

DGIM Project Summary

Name of Project: Integrating Non-pharmacologic Strategies for Pain with Inclusion, Respect, and Equity (INSPIRE)

Investigator(s) (include phone numbers and email address, indicate PI and primary contact):

PI: Jason Satterfield (primary contact)

Co-I: Jesse Ristau

DGIM clinical advisor: Nicole Appelle

Research question(s): This is a 2 year iterative development project to create a mobile app that combines CBT with physical therapy and mindfulness. The app will be paired with a telehealth pain coach. We will use focus groups and interviews to get input on the design. We will beta-test and do a brief pilot/field test near the end of year 2. If successful, we will then do a 3 year RCT.

R61 Developmental Specific Aims

1. Iteratively develop INSPIRE blending a patient-facing smartphone application with telehealth coaching and primary care coordination
2. Develop educational, dissemination, and implementation strategies to enhance provider knowledge, promote program referrals and integrate pain coaching into primary care clinician workflows, EHR documentation, and medical decision making.
3. Assess the feasibility and acceptability (F&A) of the developed INSPIRE intervention and pragmatic RCT protocol with a time-limited, single-arm pilot study.

Brief Background/Significance:

Only 3% of people with chronic pain (CP) have access to evidence-based, non-pharmacologic, integrative treatments even though CP is among the most common, and substantial diseases with an estimated incidence higher than that of diabetes, cancer, and heart disease combined. CP substantially impacts physical and mental functioning, productivity, and quality of life; it is the leading cause of disability and is often refractory to medical treatment. The CDC and the American College of Physicians recommend nonopioid and nonpharmacologic treatment for CP given the strong evidence for mind-body interventions such as cognitive-behavioral therapy (CBT), mindfulness-based interventions, and physical therapy and the recognition of harms caused by the inappropriate use of opioids for CP.

Inclusion/exclusion criteria (list):

Patient participants must be

- 1) age 18 or older;
- 2) speak English, Spanish, or Cantonese;
- 3) have a UCSF Health or SFHN PCP;
- 4) be willing to use a smartphone (iOS or Android – either their own or one provided by the study),
- 5) have chronic, non-malignant pain for at least 3 months and

Any individuals with conditions that prevent informed consent (e.g. dementia or active psychosis) will be excluded.

Method of contact/recruitment (be specific):

Each study clinic has “clinical advisor” who will determine the best method(s) to recruit a small number of pt participants. Nicole Appelle has mentioned she might email a handful of providers about the study and ask for direct referrals. We may also request 5min of a faculty meeting to request referrals.

Benefits/burdens for participants (clearly identify potential for harm):Potential Risks:

- *Loss of confidentiality*
- *Invasion of privacy*
- *Anxiety or discomfort from discussing potentially sensitive topics such as chronic disease, depression, and non-adherence to treatment recommendations*
- *Discomfort talking about preferences, values, and goals related to your chronic pain*

Potential Benefits: None directly. May help to shape an effective digital health intervention to help other chronic pain patients. All subjects financially compensated.

Benefits/burdens for DGIM practitioners and/or staff:

Providers may be asked to directly refer patients to the focus groups. Total number of patients will be 18-24 over a 6 month period so burden should be low.

We will interview 2-3 staff and 2-3 providers in spring 2023 about how to minimize burden and optimize attractiveness of the program.

Timeline for recruitment (include projected start and stop dates):

Start: 12/1/2022

Stop: 5/31/2023

Funding source(s): NIH/NINDS R61/R33

Potential for DGIM collaborators (e.g., we encourage DGIM resident and fellow involvement in particular): Residents and fellows are welcome to participate. There are opportunities for researchers and educators.

Do you agree to notify us when the study is completed?: Yes

Date form completed: 11/18/2022