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

GRACE Trial

Steering Committee Meeting

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GRACE Trial Team

Ardith Doorenbos
Robert Molokie
Judith Schlaeger
Miriam Ezenwa
Nirmish Shah
Crystal Patil
Alana Steffen
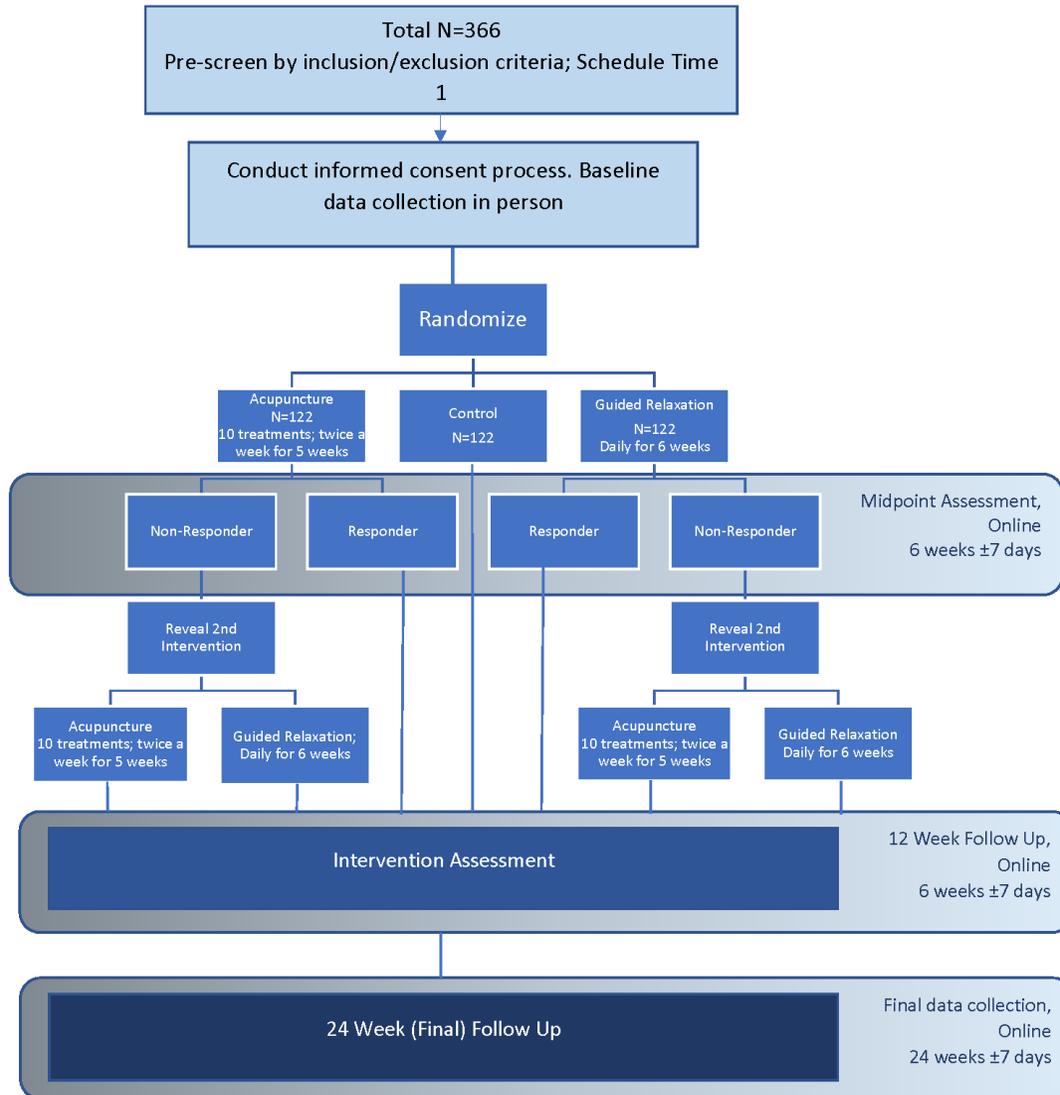Andrew Boyd
Diana Wilke
Molly Mandernach
Mitchell Knisely

Welcome & Agenda

Item
Welcome
Project Intro & Outline
Regulatory items
EPIC Integration
REDCap/Statistical Design
Implementation Blueprint
Acupuncture
Guided Relaxation
Wrap up

Project Introduction

- Hybrid effectiveness-implementation randomized clinical trial exploring the integration of **Acupuncture** and **Guided Relaxation** to help manage chronic pain in patients with Sickle Cell Disease
- 366 patient participants randomized in one of three arms
  - Acupuncture
  - Guided Relaxation
  - Usual care
- Qualitative interviews throughout to identify barriers/facilitators of adding these therapies to usual clinical care
- 3 Sites/Health systems
  - University of Illinois at Chicago
  - Duke University
  - University of Florida

Project Outline

Regulatory items

⚙	**IRB**	UIC (Reviewing Site) has IRB approval UF and Duke are in the process of review
✓	**DSMB**	Approved by NIH
📋	**Protocol**	Resubmitting for NIH review
🧱	**MOP**	In progress

EPIC

- Epic Integration of 4 PRO's
  - UI Health – no optimization till July, focus on stabilizing EPIC and COVID vaccine developments
  - UF – received detailed data from Clinical Research Information Officer (CRIO) about time and effort to build out, awaiting final decision on where surveys will be deploy through Epic
  - Duke – met with CRIO team still waiting for time and effort status update

- PRO visualization within Epic of T scores
  - Why visualization is important, T-score result interpretation is survey dependent
    - low T score is good, and high T score bad
    - Low T score bad, and high T score good
    - Low T score bad, 50 T Score good, High T score bad

Using PROMIS in Epic

REDCAP / Statistical Design

- UIC REDCap database set-up with the following features:
  - All HEAL CDE questionnaires and supplemental questionnaires for GRACE
  - Longitudinal data collection
  - Multi-site administration
  - Database permissions set-up by study role
  - Automated survey administration via email
  - Scheduling module and calendar for tracking participant appointments
  - Still needed: randomization and consenting

REDCAP / Statistical Design

▶ REDCap checklist created to guide development of database.

GRACE REDCap Development Timeline

Tasks Required	Date Completed
All survey questionnaires are built into REDCap as well as all forms to track participant status (screening and enrollment logs, contact logs, adverse events logs, etc).	
Branching logic, calculated fields, and data validation for questions are built into questionnaires where necessary. All required fields are marked as required and any fields that will collect information identifying participants are marked as identifiers.	
Customized Users Rights for all project roles are built into project	
Database set-up for longitudinal administration of questionnaires.	
Auto-survey administration set up for follow-up questionnaires	
Scheduling Module set-up for tracking of scheduled patient appointments.	
Randomization built into REDCap database.	
At least 10 cases created to test project questionnaires, randomization, and auto-surveys and other project functionality.	
Ensure all questionnaires and fields are finalized and in proper order. All database structure is finalized and functioning properly.	
REDCap project moved to Production status in preparation for entry of real project data.	
All research staff are added to database with correct privileges.	
Project staff at all recruitment sites trained for use in REDCap database.	

GRACE REDCap Instruments Check List

Study Instruments	Quality Assurance Checks								Time Points*					Permissions by Role**			
	All items present	Proofread all items	Response options are accurate and exhaustive	Validation checks for text items	Identifiers and required fields marked	Branching Logic where needed and correct	Auto-survey set-up	Calculation / Special Functions Working	Base-line	Week 6	Week 12	Week 24	All Times	Blinded Research Staff	Unblinded Research Staff	Database Admin	Acupuncturist
Screening and Tracking									IA					EDIT	EDIT	ADMIN	EDIT
Consent									IA						EDIT	ADMIN	VIEW
Randomization									IA						EDIT	ADMIN	VIEW
Demographics									IA					EDIT	EDIT	ADMIN	VIEW
Pain Intensity									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
PEG									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Pain Interference									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Physical Function									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
GAD-7									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
PHQ-9									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Sleep Disturbance									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Sleep Duration Item									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Global Health Item									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
PCS-13									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
PGIC									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
TAPS1									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Constipation									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
PSQI									IA	SA	SA	SA		EDIT	EDIT	ADMIN	
Adverse Event Log													RC	EDIT	EDIT	ADMIN	EDIT
Acupuncture Visits													RC		EDIT	ADMIN	EDIT

Notes: *IA = Interviewer Administered. SA = Self-Administered. RC = Researcher Staff Member Completes.
**Edit = View and edit data. Admin = Edit form design. View = Read only.

Implementation BLUEPRINT

"Chapters"

- EPIC
  - Steps
  - Data visualization
- Clinic walk-throughs & patient flow
- Pre-implementation
  - Facilitators/Barriers
  - Suggestions/solutions
    - Brochures
    - Communications
    - Demonstrations

Qualitative

- IRB approval at coordinating site
  - sIRB process initiated for Duke and UF
- Interview Guides
  - Reviewed by team
  - Revised
- Interviews completed – 6 patients, 3 nurses and 3 providers

Patients

Sample

- **6 patients in UIH system**
  - **4 Women**
  - **2 Men**

Emerging Ideas

- All patients are willing to try both CIH therapies
  - Acu: even with 2 visits/wk for 5 wks willing to try to find a way to deal with pain
  - GR: all have unlimited data plans and access to smart devices
- All mentioned some form of social support (friends/family with SCD, Facebook groups, informal groups)
- All mentioned being comfortable talking about these therapies with their providers

Providers and Staff

Sample

- **3 Nurses**
- **3 Providers (aside from project PIs)**

Emerging Ideas

- Would like presentations and/or demonstrations of interventions
- Those on the health systems side anticipate patients wanting more information about therapies than patients have expressed
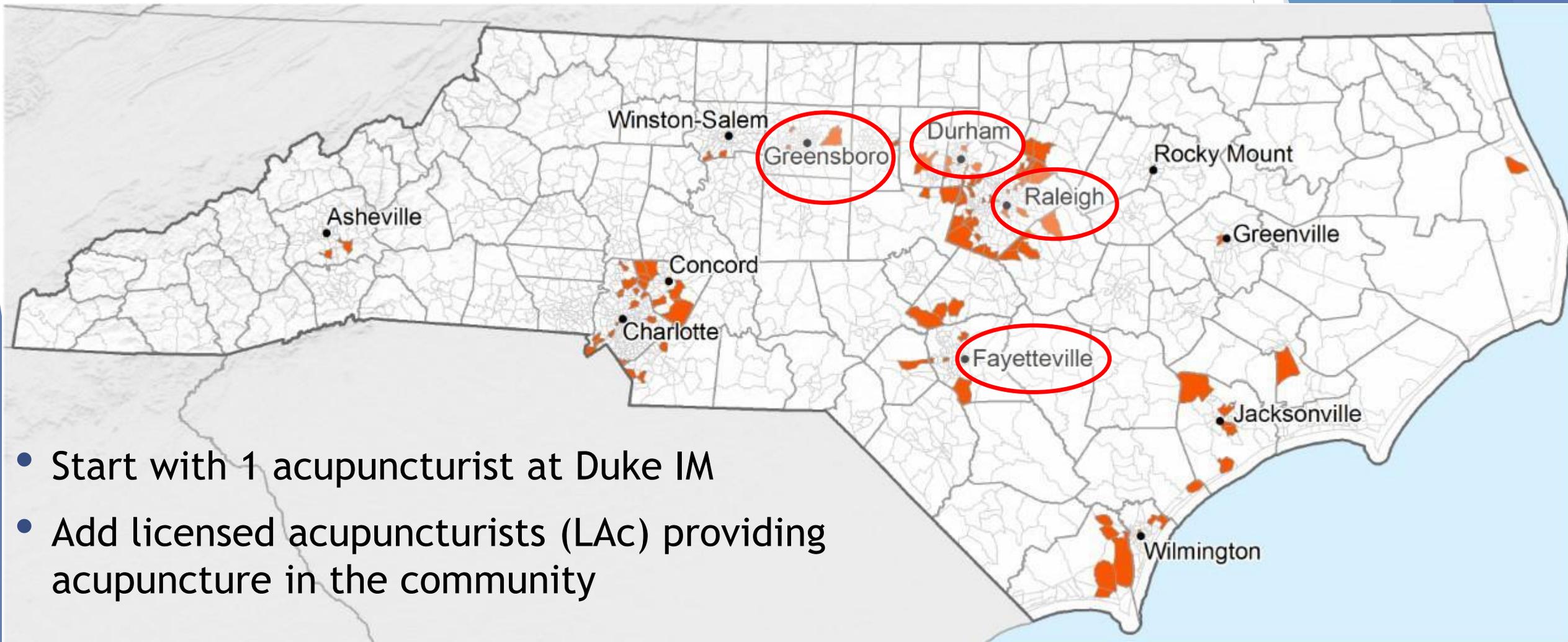- Do not anticipate any disruptions to workflow

ACUPUNCTURE

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UIH

- 1 clinic, 1 acupuncturist

DUKE/UF

- Integrative Medicine
- Offsite clinics/acupuncturists

Duke – Patient Distribution

- Start with 1 acupuncturist at Duke IM

- Add licensed acupuncturists (LAc) providing acupuncture in the community

UF Acupuncture

- ▶ 2 MDs provide acupuncture at IM
- ▶ 2 LAc acupuncture in the community

GUIDED RELAXATION

Thank you