

VERDICT (Veterans Response to Dosage in Chiropractic Therapy): A Pragmatic Randomized Trial Addressing Dose Effects for Chronic Low Back Pain: What, Why and How?

January 7, 2020

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RELEVANT DISCLOSURES

1. Nothing to Report

PRESENTATION SUMMARY

- 1. Public Health Impact of Low Back Pain**
- 2. Current Guidelines & Recommendations**
- 3. Preliminary Pilot Work to Evaluate Chiropractic Care for Veterans**
- 4. VERDICT Chiropractic Dosing Project**

Public Health Impact of Low Back Pain

LOW BACK PAIN

#1 CAUSE OF
GLOBAL DISABILITY

80%

**LIFETIME PREVALENCE
IN ADULTS**

37%

**GLOBAL ANNUAL
PREVALENCE**

7.3%

GLOBAL POINT
PREVALENCE

540 MILLION

PEOPLE IMPACTED

 **54%**

**IN YEARS LIVED WITH
DISABILITY**

(FROM 1990 – 2015)

THE ESTIMATED TOTAL COSTS FOR
LOW BACK PAIN IS AS HIGH AS

\$200 BILLION

ANNUALLY IN THE U.S.

Current Guidelines & Recommendations

Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline

Roger Chou, MD; Richard Deyo, MD, MPH; Janna Friedly, MD; Andrea Skelly, PhD, MPH; Robin Hashimoto, PhD; Melissa Weimer, DO, MCR; Rochelle Fu, PhD; Tracy Dana, MLS; Paul Kraegel, MSW; Jessica Griffin, MS; Sara Grusing, BA; and Erika D. Brodt, BS

Background: A 2007 American College of Physicians guideline addressed nonpharmacologic treatment options for low back pain. New evidence is now available.

Purpose: To systematically review the current evidence on nonpharmacologic therapies for acute or chronic nonradicular or radicular low back pain.

Data Sources: Ovid MEDLINE (January 2008 through February 2016), Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and reference lists.

Study Selection: Randomized trials of 9 nonpharmacologic options versus sham treatment, wait list, or usual care, or of 1 nonpharmacologic option versus another.

Data Extraction: One investigator abstracted data, and a second checked abstractions for accuracy; 2 investigators independently assessed study quality.

Data Synthesis: The number of trials evaluating nonpharmacologic therapies ranged from 2 (tai chi) to 121 (exercise). New evidence indicates that tai chi (strength of evidence [SOE], low) and mindfulness-based stress reduction (SOE, moderate) are effective for chronic low back pain and strengthens previous find-

ings regarding the effectiveness of yoga (SOE, moderate). Evidence continues to support the effectiveness of exercise, psychological therapies, multidisciplinary rehabilitation, spinal manipulation, massage, and acupuncture for chronic low back pain (SOE, low to moderate). Limited evidence shows that acupuncture is modestly effective for acute low back pain (SOE, low). The magnitude of pain benefits was small to moderate and generally short term; effects on function generally were smaller than effects on pain.

Limitation: Qualitatively synthesized new trials with prior meta-analyses, restricted to English-language studies; heterogeneity in treatment techniques; and inability to exclude placebo effects.

Conclusion: Several nonpharmacologic therapies for primarily chronic low back pain are associated with small to moderate, usually short-term effects on pain; findings include new evidence on mind-body interventions.

Primary Funding Source: Agency for Healthcare Research and Quality. (PROSPERO: CRD42014014735)

Ann Intern Med. 2017;166:493-505. doi:10.7326/M16-2459

Annals.org

For author affiliations, see end of text.

This article was published at Annals.org on 14 February 2017

Nonpharmacologic Therapies for Low Back Pain: A Systematic Review
for an American College of Physicians Clinical Practice Guideline

“Several nonpharmacologic therapies for low back pain were associated with small to moderate, primarily short-term effects on pain.”

“Effects on function generally were smaller than those on pain, and most evidence was for chronic low back pain.”

and checked abstracts for accuracy; 2 investigators independently assessed study quality.

Data Synthesis: The number of trials evaluating nonpharmacologic therapies ranged from 2 (tai chi) to 121 (exercise). New evidence indicates that tai chi (strength of evidence [SOE], low) and mindfulness-based stress reduction (SOE, moderate) are effective for chronic low back pain and strengthens previous find-

usually short-term effects on pain; findings include new evidence on mind-body interventions.

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“Across interventions, no serious harms were noted, although the reporting of harms was suboptimal.”

“Typical harms reported were temporary increases in low back pain or other local effects (such as pain or bleeding from insertion of acupuncture needles).”

pharmacologic option versus another.

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GUIDELINES APPLICABLE TO LBP

- **Centers for Disease Control**
- **Food and Drug Administration**
- **Veterans Health Administration/Department of Defense**
- **Joint Commission**
- **American Hospital Association**
- **American College of Physicians**

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CLINICAL GUIDELINES | 4 APRIL 2017

Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians FREE

Amir Qaseem, MD, PhD, MHA; Timothy J. Wilt, MD, MPH; Robert M. McLean, MD; Mary Ann Forciea, MD; for the Clinical Guidelines Committee of the American College of Physicians *

[Article, Author, and Disclosure Information](#)[Eligible for CME Point of Care](#) [Learn More](#)

FULL ARTICLE

Abstract

Guideline Focus and Target Population

Methods

Benefits and Comparative Benefits of Pharmacologic Therapies

Harms of Pharmacologic Therapies

Comparative Benefits of

Abstract

Description: The American College of Physicians (ACP) developed this guideline to present the evidence and provide clinical recommendations on noninvasive treatment of low back pain.

Methods: Using the ACP grading system, the committee based these recommendations on a systematic review of randomized, controlled trials and systematic reviews published through April 2015 on noninvasive pharmacologic and

nonpharmacologic treatments for low back pain. Updated searches were performed through November 2016. Clinical outcomes evaluated included reduction or



PDF



CITATIONS



PERMISSIONS

Published: *Ann Intern Med.* 2017;166(7):514-530.

DOI: 10.7326/M16-2367

Published at www.annals.org on 14 February 2017

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198 Citations



SEE ALSO

[Systemic Pharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline](#)

[Nonpharmacologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline](#)

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SUMMARY OF RECOMMENDATION:

**Physicians and patients
should treat acute, sub-acute
and chronic low back pain
with non-drug therapies.**

ACP LOW BACK PAIN GUIDELINE

1. Acute/Subacute Low Back Pain

Superficial Heat

Massage

Acupuncture

Spinal Manipulation

ACP LOW BACK PAIN GUIDELINE

1. Acute/Subacute Low Back Pain

Superficial Heat

Massage

Acupuncture

Spinal Manipulation

2. Chronic Low Back Pain

Exercise (Tai Chi, Yoga)

Spinal Manipulation

Progressive Relaxation

ACP LOW BACK PAIN GUIDELINE

1. Acute/Subacute Low Back Pain

Superficial Heat

Massage

Acupuncture

Spinal Manipulation

2. Chronic Low Back Pain

Exercise (Tai Chi, Yoga)

Spinal Manipulation

Progressive Relaxation

3. Chronic Low Back Pain that doesn't respond to non-drug therapies

First line: NSAIDs

Second Line: Tramadol or Duloxetine

Last Resort: Opioids

**Evaluating
Chiropractic for
Veterans with LBP –
Preliminary Pilot Work**



COCOV

Collaborative Care for Veterans with
Spine Pain and Mental Health Conditions (COCOV)

PIs: Christine Goertz DC, PhD and Cynthia Long, PhD

STUDY BACKGROUND / RATIONALE

US VETERANS

- Musculoskeletal pain conditions
- Chronic low back pain
- Mental health co-morbidities
- Opioids and psychotropic medications

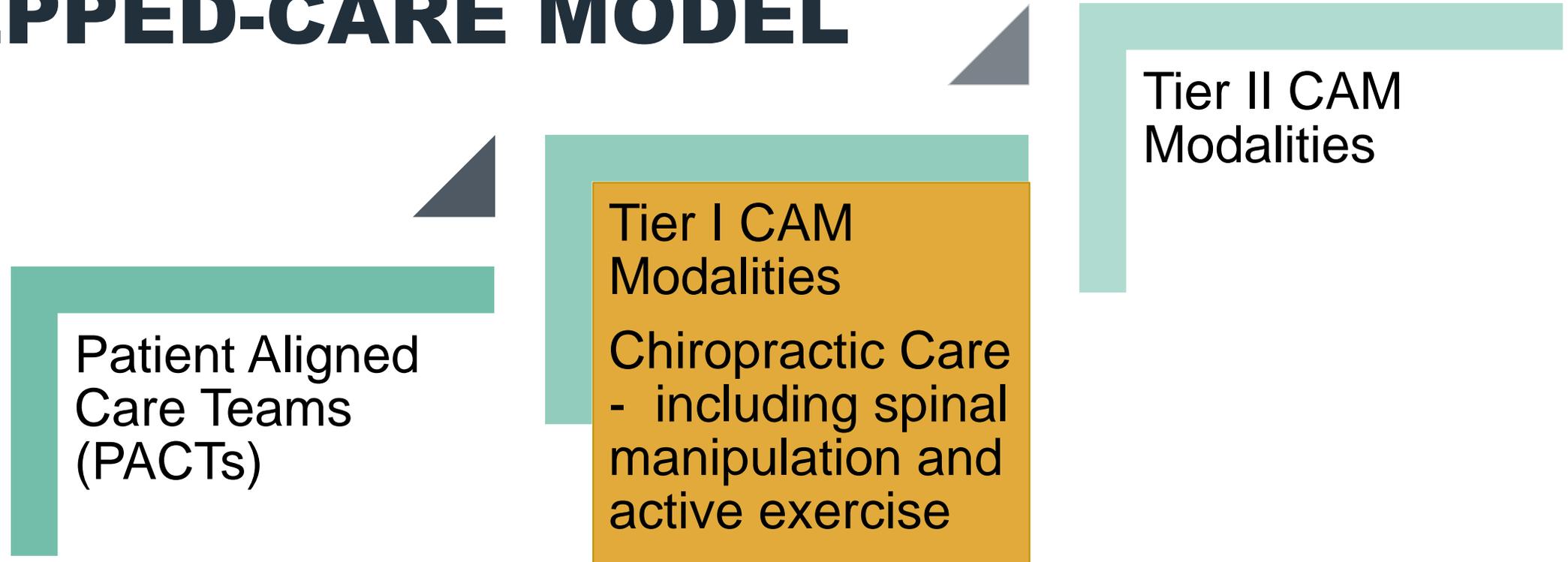
POOR OUTCOMES

- ↑ Long-term disability
- ↑ Healthcare utilization
- ↓ Work productivity
- ↓ Quality of life
- ↑ Opioid-related overdose/deaths

VHA PAIN MODEL

- Team-based management
- Stepped-care model
- Pharmacological treatments PLUS
- Complementary and integrative approaches

DoD/VHA PAIN MANAGEMENT STEPPED-CARE MODEL



2018/19

VHA Statistics

108 chiropractic clinics → 1500+ VHA facilities

180 chiropractors → 236,000 VHA employees in healthcare

52,000 chiropractic patients → 6.4 million Veterans treated in VHA settings

231,000 chiropractic visits → 121 million VHA outpatient visits

VA STAKEHOLDER PERCEPTIONS

- **Qualitative interviews at 3 research sites**
- **Patients, multidisciplinary team members, DCs**
- **Identify stakeholder viewpoints**
 - Preferences and perceived need for chiropractic care
 - Chiropractic integration into PACTs
 - Current policies and processes to support integration
 - Barriers to inclusion of chiropractic in VHA guidelines and clinical practice settings
- **Thematic content analysis with qualitative software**

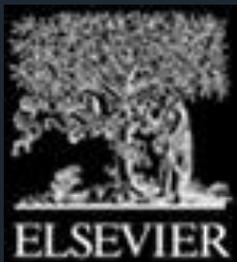


Chiropractic Integrated Care Pathway for Low Back Pain in Veterans: Results of a Delphi Consensus Process

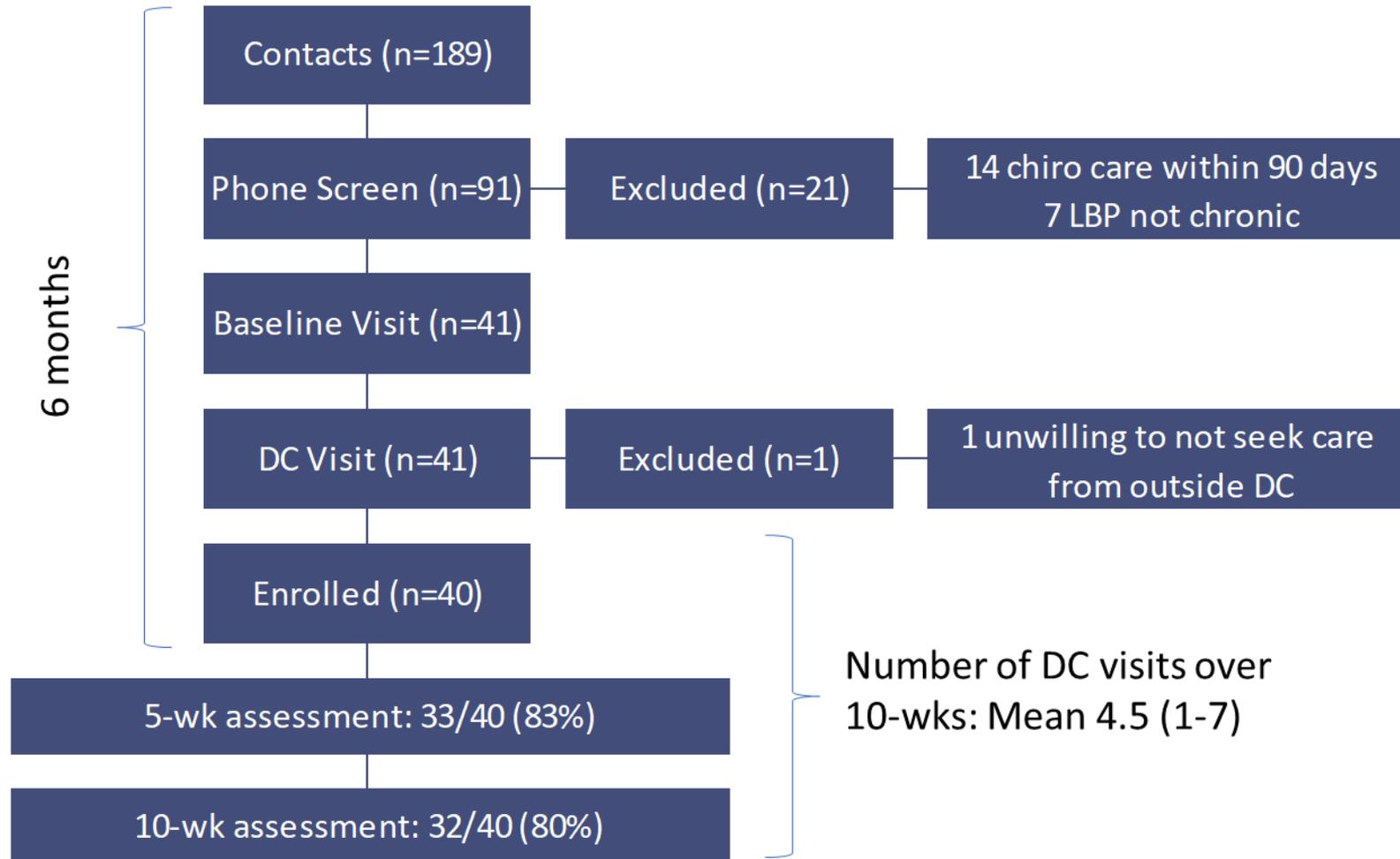
Anthony J. Lisi, DC, Stacie A. Salsbury, PhD, RN, Cheryl Hawk, DC, PhD, Robert D. Vining, DC, Robert B. Wallace, MD, MSc, Richard Branson, DC, Cynthia R. Long, PhD, A. Lucille Burgo-Black, MD, FACP, Christine M. Goertz, DC, PhD

Journal of Manipulative & Physiological Therapeutics
Volume 41, Issue 2, Pages 137-148 (February 2018)

DOI: 10.1016/j.jmpt.2017.10.001



COCOV PILOT CLINICAL TRIAL



COCOV PILOT CLINICAL TRIAL

- 40 VA patients, ages 18-55 with chronic LBP
- Integrative care pathway
- Chiropractic care for up to 10 weeks
- Assessments at baseline, weeks 5 and 10
- Qualitative interviews for patient and provider feasibility and acceptability
- Descriptive statistics to estimate effect sizes and variability

COCOV PILOT CLINICAL TRIAL

- Demonstrated the feasibility of participant recruitment and collecting outcomes via REDCap from Veterans in the VA healthcare environment.
- Successful recruitment and data collection methods have been incorporated into the protocol for a full-scale, multisite (4 VA clinics), pragmatic trial for veterans with cLBP (NIH/NCCIH Grant UH3AT009761).

ACKNOWLEDGMENTS

- Investigative team members: Christine Goertz, Cynthia Long, Robert Vining, Robert Wallace, Anthony Lisi, Thad Abrams, Rick Branson, Stacie Salsbury
- Funder: National Center for Complementary and Integrative Health (NCCIH), National Institutes of Health (NIH) grant number R34AT008427, *Collaborative Care for Veterans with Spine Pain and Mental Health Conditions (COCO V) Collaborative Care for Veterans* (Goertz and Long, PIs).
- With gratitude: Study personnel and Veteran research participants involved in the COCOV Study.

**Evaluating
Chiropractic for
Veterans with LBP –
VERDICT Dosing Study**

Fighting pain in the U.S. military and veterans

12 research projects totaling \$81 million over 6 years will address pain and related conditions using nondrug approaches*

<https://painmanagementcollaboratory.org/>

Chronic pain (more than 3 months)

26%

general public estimates

44%

U.S. military after combat deployment

Opioid use (in the past month)

4%

general public estimates

15%

U.S. military after combat deployment

These rates show an unmet need for managing chronic pain with nondrug approaches among U.S. military personnel and veterans.

* NIH's NCCIH is leading this initiative. Other NIH cofunders include NIDA, NIAAA, NINDS, NCMRR (part of NICHD), NINR, ORWH, and OBSSR. DoD is funding this initiative through CRMRP and MOMRP. The VA is providing funding through VA ORD.

Jonas WB, Schoemaker EB. Pain and opioids in the military: we must do better. *JAMA Internal Medicine*. 2014;174(8):1402-1403.



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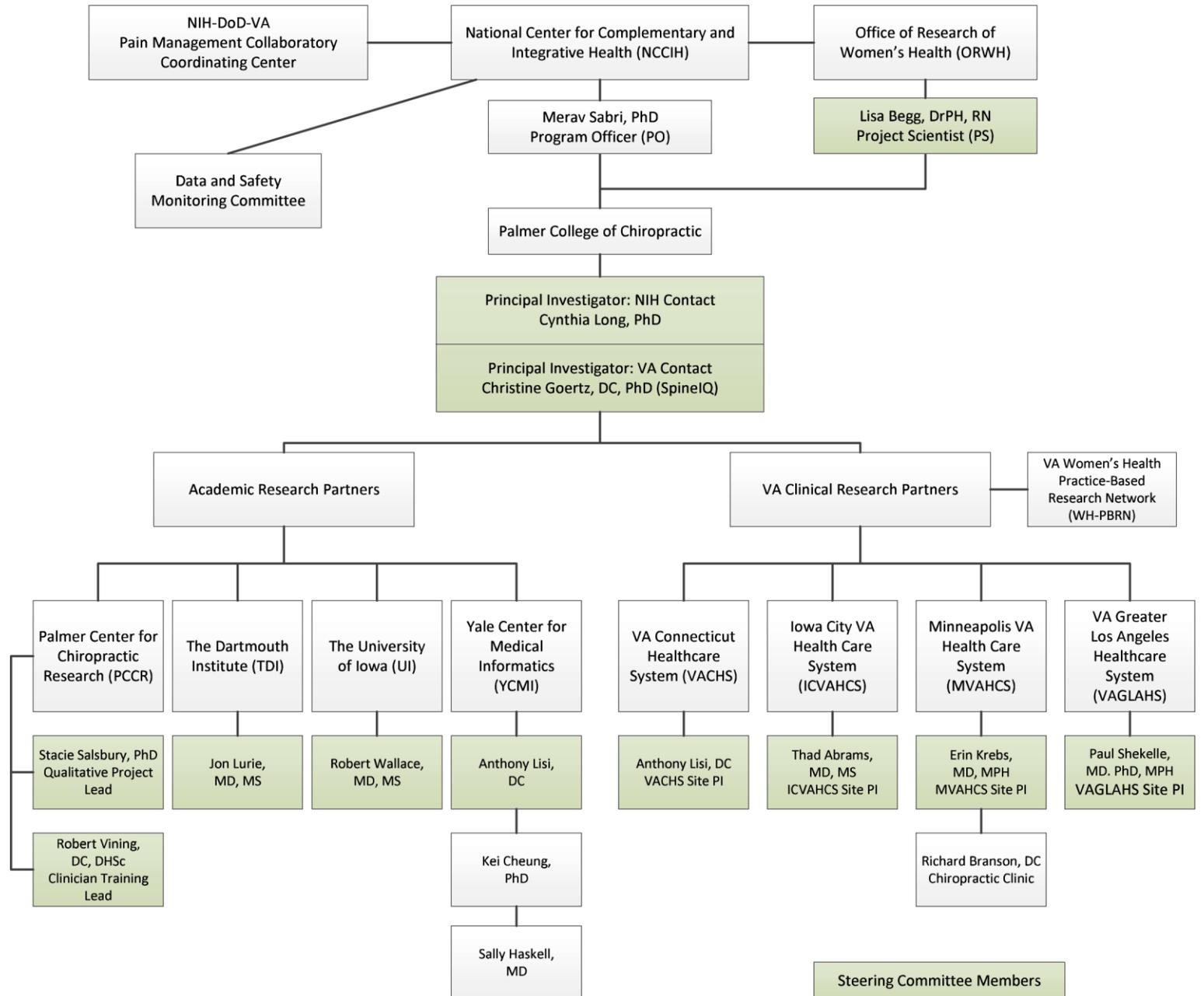
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VERDICT

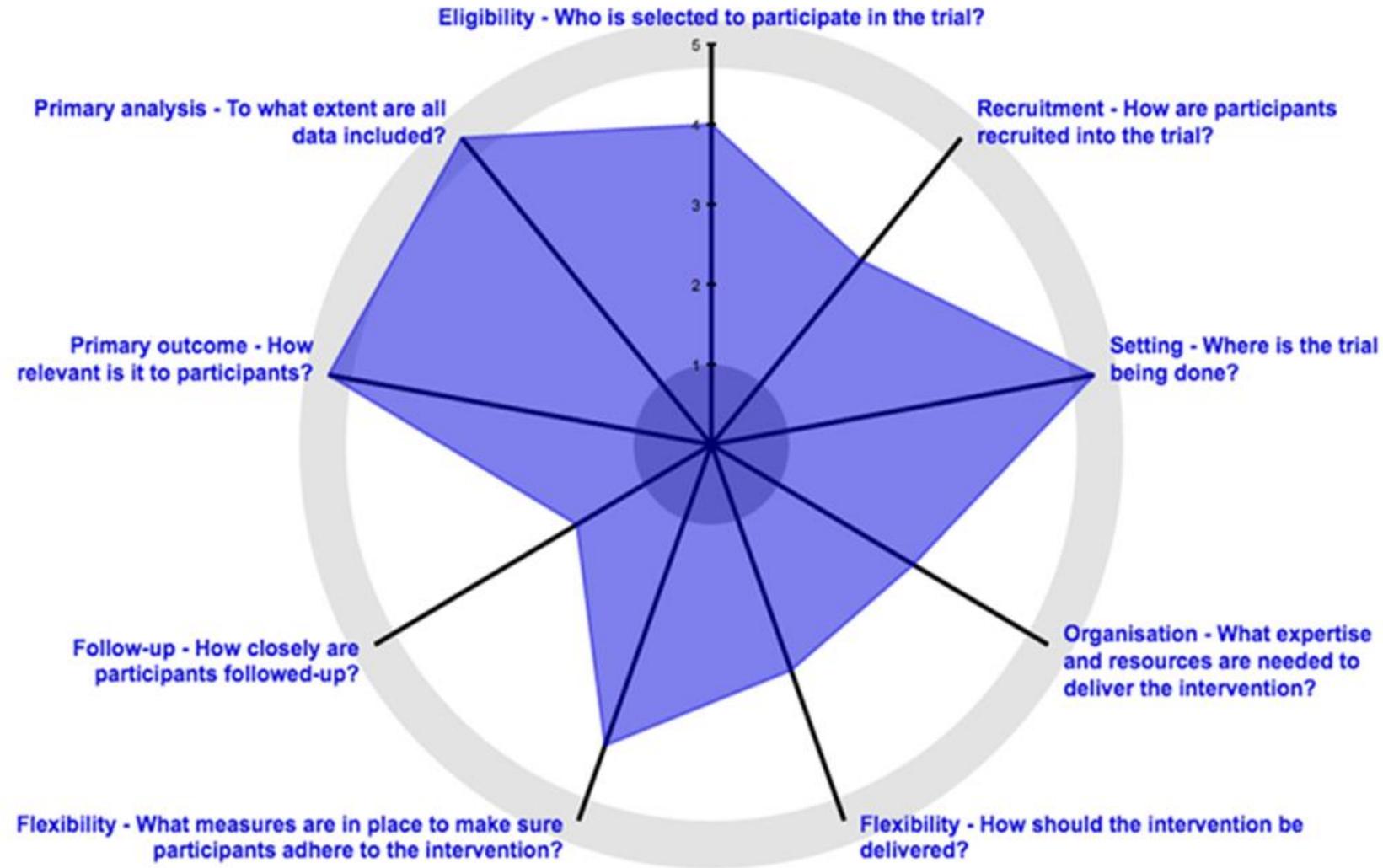
**Chiropractic Care for Veterans:
A Pragmatic Randomized Trial Addressing Dose Effects for cLBP**

PIs: Christine Goertz DC, PhD and Cynthia Long, PhD

Study Team



PRAGMATIC RANDOMIZED CLINICAL TRIAL



ELIGIBILITY CRITERIA

Patient Population

- 766 Veterans
- 18 years and older
- Self-reported cLBP: persisted 3+ months with pain on at least half the days in the past 6 months

RESEARCH AIMS

Objective #1

Evaluate the comparative effectiveness of a low dose (1-5 visits) of chiropractic care against a higher dose (8-12 visits) in Veterans with cLBP at 10 weeks.

RESEARCH AIMS

Objective #2

Evaluate the comparative effectiveness at 52 weeks of chiropractic chronic pain management (CCPM; one scheduled chiropractic visit per month x 10 months), compared to no CCPM following the initial treatment period of 10 weeks.

RESEARCH AIMS

Objective #3

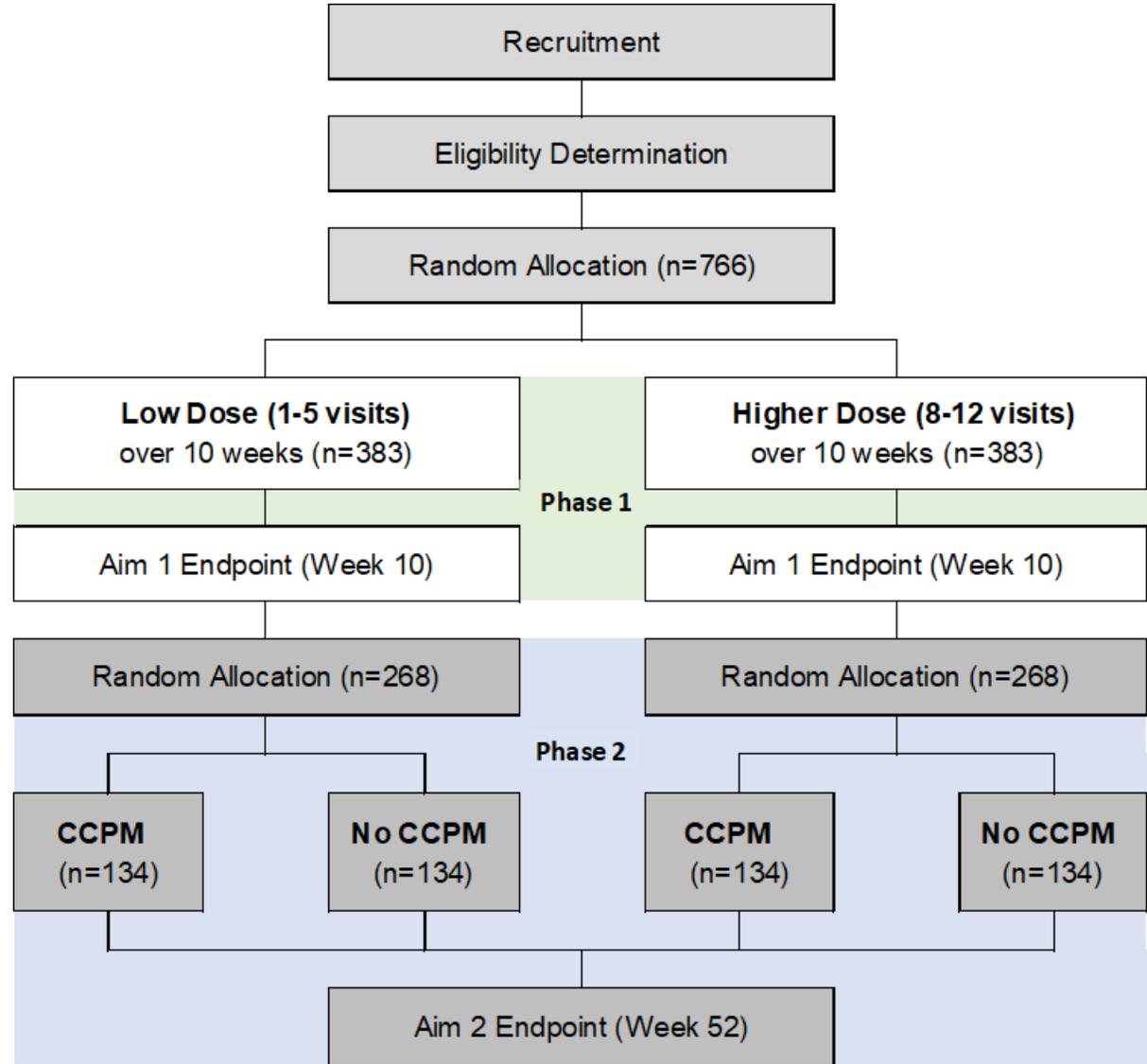
Evaluate the impact of CCPM on health services outcomes compared to usual care.

RESEARCH AIMS

Objective #4

Evaluate patient and clinician perceptions of non-specific treatment factors, effectiveness of study interventions, and impact of the varying doses of standard chiropractic care and the CCPM on clinical outcomes across 4 VA facilities using a mixed method, process evaluation approach.

STUDY FLOW



STUDY OUTCOMES

Primary Outcome

- Roland Morris Disability Questionnaire

Secondary Outcomes

- PEG-3; PROMIS PI, PF, FT, SL, GH, SS, AG, SE; PHQ-8; GAD-7; PCL-5; # of days per week with LBP

Health Services

- Prescriptions, referrals, clinic visits, hospitalizations

Qualitative

- Non-specific treatment factors, intervention effectiveness, dosage impact

Current Status

IRB Approvals

- VA cIRB Annual Renewal (December 2019)
- Yale IRB (Academic Sites: May 2019)

Training

- Study coordinators & doctors of chiropractic trained at first 2 sites

Recruitment

- Begins January 2020



Journal of Manipulative & Physiological Therapeutics

Development of a Clinical Decision Aid for Chiropractic Management of Common Conditions Causing Low Back Pain in Veterans: Results of a Consensus Process

Robert D. Vining, Zacariah K. Shannon, Stacie A. Salsbury, Lance Corber, Amy L. Minkalis, Christine. M. Goertz

DOI: <https://doi.org/10.1016/j.jmpt.2019.03.009>

Publication stage: In Press Corrected Proof

Collaborating Institutions



Duke
UNIVERSITY

VA



U.S. Department
of Veterans Affairs



PALMER

Center for Chiropractic Research



Yale University
School of Medicine



College of
Public Health



Dartmouth

ACKNOWLEDGMENTS

- Investigative team members: Christine Goertz, Cynthia Long, Robert Vining, Robert Wallace, Anthony Lisi, Thad Abrams, Rick Branson, Stacie Salsbury, Jon Lurie, Paul Shekelle, Erin Krebs
- Funder: National Center for Complementary and Integrative Health (NCCIH), National Institutes of Health (NIH) grant number UG3/UH3AT009761, *Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for cLBP*, (Goertz and Long, PIs).

**THANK
YOU!**