

National Institutes of Health • Department of Defense • Department of Veterans Affairs

Pain Management Collaboratory:

Pragmatic Clinical Trials of Nonpharmacologic Approaches for the Management of Pain
and

Co-occurring Conditions

Pain Management Collaboratory



NIH Pragmatic Trials Collaboratory Steering Committee

April 20, 2022

PMC Objectives (From RFA-AT-17-001; UG3/UH3)

- Establish a Coordinating Center to provide leadership and technical expertise
- Support the design and successful execution of pragmatic clinical trials
- Disseminate data, tools, best practices and resources

“Ultimately, it is expected that successful approaches and best practices ...will have a major impact on clinical research, and importantly, care for military and veteran populations.” (page 6)

11 Pragmatic Clinical Trials

J. Fritz/D. Rhon:

SMART Stepped Care Management for Low Back Pain in Military Health System (NIH)

A. Heapy/D. Higgins:

Cooperative Pain Education and Self-management: Expanding Treatment for Real-world Access (COPEs ExTRA) (NIH)

K. Seal/W. Becker:

Implementation of a Pragmatic Trial of Whole Health Team vs. Primary Care Group Education to Promote Non-Pharmacological Strategies to Improve Pain, Functioning, and Quality of Life in Veterans (NIH)

S. George/S.N. Hastings:

Improving Veteran Access To Integrated Management of Chronic Back Pain (AIM-BACK) (NIH)

Burgess:

Learning to Apply Mindfulness to Pain (LAMP) (DOD)

S. Taylor/S. Zeliadt:

Complementary and Integrative Health for Pain in the VA: A National Demonstration Project (VA)

B. Ilfeld:

Ultrasound-Guided Percutaneous Peripheral Nerve Stimulation: A Non-Pharmacological Alternative for the Treatment of Postoperative Pain (DOD)

C. Goertz/C. Long:

Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP (NIH)

M. Rosen/S. Martino:

Engaging Veterans Seeking Service-Connection Payments in Pain Treatment (NIH)

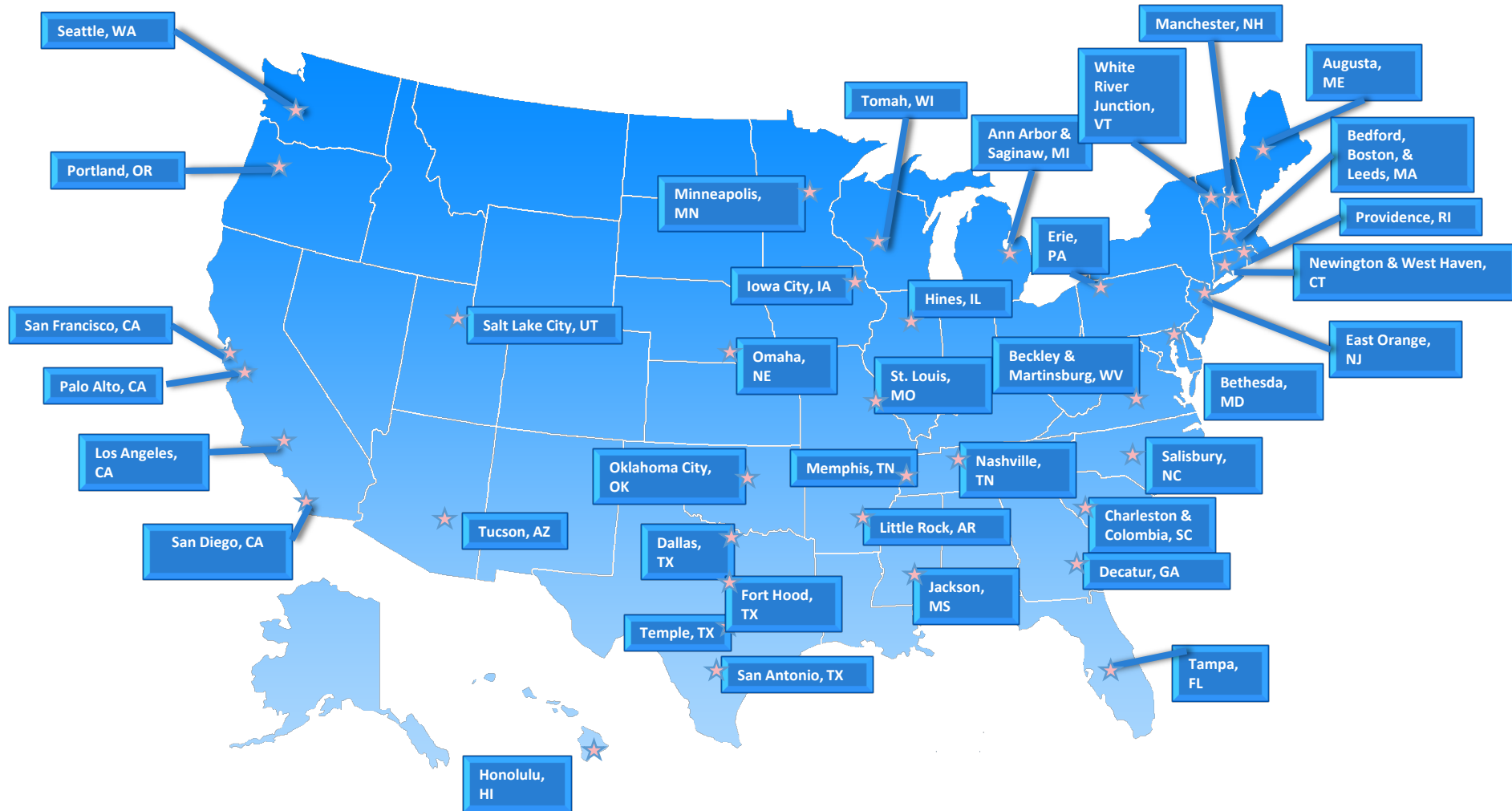
S. Farrokhi/C. Dearth:

Resolving the Burden of Low Back Pain in Military Service Members and Veterans (RESOLVE Trial) (DOD)

D. McGeary/J. Goodie:

Targeting Chronic Pain in Primary Care Settings Using Internal Behavioral Health Consultants (DOD)

Pragmatic Clinical Trial Sites



PMC Progress

- All projects have transitioned to implementation phase
 - Strong partnership with Work Groups, including project specific consultations
 - Pilot studies and other formative work informed refinements to Pragmatic Clinical Trials
- COVID impacts addressed
 - Project impacts (PI responses to survey and qualitative interviews)
 - Questionnaire for study participants
 - Monitored changes in healthcare delivery systems
- Extensive data harmonization efforts
 - Agreement on use of PEG as a key phenotyping and outcome measure
 - Agreement on several additional standardized phenotyping measures
 - Healthcare Utilization: Outpatient Visits using EHR data
 - Healthcare Utilization: Primary Care Visits using EHR data
 - Substance Use Disorder: Harmonized and EHR script developed
 - Long-term Opioid Use: Refined definition and EHR script developed
- Ongoing efforts to optimize use of electronic health record data
- Aided PCTs in shift to electronic informed consent and addressing other regulations
- Ongoing efforts to address complexity of data sharing and data aggregation across projects

PMC Progress

- External Board and Patient Resource Group actively engaged
- Stakeholder Engagement Work Group provides forum for addressing challenges and sharing best practices
 - Proactive outreach to health care system leaders
 - Aggressive efforts to promote sustained engagement of key clinical and organizational partners
- Military Treatment Facility Engagement Committee serves as key resource for addressing emerging issues related to integration of the Defense Health Agency, EHR modernization in transition to Military Health System GENESIS, and regulations
- Focus on optimizing recruitment, including underrepresented groups
- Initiated cross-cutting discussion groups
 - Virtual delivery
 - Justice/equity
 - Pragmatism
 - Monitoring changes in pain management healthcare delivery
 - “Reverse translation” (*Health Psychology*)
- Product dissemination
 - Publication Policy updated and approved by Steering Committee
 - Product Development Process Guidance approved by Steering Committee

Selective PMC Products

- *Pain Medicine* Supplement; Volume 21, Suppl 2, 2020
 - Robert D. Kerns, PhD, and Cynthia A. Brandt, MD, MPH; **NIH-DOD-VA Pain Management Collaboratory: Pragmatic Clinical Trials of Nonpharmacological Approaches for Management of Pain and Co-occurring Conditions in Veteran and Military Health Systems: Introduction**
 - Eric B. Schoomaker, MD, PhD, FACP; **Promising Solutions to a Major Epidemic**
- Coleman, B.C. et al. (2020). **Adapting to disruption of research during the COVID-19 pandemic while testing nonpharmacological approaches to pain management.** *Translational Behavioral Medicine*, 10, 827-834.
- Coleman, B.C., et al. (2021). **Assessing the impact of COVID-19 on pragmatic clinical trial participants.** *Contemporary Clinical Trials*, 111, 106119.
- Ali, J. et al. (2021). **Justice and equity in pragmatic clinical trials: Considerations for pain research in integrated health systems.** *Learning Health Systems*, e10291.
- Fritz, J.M. et al., (2021). **Pivoting to virtual delivery for managing chronic pain with nonpharmacological treatments: implications for pragmatic research.** *Pain*, 162, 1591-1596.
- Anicich, A. et al. (2022). **Engaging veterans and military service members to optimize pragmatic clinical trials of nonpharmacological approaches for pain management.** *Pain Medicine*.

Steering Committee 2018



Testimonials

“I love being part of the Pain Management Collaboratory because I get to work closely with pain experts in the field regularly in real time.... For instance, when the COVID-19 crisis emerged, we had to scramble to determine the impact on our trials, but we were able to work rapidly in real time to come up with measures that everybody was going to add to their battery of baseline measures, and potentially measures throughout the trial, to factor in the impact of COVID.”

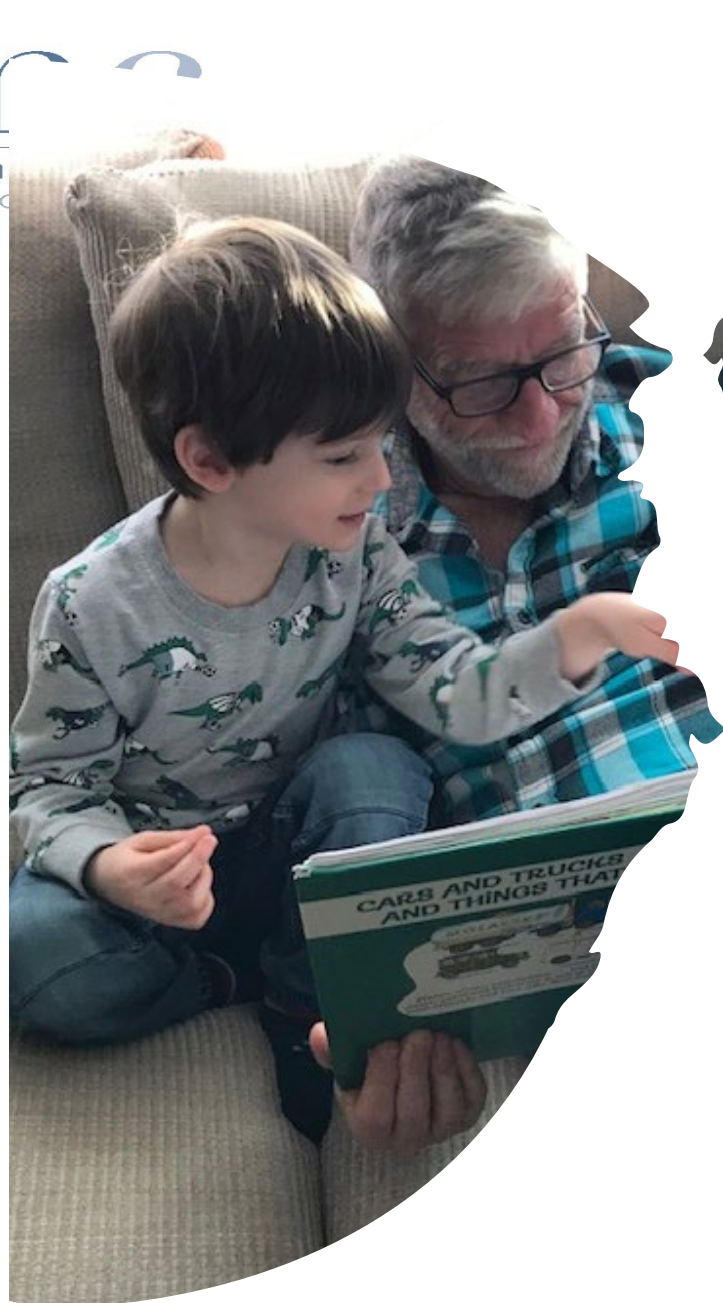
- **Diana Burgess, Ph.D.**

“I appreciate this type of camaraderie at a high level.”

-**Steven George, PT, Ph.D.**

[The Collaboratory] allows us to all be in tune with one another and benefit from the addition of all our projects together, rather than just from the individual project alone.

- **Brian Ilfeld, M.D., M.S.**



Thanks

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Follow the PMC on Twitter @[painmc3](https://twitter.com/painmc3)