The STAMP (Strategies to Assist with Management of Pain) Study: A Comparative Study of Mindfulness Meditation vs. Cognitive Behavioral Therapy for Opioid-Treated CLBP

Robert Edwards
Pain Psychologist, Associate Professor, BWH
RREdwards@BWH.Harvard.Edu
September 19, 2019
Robert Edwards

• Has nothing to disclose.
Beyond Opioids: Improving Chronic Pain Management through Evidence-Based Nonpharmacological Treatment

• Strategies to Assist with Management of Pain: A multisite trial of CBT and Mindfulness Meditation for patients with chronic low back pain who are on long-term opioid treatment.
CLBP Background

• Common, affecting all groups, with rising prevalence

• Challenging to treat

• Costly: Nearly 1 trillion dollars annually

• Co-occurring mental health disorders / addiction make treatment more challenging and worsen outcomes

• Crisis of opioid abuse, overdose deaths

Institute of Medicine, Relieving Pain in America [Report], 2011
Opioids for Pain

- Opioids have been widely prescribed for chronic pain in the U.S.
Effectiveness?

JAMA | Original Investigation

Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain
The SPACE Randomized Clinical Trial

Erin E. Krebs, MD, MPH; Amy Gravely, MA; Sean Nugent, BA; Agnes C. Jensen, MPH; Beth DeRonne, PharmD; Elizabeth S. Goldsmith, MD, MS; Kurt Kroenke, MD; Matthew J. Bair; Siamak Noorbai, PhD

Conclusions
Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months. Results do not support initiation of opioid therapy for moderate to severe chronic back pain or hip or knee osteoarthritis pain.
There has been a focus on “Traditional Approaches” to managing pain.

Adapted from DeBar L, PCORI 2017 Annual Meeting.
Non-pharmacologic treatments are highly effective, but are under-utilized and less likely to be covered.
Based on the available evidence, we do not know the best method of reducing opioids in adults with chronic pain conditions. We found mixed results from a small number of studies [...].
766 patients with opioid-treated CLBP

Mindfulness meditation (MM)
- eight weekly two-hour sessions; daily home practice

Cognitive behavior therapy (CBT)

Patient-reported outcomes at 12 months:
- ↓ pain, ↑ function, ↑ quality of life,
- ↓ daily opioid dose

STAMP Study

Patient-Centered Outcomes Research Institute (# OPD-1601-33860)
STAMP Study: 12-month Follow-up
ongoing recruitment (n>400 as of July 2019)

• Two in-person visits (entry; exit)
  • Surveys
  • Opioid medication prescriptions
  • Video-recorded function test

• Three “remote” visits (web; phone)
  • surveys only

• Check-ins every 2 weeks (web; phone)

• In-depth exit interview (phone)
  • subgroup of participants
Multicenter randomized controlled trial
(Investigators: A. Zgierska, R. Edwards, E. Garland)
Psychosocial treatments--which help patients make adaptive changes in behaviors, thoughts, and emotions--can lead to positive changes in brain function and structure, improvements in health, and reductions in the severity and impact of pain:
MM and CBT offer different skills for pain coping and chronic pain management:

**Mindfulness Meditation (MM)**
Nonjudgmental, accepting awareness of present-moment experiences to *change one’s relationship* with these experiences

**Cognitive Behavior Therapy (CBT)**
Focus on modifying unhealthy thoughts, emotions and behaviors to *change the experience* and control symptoms.
38 heterogenous RCTs:

- it is safe
- ↓ pain intensity
- ↓ depression symptoms
- ↑ quality of life across many domains
- ↑ physical function and activity
- may help patients to reduce use of opioids

Ann Behav Med 2017; 51:199-213
"Data Synthesis: We found good evidence that cognitive-behavioral therapy . . . is moderately effective for chronic or sub-acute (4 weeks’ duration) low back pain. Benefits over placebo, sham therapy, or no treatment averaged 10 to 20 points on a 100-point VAS pain scale . . ."

Chou et al., 2014
Approach:

- Patient/Stakeholder-Led Approach
- Sound Science/Methods
- Answer to questions that matter to patients and clinicians

What works best? How? For who?
Clinical Implications:

• Guide clinical decision-making
  • Which treatment is most effective for opioid-treated CLBP....?
  • Which treatment is most effective for specific patient groups..?

• Guide coverage decisions by health plans

• Promote the holistic approach to health
  • Integration of “mind” and “body” treatments
Lessons Learned to Date

• Opioid prescriptions for chronic pain are becoming less common.
• A broad variety of advertising/recruitment methods is necessary in order to reach potential participants.
• Some people have strong initial preferences for treatment, but most are willing to be flexible (and randomized).
• Living with chronic pain is extremely challenging - designing the study to accommodate those challenges (e.g., wheelchair access for rooms, timing of study visits, providing breaks and opportunities to move/stretch) is critically important.
• Social aspects of treatment are tremendously important.
Anonymous Exit Interview Comments

• “It helped. It really did, it helped. It made me, remember some things I've been taught, as a young girl. And, it gave me some other tools as well, which has been lovely.”

• “It was nice to ... find that I'm really not alone. There really are other people out there that are dealing with pain like I have, every day.”

• “I learned new things that I could do. I learned that I was not helpless, that I am not a victim of pain, that I can change the way I think about it and how I approach it. And I think I've kept that, I retained that so it's, that's been a positive experience for me.”

• “It's given other alternatives to, what can be done for the pain. I haven't had to take as much of the medication, so that's always useful.”
Looking Ahead

• Continuing recruitment of approximately 300 more participants.
• Completing long-term follow-up assessments of study participants.
• Study findings will help to guide treatment recommendations for patients with chronic back pain.
• We are taking steps to ensure that these treatments are available and covered for patients within our health systems (BWH has recently begun offering monthly CBT groups for chronic pain).
• We are hopeful that studies such as this one, in concert with the other important work being presented here at PCORI’s annual meeting, will help to highlight the need for effective, multidisciplinary, multimodal treatment for chronic pain.
Learn More

- www.pcori.org
- info@pcori.org
- #PCORI2019
- STAMPstudy
Questions?
Thank You!

Robert Edwards, Pain Psychologist
Associate Professor
BWH Department of Anesthesiology
RREdwards@BWH.Harvard.Edu
September 19, 2019