DGIM Project Summary

Name of Project: Cognitive-activity Assessment in Response to Rx Interventions (CARRI)

Investigator(s).
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Research question(s): Pilot test this mHealth application in older adults with multiple chronic conditions, both on opioids and not on opioids, in order to understand usability and feasibility and to gain preliminary response data, effect sizes, and effect variation. We will recruit 20 participants with multiple chronic conditions, age 75 and older with pain, who are either starting a new opioid (previously opioid naïve) or adding a short or long acting opioid to their pain regimen and 10 participants with multiple chronic conditions, age 75 and older, who are not taking opioids. We will again pilot test the usability of the tool in this more vulnerable population, and gain preliminary data on the magnitude and between- and within-individual variability of opioids on pain and cognitive and physical function, including temporal relationship of these signs and symptoms to medication dosing. This preliminary data will provide the foundation for a definitive study on the impact of opioids and on pain control, cognitive functioning, sleep and physical activity in older adults.

Brief Background/Significance: Chronic pain occurs in over 18 million older adults in the United States. Older adults are particularly vulnerable to severe and persistent pain. Pain in older adults often takes place in the setting of multiple chronic conditions, adding complexity to management. With multimorbidity comes an increased likelihood for polypharmacy and increased risk for drug-drug interactions. Likewise, poorly controlled pain and other symptoms can contribute to increased healthcare utilization and reduced physical function.

Opioids are increasingly used to manage chronic pain in older adults, since drugs like Acetaminophen is limited by a dosing ceiling. But, the risks and benefits of opioids are not understood in older patients with chronic pain. In a meta-analysis of opioid use in older adults, overall functional benefit and decreased mental functioning was found. Other common effects included improved sleep, constipation, nausea and, dizziness. However the studies in this meta-analysis used self-report functional status measures or performance-based measures at one or two points in time. Likewise cognitive effects and other symptoms were captured through symptom diaries and at infrequent time intervals, increasing risk for recall bias. The real-time effects of short and long acting opioids were not captured in these studies.

mHealth applications have the potential to improve objective assessment of pain and pain medication-related effects by providing the means to monitor daily pain levels, assess for associated symptoms (e.g., constipation, dizziness, sleep disturbance), and capture treatment-related side effects (such as cognitive and physical function). To our knowledge, however, a tool that offers integration of computer-administered symptom assessments with real-time cognitive and functional monitoring to facilitate better pain research or pain monitoring does not yet exist.

We seek to develop an app that provides meaningful insights on real-time outcomes that will combine tablet-based assessment with accelerometry-based physical activity monitoring. The tool aims to eliminate recall bias and enable better evaluation of
fluctuations in drug effectiveness and harms (i.e. pain intensity, cognitive effects). The cognitive evaluation will emphasize measures of executive control and psychomotor speed. The accelerometer will allow in-the-moment assessment of both physical activity and gait. In addition to symptoms, cognition and function, the tool will also evaluate adherence with the medication regimen. Once this tool is developed and tested, we will use it in a large observational study of older adults with chronic pain who are using opioids, in order to better characterize the impact of opioids on symptoms, function and cognition.

Inclusion/exclusion criteria (list)

**Recruiting for the CONTROL arm of the CARRI study**

**Inclusion criteria:**
- 10 adults 75 or older,
- 2 or more chronic conditions,
- **no acute or chronic pain,**
- NO evidence of cognitive impairment,
- English-speaking and reading,
- physically able to hold a tablet, and
- vision adequate to complete the tablet-based assessments.

**Method of contact/recruitment (be specific):** Dear Patient Letter to eligible patients. CARRI study team will identify potentially eligible patients through an Apex data pull. The care providers of the patients will be given database of patients to review if they would be appropriate for contact on the study. Those identified by care providers as eligible will receive Dear Patient Letter. CARRI study team has drafted letter and will mail letters out.

**Benefits/burden for participants (clearly identify potential for harm):**

**Benefits**
- Greater understanding of cognition and functioning of older adults on opioids.

**Burden**
- Time it would take to identify eligible patients from Apex data pull.

Any benefits or burden to DGIM practitioners? Benefits- Greater understanding of cognition and functioning of older adults on opioids. Burden- Time it would take to identify eligible patients from Apex data pull.

**Timeline for recruitment (projected start and stop dates):** Send rolling Dear Patient letters to eligible patients January 2016 and complete study enrollment by May 2016.

**Funding source:** National Palliative Care Research Center (NPCRC)

**Potential for DGIM collaborators?** Dr. Mike Rabow, MD (listed on grant as an Investigator).

**Do you agree to notify us when recruitment is completed?** Yes.

**Date form completed:** 12/7/15