



NIH Collaboratory
Rethinking Clinical Trials[®]

Health Care Systems Research Collaboratory

Barriers, Challenges, and Opportunities Encountered From COVID-19 and Lessons Learned From the UH3s: Changes in Study Conduct

April 14, 2021

Steering Committee Meeting

Moderators

Eric Larson, MD

Rachel Richesson, PhD



Panelists

- GGC4H
 - Margaret Kuklinski
 - Stacy Sterling
- OPTIMUM
 - Natalia Morone
- Nudge
 - Michael Ho
- BackInAction
 - Karen Sherman
 - Lynn DeBar
- FM-TIPS
 - Kathleen Sluka
 - Leslie Crofford
- EMBED
 - Ted Melnick
 - Gail D’Onofrio
- NOHARM
 - Andrea Cheville
 - Jon Tilburt

Questions

1. What did your team do/what actions did you take in response to stay-at-home orders issued in March 2020?
2. What, if any, changes did you make to your intervention or study operations in response to COVID-19?
3. What new data are you collecting in response to COVID-19? How are you collecting or coding these new data?
4. What is the biggest lesson you have learned from COVID-19 related to pragmatic clinical trials and research?

Nudge

Personalized Patient Data and Behavioral Nudges to Improve Adherence to Chronic Cardiovascular Medications

- Randomized trial using population-level pharmacy data to test the effectiveness of text message–based “nudges” on adherence and outcomes among patients with chronic cardiovascular conditions who take medications to treat hypertension, atrial fibrillation, coronary artery disease, diabetes, or hyperlipidemia
- 3 integrated healthcare systems



Michael Ho, MD, PhD



Sheana Bull, PhD, MPH

Nudge

EMBED

*Pragmatic Trial of User-Centered Clinical Decision Support to Implement
Emergency Department-Initiated Buprenorphine for Opioid Use Disorder*

- Constrained group randomized trial to evaluate the effects of user-centered computerized clinical decision support on rates of emergency department–initiated buprenorphine and referral for ongoing medication-assisted treatment for patients with opioid use disorder
- 20 emergency departments in 5 healthcare systems



**Edward Melnick,
MD, MHS**



**Gail D'Onofrio,
MD, MS**



FM-TIPS *Fibromyalgia TENS in Physical Therapy Study*

- Cluster randomized trial to assess feasibility of using transcutaneous electrical nerve stimulation (TENS) in addition to physical therapy for treatment of fibromyalgia to improve symptoms, increase adherence to physical therapy, and reduce medication use
- Approximately 600 patients with fibromyalgia in 20 to 25 physical therapy practices in 6 healthcare systems



Kathleen Sluka,
PT, PhD



Leslie Crofford, MD



FM-TIPS
*Fibromyalgia TENS In
Physical Therapy Study*

BackInAction

Pragmatic Trial of Acupuncture for Chronic Low Back Pain in Older Adults

- Three-arm randomized trial comparing a standard course of acupuncture, enhanced acupuncture, and usual medical care to improve back-related function in patients with chronic low back pain
- 789 to 840 adults 65 years or older in 4 healthcare systems



Karen J. Sherman,
MD, MPH



Lynn DeBar, MD, MPH



OPTIMUM

Group-Based Mindfulness for Patients With Chronic Low Back Pain in the Primary Care Setting

- Randomized clinical trial to integrate and test a group-based mindfulness stress reduction program to reduce chronic low back pain, improve physical and psychological function, and reduce or stop opioid prescriptions
- 450 adults with with chronic low back pain in 3 healthcare systems



Natalia Morone, MD, MS



GGC4H *Guiding Good Choices for Health: Testing Feasibility and Effectiveness of Universal Parent-Focused Prevention in Three Healthcare Systems*

- Cluster randomized trial testing the feasibility and effectiveness of implementing a universal, evidence-based anticipatory guidance curriculum for parents of early adolescents to reduce adolescent alcohol, tobacco, and drug use; depression; and delinquent behavior
- Approximately 4500 families in 24 pediatric primary care practices in 3 large, integrated healthcare systems



Margaret Kuklinksy, PhD



Stacy Sterling, DrPH, MSW



**GUIDING
GOOD CHOICES**

NOHARM

Nonpharmacologic Options in Postoperative Hospital-Based and Rehabilitation Pain Management

- Stepped-wedge, cluster randomized trial testing EHR-based clinical decision support to elicit preferences for, document, and direct patients toward evidence-based nonpharmacologic postoperative pain care
- Up to 140,000 patients in surgical practices in 4 healthcare systems



Andrea Cheville, MD



Jon Tilburt, MD

Discussion

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3. What new data are you collecting in response to COVID-19? How are you collecting or coding these new data?
4. ***What is the biggest lesson you have learned from COVID-19 related to pragmatic clinical trials and research?***

What is the biggest lesson you have learned from COVID-19 and pragmatic research?



Panelist use 'raise hand' feature in Zoom

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