

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

GRACE Trial

Steering Committee Meeting

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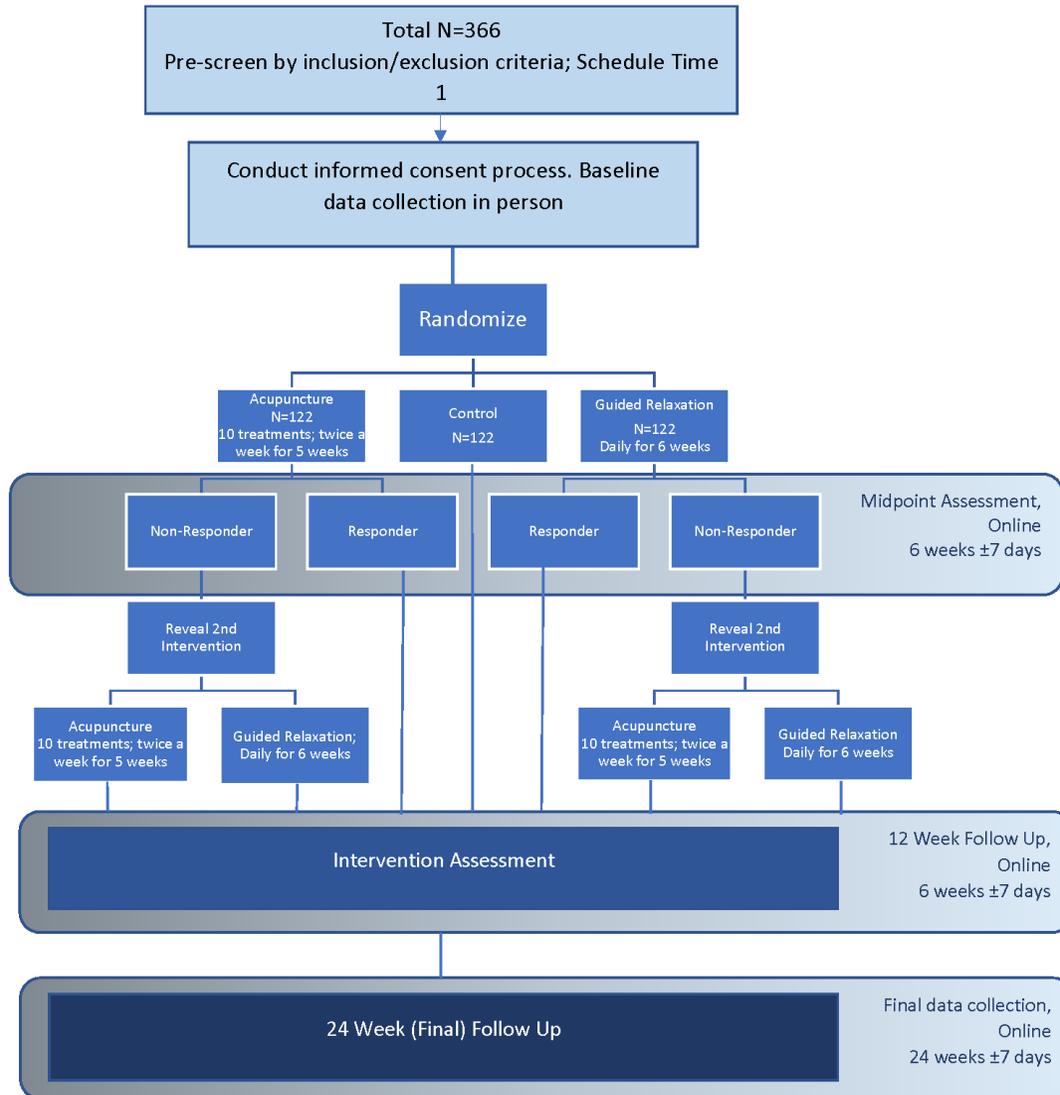
Welcome & Agenda

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

Active Questionnaire Series Expand All Collapse All

Global Health ⌵

Tdd Promis Global Health 1.2
Submitted 4/25/19

PROMIS Global Mental Health T-Score ↘ **31 (Fair) !**

PROMIS General Health Score ↗ **3**

PROMIS Global Mental Health T-Score
Last 3 Responses (out of 3)

📄

Higher is better

Date	T-Score
4/19/19	50
4/24/19	36
4/25/19	31

[View all responses](#)

Question	4/24/19	4/25/19
In general, would you say your quality of life is:	Poor !!	Fair !
In general, how would you rate your mental health, including your mood and your ability to think?	Good	Fair !
In general, how would you rate your satisfaction with your social activities and relationships?	Fair !	Poor !!

Unchanged responses ⌵
(Contains flagged data)

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



UIC CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE
UNIVERSITY OF ILLINOIS AT CHICAGO
University of Illinois at Chicago
Center for Clinical and Translational Science

GRACE PID 8827

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Dashboard displayed: [Default dashboard] Create custom dashboard

Displaying Data Access Group: --ALL--

Displaying record: Page 1 of 1: "1" through "2163-1" of **4** records ALL (4) records per page

+ Add new record

Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Record ID	Baseline														
	Screening, Enrollment & Withdrawal	Demographics	PROMIS Scale v2.0 - Pain Intensity 3a	PROMIS SF v1.1 - Pain Interference 4a	PROMIS SF v1.2 - Physical Function 6b	PEG	Generalized Anxiety Disorder 7 Item (GAD7) Scale Score	Patient Health Questionnaire Depression Scale (PHQ) Scored	Sleep Duration	1) PROMIS Global General Health Item	PCS	PGIC	TAPS-1	PROMIS Scale v1.0 - GI Constipation 9a	Pittsburgh Sleep Quality Index (PSQI)
1															
2161-1															
2162-1															
2163-1															

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	Acupuncture
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	
RGIC								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

ACUPUNCTURE

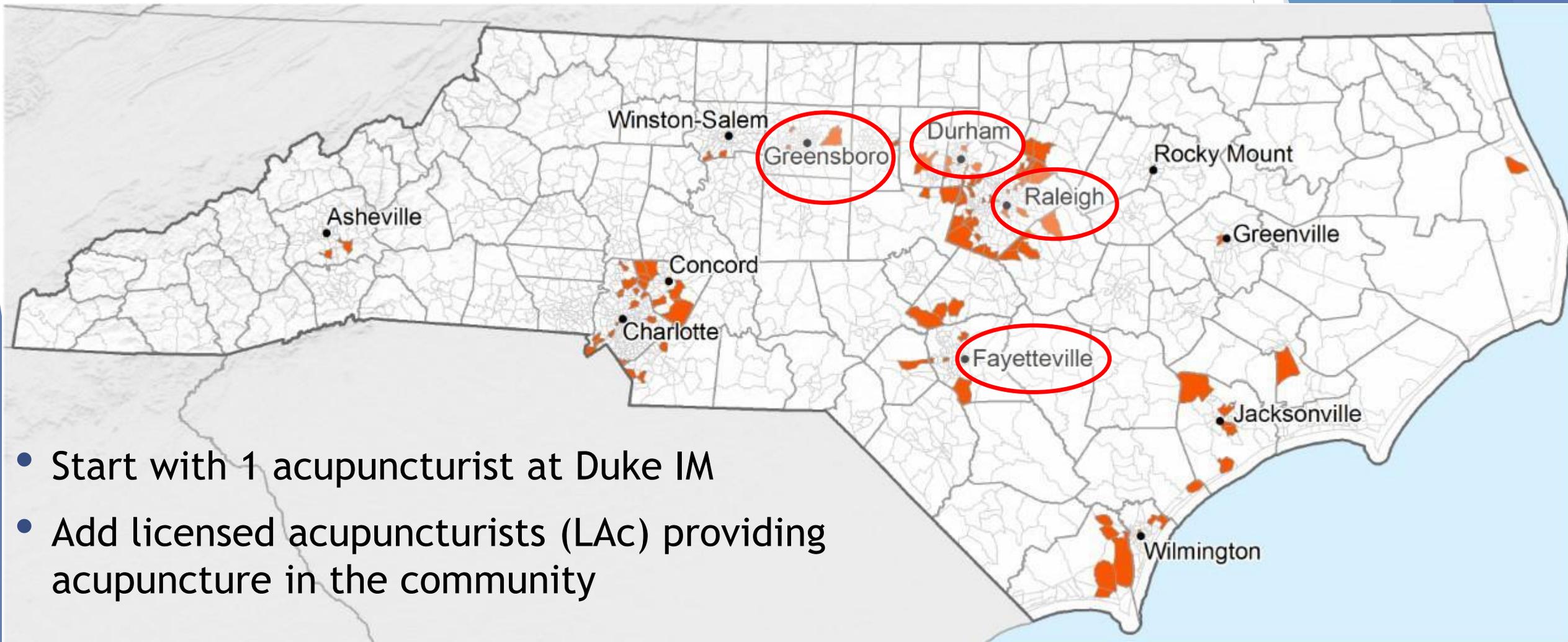
UIH

- ▶ 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