell Disease: A Mixed-Methods Pilot Study (2021)
- Video Interview: GRACE Trial Seeks More Options for Sickle Cell Pain (2021)
- Presentation: Presentation to the NIH Collaboratory Steering Committee (2021)
- Article (Study Design): Hybrid Effectiveness-Implementation Trial of Guided Relaxation and Acupuncture for Chronic Sickle Cell Disease Pain (GRACE): A Protocol (2023)
- Article: Monitoring and Responding to Signals of Suicidal Ideation in Pragmatic Clinical Trials: Lessons From the GRACE Trial for Chronic Sickle Cell Disease Pain (2023)