

# The use of Acupuncture in a Civilian Acute Care Settings: Results from Randomized Trials and Practice Based Research Evaluation

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March 19, 2020

# AMAZING NEWS- As of 1/21/20

## Decision Memo for Acupuncture for Chronic Low Back Pain (CAG-00452N)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

### Decision Summary

A. The Centers for Medicare & Medicaid Services (CMS) will cover acupuncture for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act. Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstances:

- For the purpose of this decision, chronic low back pain (cLBP) is defined as:
  - Lasting 12 weeks or longer;
  - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
  - not associated with surgery; and
  - not associated with pregnancy.
- An additional eight sessions will be covered for those patients demonstrating an improvement. No more than 20 acupuncture treatments may be administered annually.
- Treatment must be discontinued if the patient is not improving or is regressing.

# Pain Burden in the United States

- Pain affects an estimated 100 million adults in the United States.<sup>1</sup>
- Annual cost related to pain in the US is estimated to be between \$560 to \$635 billion.<sup>1,2</sup>
- Pain is a public health problem, a major driver of health care seeking and for taking medications, a major cause of disability, and a key factor in quality of life and productivity.<sup>1</sup>
- In 2012, there were 50 times more opioid prescriptions in the US than in the rest of the world combined.<sup>3</sup>

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#### Sources:

- 1- Institute of Medicine, Committee on Advancing Pain Research, Care and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington (DC): National Academies Press (US); 2011.
- 2- Gaskin DJ, Richard P. The economic costs of pain in the United States. *J Pain*. 2012;13(8):715-724.
- 3- Manchikanti L, Helm S, 2nd, Fellows B, et al. Opioid epidemic in the United States. *Pain Physician*. 2012;15(3 Suppl):ES9-38.

# Pain Burden in the United States - 2018

- **130+** Deaths daily from opioid-related overdose.<sup>1</sup>
  - **15,349** Deaths attributed to overdosing on heroin (in 12- month period ending February 2019)<sup>3</sup>
  - **32,656** Deaths attributed to overdosing on synthetic opioids other than methadone (in 12-month period ending February 2019)<sup>3</sup>
  - **47,600** People died from overdosing on opioids<sup>3</sup>
- 
- **10.3 million** People misused prescription opioids in 2018<sup>2</sup>
  - **2 million** People misused prescription opioids for the first time<sup>2</sup>
  - **2 million** People had an opioid use disorder in 2018<sup>2</sup>
  - **81,000** People used heroin for the first time<sup>2</sup>
  - **808,000** People used heroin in 2018<sup>2</sup>
- 

Sources:

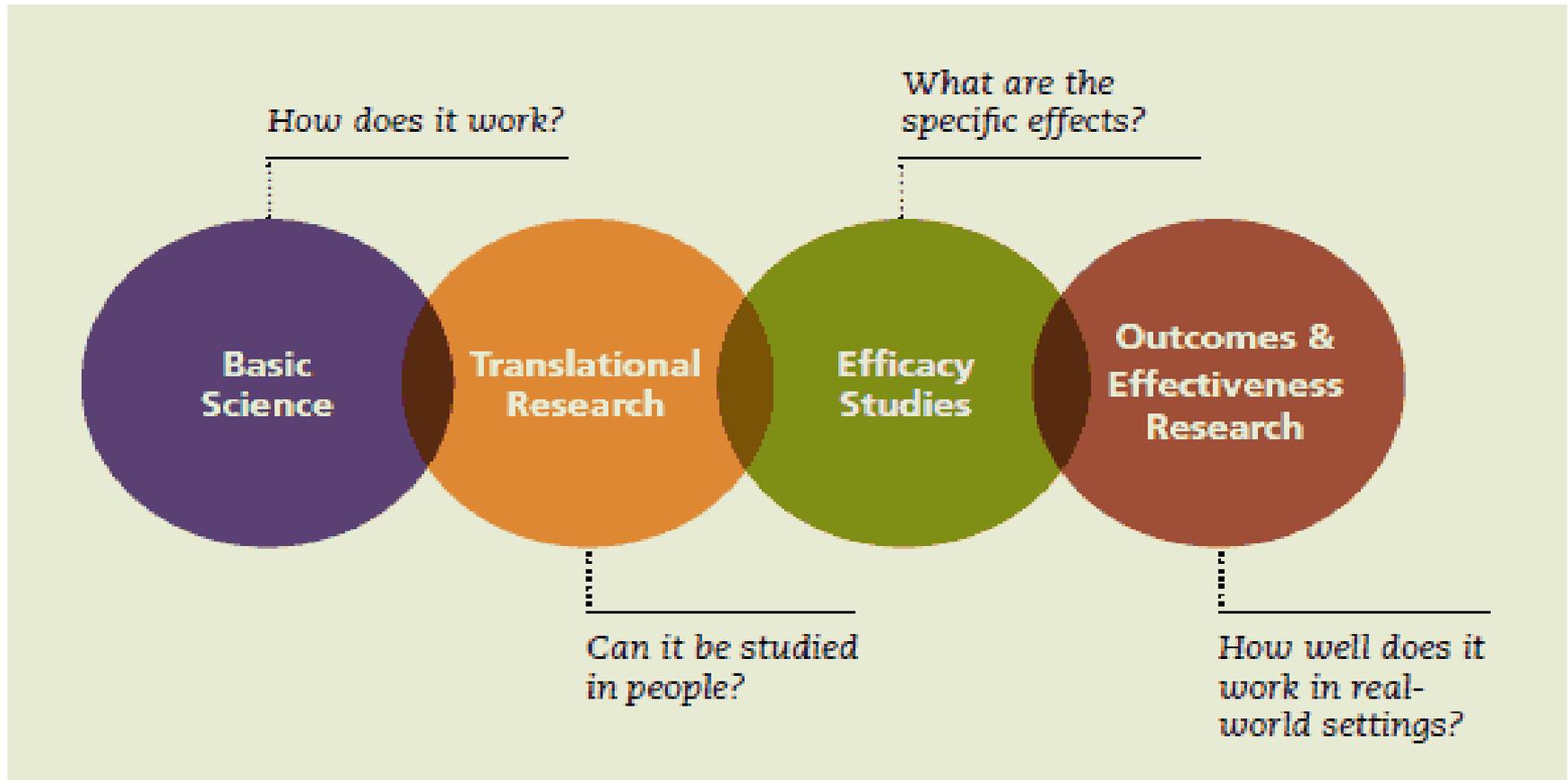
1- NCHS, National Vital Statistics System. Estimates for 2018 and 2019 are based on provisional data. <http://www.hhs.gov/opioids/> Accessed January 22, 2020

2- 2019 National Survey on Drug Use and Health. Mortality in the United States, 2018

3- National Center for Health Statistics Data Brief No. 329, November 2018

Updated October 2019. For more information, visit: <http://www.hhs.gov/opioids/>

# NCCIH- Range of Research Questions



**The Range of Research Questions** from National Center for Complementary and Integrative Health of National Institutes of Health (<https://nccih.nih.gov/about/whystudyCHA>)

# 2016 NIH, NCCIH Systematic Review

SYMPOSIUM ON PAIN MEDICINE



## Evidence-Based Evaluation of Complementary Health Approaches for Pain Management in the United States

Richard L. Nahin, PhD, MPH; Robin Boineau, MD, MA; Partap S. Khalsa, DC, PhD; Barbara J. Stussman, BA; and Wendy J. Weber, ND, PhD, MPH

[Mayo Clin Proc. 2016;91\(9\):1292-1306](#)

# Evidence-based Evaluation of CHA for Pain- 2016

- **105 Randomized Trials included**
- **Based on the number of positive vs negative trials, the following approaches may help some patients manage painful conditions:**

## Acupuncture:

- back pain
- osteoarthritis of the knee

## Massage therapy:

- neck pain (with adequate doses and for short-term benefit)
- back pain<sup>a</sup>

## Osteopathic manipulation:

- back pain<sup>a</sup>

## Relaxation techniques:

- severe headaches and migraine
- fibromyalgia<sup>a</sup>

## Spinal manipulation:

- back pain<sup>a</sup>

## Tai chi:

- osteoarthritis of the knee
- fibromyalgia<sup>a</sup>

## Yoga:

- back pain

<sup>a</sup> Weaker evidence based on qualitative assessment

Source:

## News & Analysis

### Medical News & Perspectives

# As Opioid Epidemic Rages, Complementary Health Approaches to Pain Gain Traction

Jennifer Abbasi

[JAMA](#). 2016 Nov 2. doi: 10.1001/jama.2016.15029. [Epub ahead of print]

## News & Analysis

### Medical News & Perspectives

## As Opioid Epidemic Rages, Complementary Health Approaches to Pain Gain Traction

Unlike a typical systematic review that assigns quality values to the studies, the investigators conducted a narrative review, in which they simply looked at the number of positive and negative trials. “If there were more positives than negatives then we generally felt the approach had some value,” Nahin

Based on a “preponderance” of positive vs negative trials, complementary approaches that may offer pain relief include acupuncture and yoga for back pain; acupuncture and tai chi for osteoarthritis of the knee; massage therapy for neck pain; and relaxation techniques for severe headaches and migraine.

[JAMA](#). 2016 Nov 2. doi: 10.1001/jama.2016.15029. [Epub ahead of print]

# Perspective from NIH, NCCIH

## Beyond RCTs

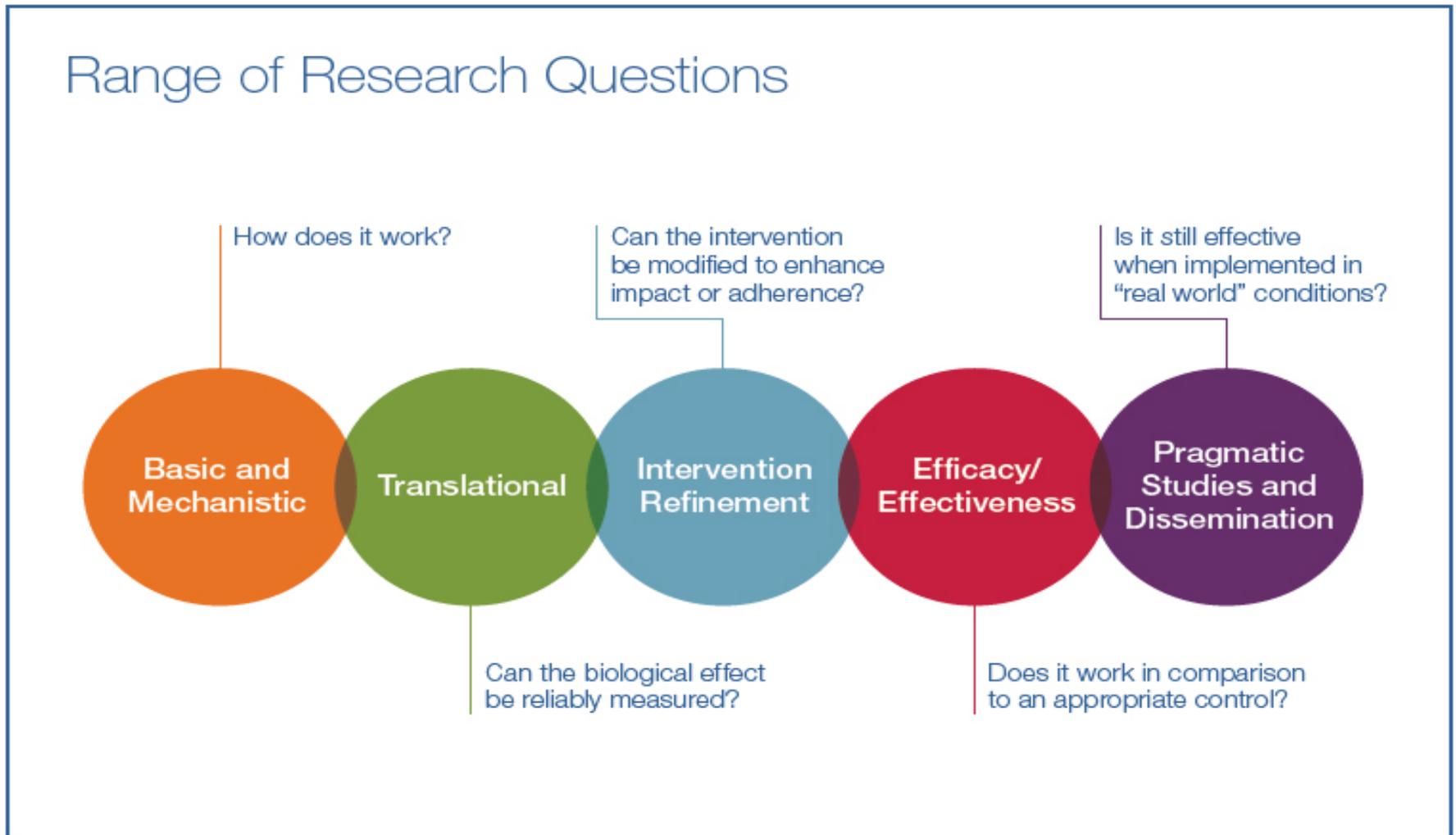
Nahin noted that the clinical trials that met the bar for his review tended to be small and participants were limited primarily to older white women. “The review identified a lot of gaps in the data,” he said, adding that “there’s still a lot of research that needs to be done to see whether these data can be generalized to the larger US demographic population.”

# Perspective from NIH, NCCIH

A next step for the NCCIH, Shurtleff said, is to conduct “pragmatic” studies that look at the effectiveness of complementary health strategies for pain outside of the strict inclusion/exclusion criteria of RCTs. “We’re looking to see how this works in real time in the real world, with all the warts and things that go along with that,” he said.

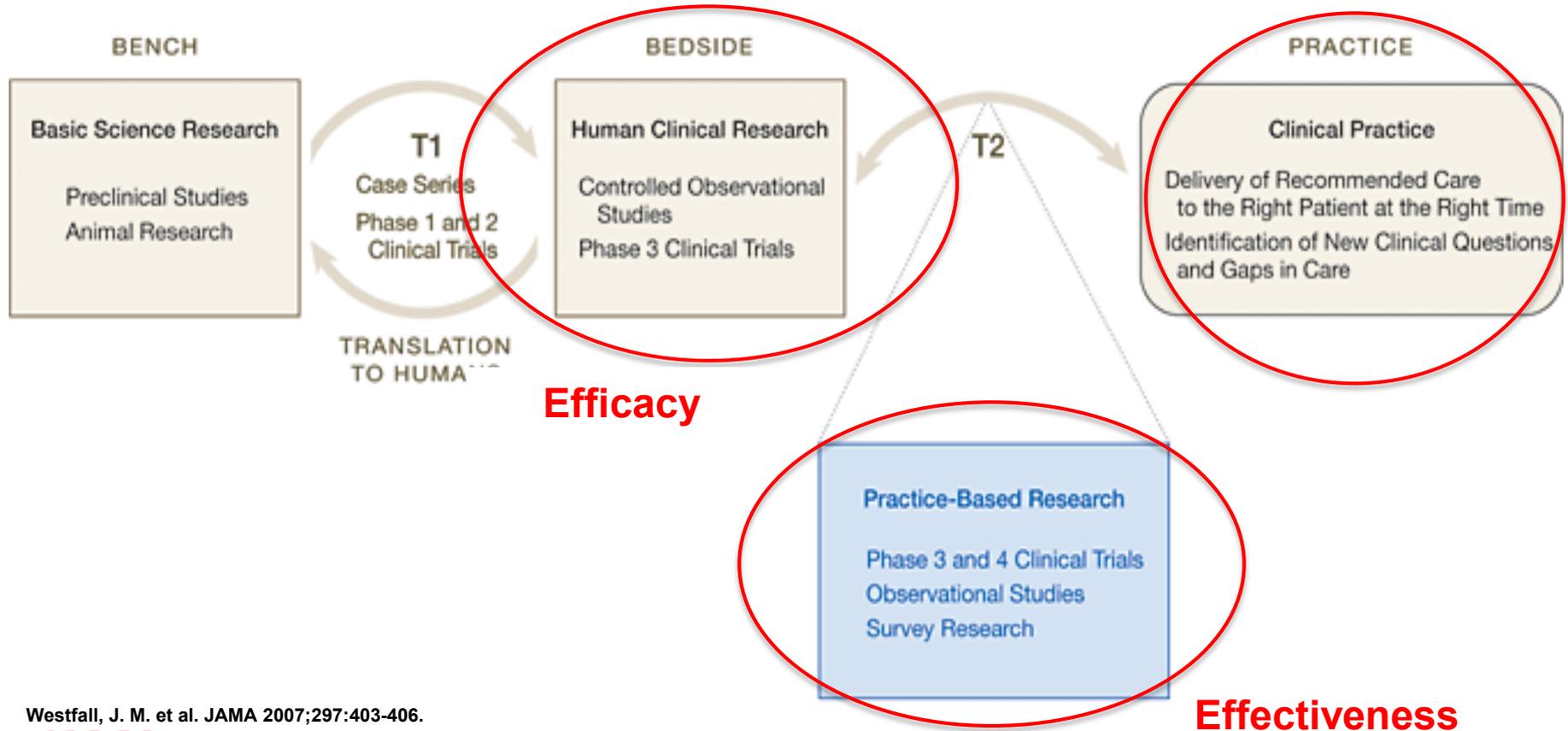
“At the end of the day, if an approach is successful you’ll be able to generalize it more to everyone with the disease, versus a very small cohort of individuals,” Nahin added.

# NCCIH- Range of Research Questions



**The Range of Research Questions** from National Center for Complementary and Integrative Health of National Institutes of Health (<https://nccih.nih.gov/about/research/range-research-questions>)

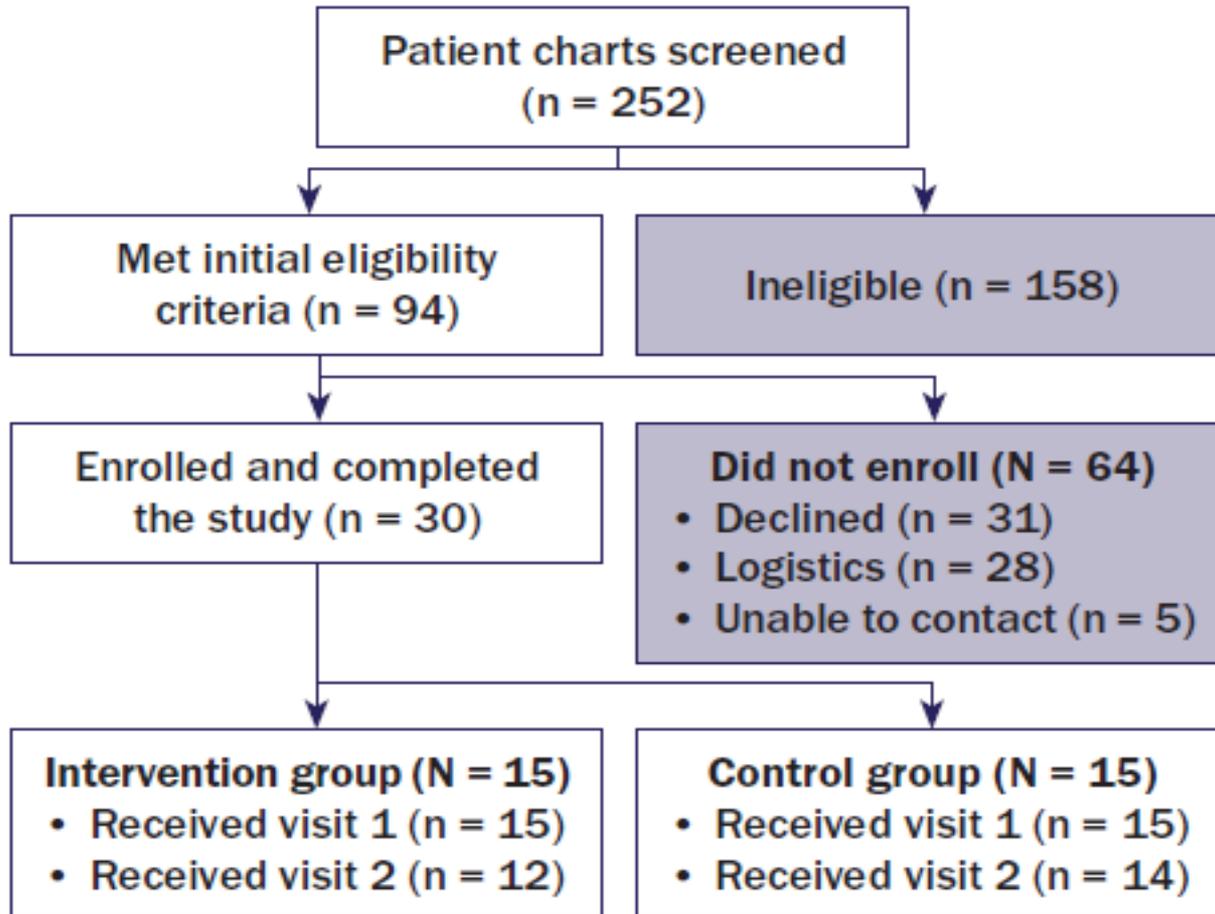
# Practice-Based Research



Westfall, J. M. et al. JAMA 2007;297:403-406.

**JAMA**

# Pilot Randomized Trial: Acupuncture for Breast Cancer



**FIGURE 1. Consolidated Statements of Reporting Trials (CONSORT) Diagram**

# Pilot Randomized Trial: Acupuncture for Breast Cancer

**TABLE 2. Visit 1 Mean Change in Outcome Measures by Treatment Group**

Measure	Intervention (N = 15)							Control (N = 15)						
	Pre		Post		Change		p	Pre		Post		Change		p
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD		$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	
Anxiety	2.33	1.8	1	1.31	-1.33	1.59	0.006	1.27	1.39	1.8	2.37	0.53	2.88	0.484
Coping	6.67	2.72	8.53	2.17	1.87	2.97	0.029	8.53	1.81	8.07	2.25	-0.47	1.36	0.204
Nausea	2.6	3.31	1.07	2.12	-1.53	2.7	0.045	0.27	0.46	1	1.69	0.73	1.75	0.127
Pain	4.2	1.01	2.73	1.39	-1.47	1.06	< 0.001	3.67	2.13	3.60	1.99	-0.07	1.67	0.879

Mean change scores between the acupuncture and control groups were statistically significantly different for all outcome measures (pain,  $p = 0.011$ ; nausea,  $p = 0.011$ ; anxiety,  $p = 0.039$ ; coping,  $p = 0.012$ ).

# Pilot Randomized Trial: Acupuncture for Breast Cancer

**TABLE 3. Visit 2 Mean Change in Outcome Measures by Treatment Group**

Measure	Intervention (N = 10)							Control (N = 14)						
	Pre		Post		Change		p	Pre		Post		Change		p
	$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD		$\bar{X}$	SD	$\bar{X}$	SD	$\bar{X}$	SD	
Anxiety	1.4	1.65	0.5	0.71	-0.9	1.45	0.081	1.57	1.5	1.71	1.82	0.14	1.03	0.612
Coping	7.6	3.06	7.9	3.73	0.3	3.06	0.763	8.5	1.51	8.57	1.7	0.07	0.47	0.583
Nausea	1	1.7	0.5	0.97	-0.5	1.27	0.244	0.79	1.97	0.5	1.16	-0.29	1.38	0.453
Pain	3.1	1.52	1.6	1.35	-1.5	0.97	< 0.001	3.07	2.13	2.64	2.31	-0.43	1.02	0.139

in any of the four outcome measures. Mean change scores between the acupuncture and control groups were statistically significantly different for pain ( $p = 0.017$ ) and anxiety ( $p = 0.051$ ) at visit 2.

# Poll Question #1

- What is your primary role in VA?
  - student, trainee, or fellow
  - clinician
  - researcher
  - Administrator, manager or policy-maker
  - Other

# The Impact of Integrative Medicine on Pain Management in a Tertiary Care Hospital

*Jeffery A. Dusek, PhD,\* Michael Finch, PhD,† Gregory Plotnikoff, MD, MTS, FACP‡ and Lori Knutson, RN, BSN, HN-BC§ and on behalf of the Penny George Institute for Health and Healing Inpatient Care Team*

**Design:** Retrospective, observational study.

**Setting:** Abbott Northwestern Hospital, a 629-bed tertiary-care hospital in Minneapolis, Minn, that is part of Allina Hospitals & Clinics.

**Participants:** Approximately 1837 patients hospitalized between January 1, 2008, and June 30, 2009.

**Measurements:** Pretreatment and posttreatment pain scores on a verbal scale of 0 to 10.

**Results:** Most patients (66%) had never previously received integrative services. Provision of integrative services had immediate and beneficial effects on pain scores. The average reduction in pain scores was 1.9 points (on a 10-point scale), and the average percentage in pain reduction was approximately 55%.

# National Institute of Health grant: 2011-2016

**Project Number:** 5R01AT006518-03  
**Title:** EFFECT OF COMPLEMENTARY AND ALTERNATIVE MEDICINE ON PAIN AMONG INPATIENTS

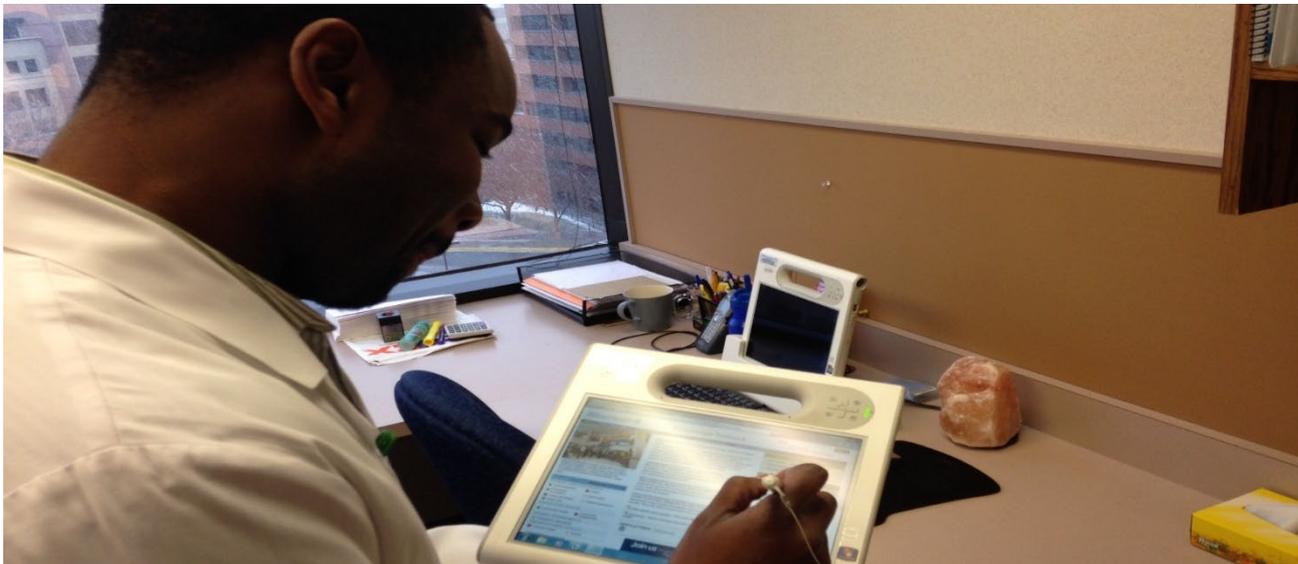
**Contact PI / Project Leader:** [DUSEK, JEFFERY A](#)  
**Awardee Organization:** ALLINA HEALTH SYSTEM

## Abstract Text:

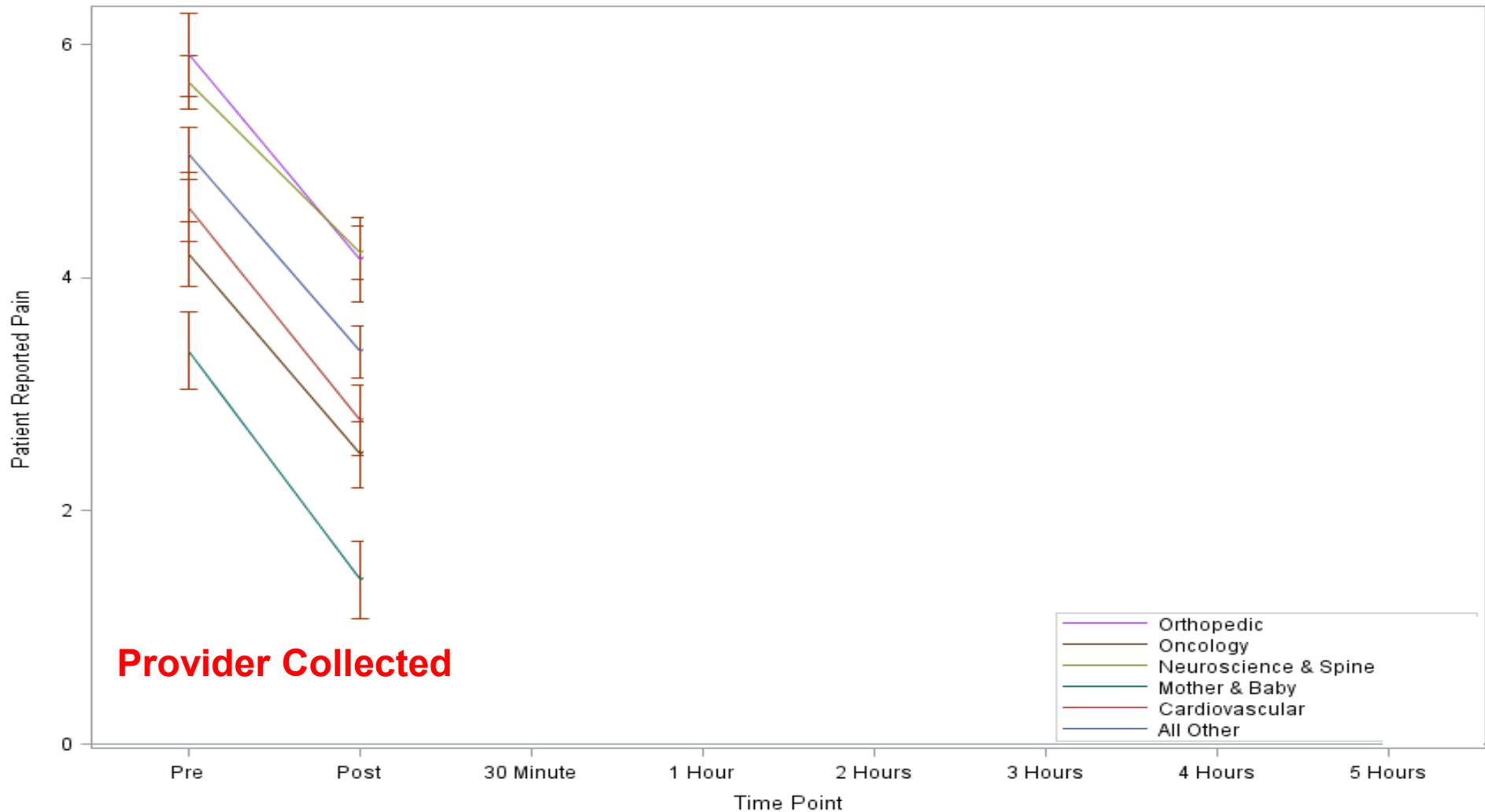
DESCRIPTION (provided by applicant): Effective and safe pain management is a major health priority for the US healthcare system. Pharmaceutical interventions remain the primary approach to pain management, despite their well documented risk of adverse events, potential for addiction, and adverse impact on recovery if used excessively. Nowhere is this more evident than in the post-operative period where roughly 80% of patients report moderate to severe pain after surgery even after receiving pharmaceutical interventions. In inpatient settings, finding an effective non-pharmacologic intervention to augment narcotic medications would be a significant benefit. National surveys indicate that complementary and alternative medicine (CAM) interventions are currently used by 15% of American hospitals. Most often, these therapies are employed to address specific unmet clinical needs, the most frequent of which is pain. Eleven clinical trials have demonstrated the efficacy of CAM therapies to reduce pain (short- and long-term) in hospitalized patients along with traditional pharmaceutical interventions. Generating additional evidence of the effectiveness of these therapies for pain relief would advance knowledge and potentially affect practice patterns. In a preliminary study, we retrospectively studied 1,837 patients who received CAM therapies at Abbott Northwestern Hospital. We found an average reduction in immediate pain of 56% and roughly 33% reported complete pain relief after the initial CAM visit. We recognize inadequacies of this study that limit both our knowledge of how adjunctive CAM therapies are implemented in hospitals and the effect of various CAM therapies on pain management, which can only be answered with prospective data collection. Using a prospective, **observational** design, we propose a large scale study to build on this exploratory work. It will document predictors of CAM referral, service delivery, and therapy selection for pain management. It will also examine the impact of CAM therapies as adjuncts to traditional interventions on short and long-term changes in pain across clinical groups in a hospital setting. The setting for this study of CAM is the Penny George Institute for Health and Healing at Abbott Northwestern Hospital. The George Institute is uniquely suited for this work as it is the nation's largest inpatient CAM program serving over 19,000 patients since 2004. The proposed study has 3 aims: 1) quantitatively describe a model for delivering CAM therapies to understand selection of patients and CAM therapies for pain management, 2) examine the effects of selected CAM therapies on immediate change in pain, and 3) examine the effects of selected CAM therapies on duration of pain change. Positive results from this study will assist hospitals in the integration of usual care and CAM therapy for pain reduction. Findings may also drive future research on the cost effectiveness of these therapies for pain management, as well as impact on patient outcomes such as length of stay and use of narcotics.

# Methods

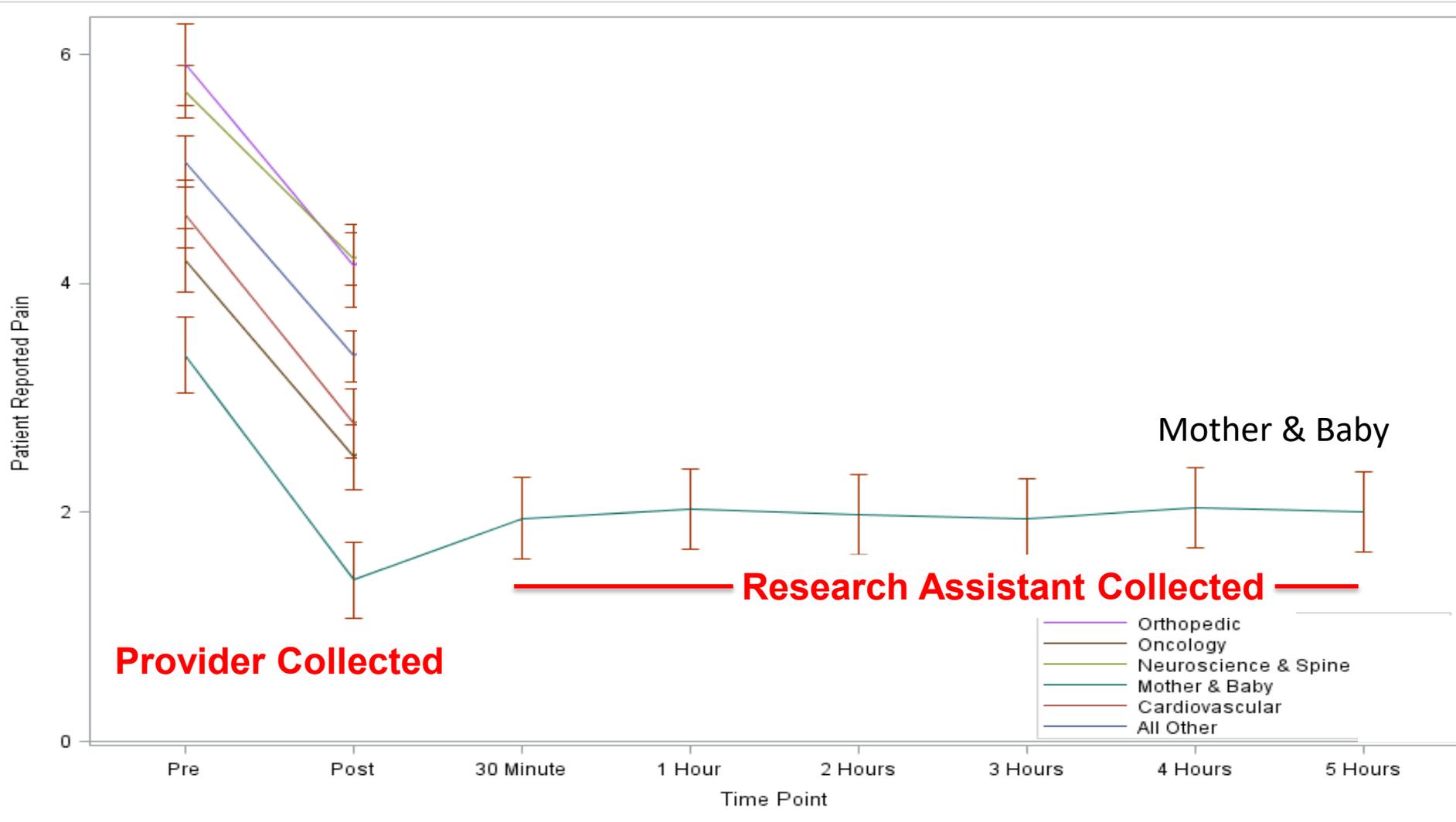
- Collect six post-IM therapy pain scores:
  - 30 minutes
  - 1, 2, 3, 4 and 5 hours



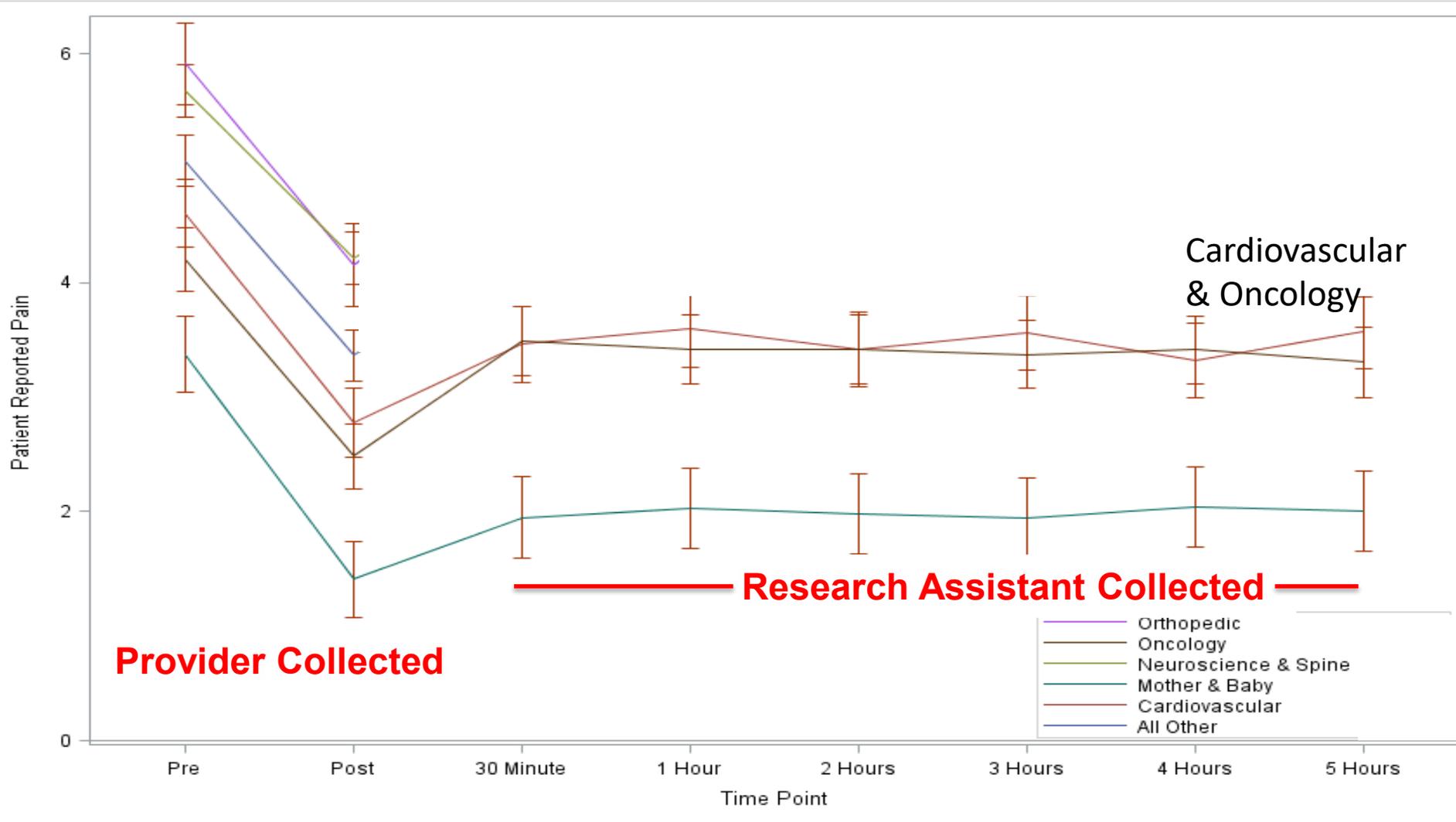
# Duration of Pain Outcomes



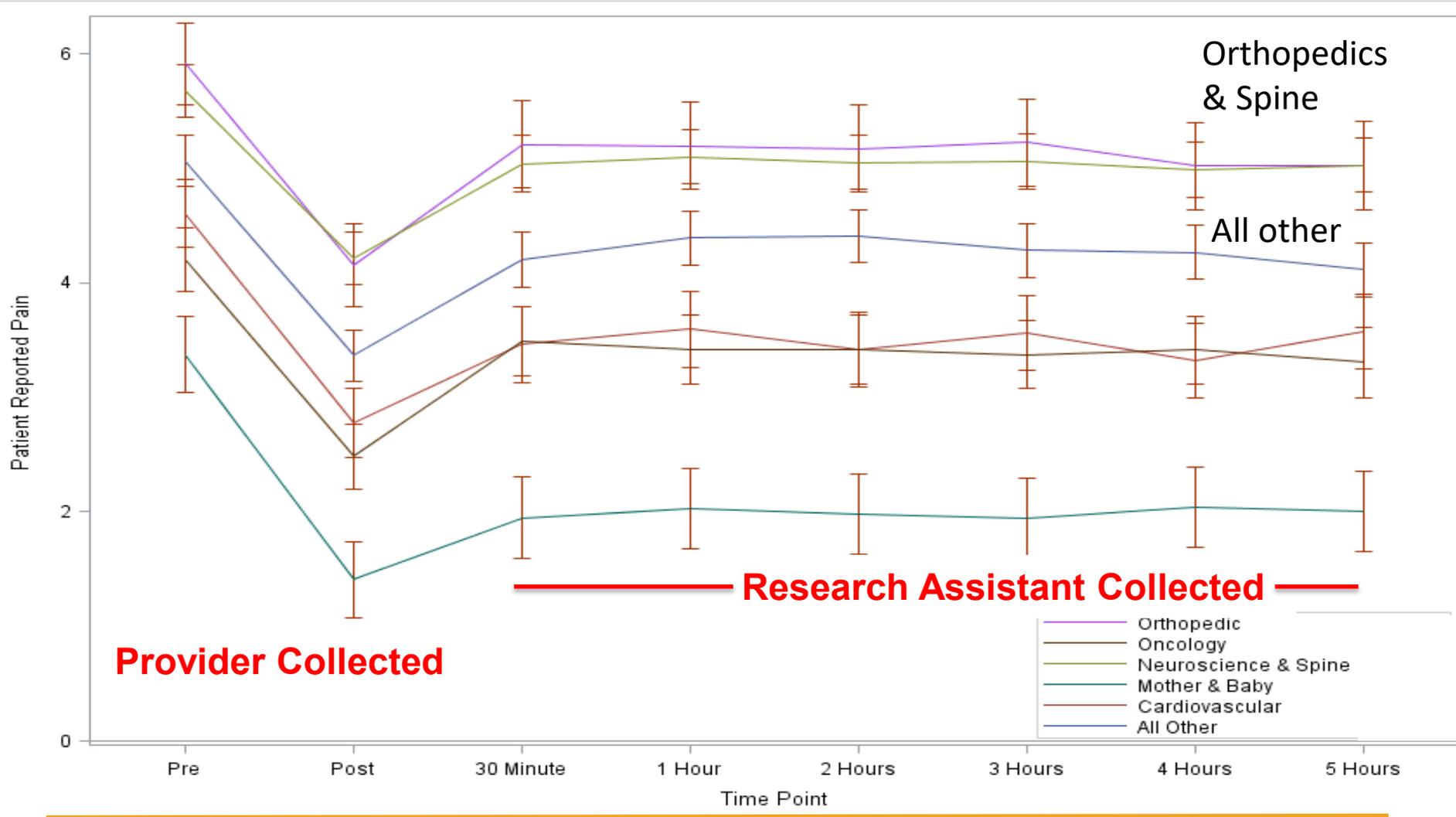
# Duration of Pain Outcomes



# Duration of Pain Outcomes



# Duration of Pain Outcomes



Source: Presented at International Congress on Integrative Medicine & Health, Las Vegas (May 2016). Article in preparation.

# Cost implications of IM for Pain Relief

- A retrospective analysis including data from an EPIC-based electronic health record (EHR)
  - Patient demographics,
  - Length of stay (LOS), and
  - All Patient Refined Diagnosis Related Groups (APR-DRG) severity of Illness
- Total of 2,730 patients received IM for pain and met eligibility criteria
- Regressed the demographic, change in pain, LOS, and APR-DRG variables with changes in pain on total cost for the hospital admission.
- Pain was reduced by an average of 2.05 points.
- Pain reduction was associated with a cost savings of \$898 per hospital admission.

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Source: Dusek JA, Griffin KH, Finch MD, Rivard RL, Watson D. Cost Savings from Reducing Pain Through the Delivery of Integrative Medicine Program to Hospitalized Patients. *J Altern Complement Med.* 2018 Feb 23. doi: 10.1089/acm.2017.0203.

# Acupuncture in an Outpatient Clinic



- Spacious
- Relaxed
- Quiet Instrumental Music
- Softly Lit
- Pleasant Smelling

# Acupuncture in the Emergency Department

- Cramped
- Stressful
- Loud Beeping (screaming?)
- Brightly Lit
- Offensive Smelling

# Acupuncture in ED: Acceptability & Outcomes

- Would MDs refer?
  - Yes: 73% of MDs/NPs/PAs referred for AQ.
- Would patients accept acupuncture?
  - Yes: 89% of patients accepted AQ. (248/279)
- Would acupuncture provide pain relief?
  - The final sample: 182 patients with acute pain received acupuncture and had a post-treatment score.
    - 49% (88/182) of patients received pain medications before AQ
      - 6.88 on the pain pre-score and a change of -2.68 units (SD 2.23).
    - 51% (94/182) received no pain medications before AQ
      - 6.71 on the pain pre-score and a change of -2.37 units (SD 2.23).
    - As a -2.0 unit decrease in pain on NRS is considered clinically significant, patients in both groups exceeded this threshold.
- Any effect on pain medication?
  - Yes: 62% were discharged from ED without any additional pain meds.
  - 25% received an opioid and 13% received a non-opioid (NSAID)

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Source: Reinstein AS, Erickson LO, Finch MD, Rivard RL, Kapsner CE, Dusek JA. Acceptability and Clinical Outcomes of Acupuncture provided in the Emergency Department: A Retrospective Pilot Study. Pain Med. 2017; 18(1): 169-178.

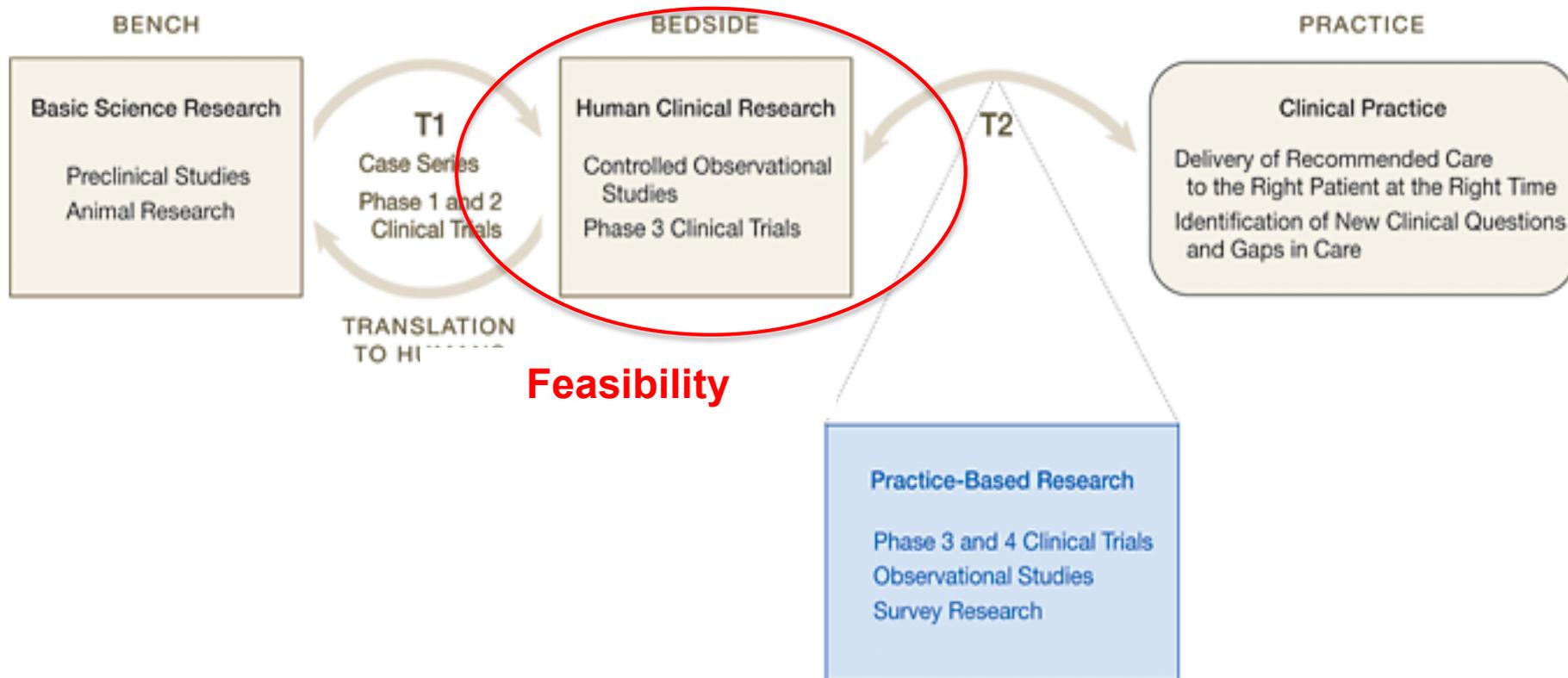
# Acupuncture in ED: Concerns

- There was no control group nor any randomization;
- The acupuncturist was involved in data collection; and
- Patients were referred to acupuncture by their physicians.
- To overcome these limitations, we conducted a pilot RCT

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Source: Reinstein AS, Erickson LO, Finch MD, Rivard RL, Kapsner CE, Dusek JA. Acceptability and Clinical Outcomes of Acupuncture provided in the Emergency Department: A Retrospective Pilot Study. *Pain Med.* 2017; 18(1): 169-178.

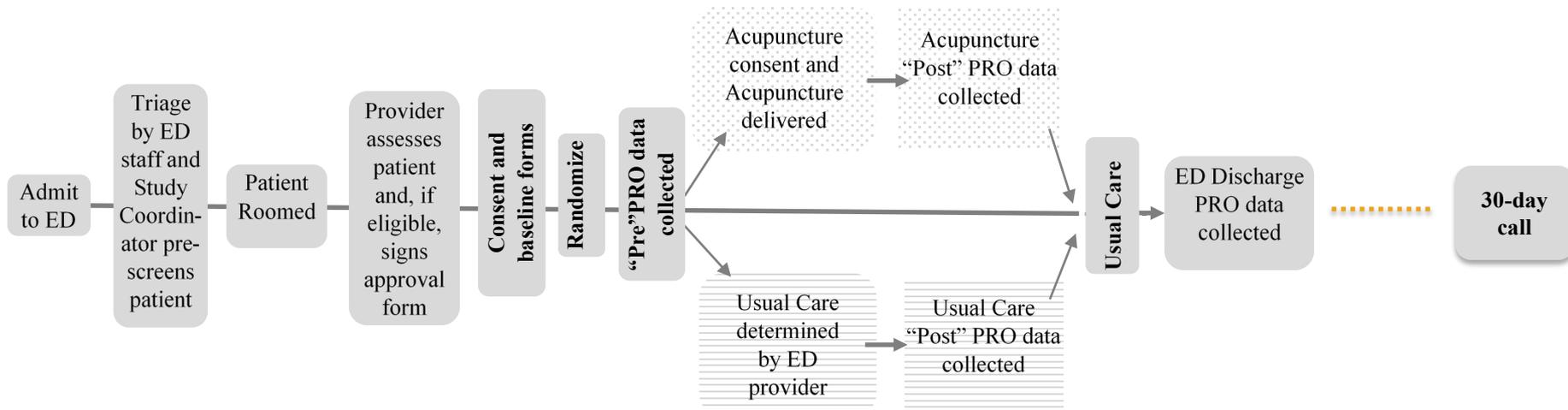
# Practice-Based Research



Westfall, J. M. et al. JAMA 2007;297:403-406.

**JAMA**

# Acupuncture in ED Pilot RCT: Flow



# Acupuncture in ED Pilot RCT: Outcomes

- Would patients (pain  $\geq 4$ ) enroll?
  - Yes: 78% of patients enrolled. (46/59)
- Subjects were randomized to either AQ (n=23) or Usual Care (n=23)
  - The average age was 36.3 (15.5 SD), 78% were female and 55.0% were non-white.
  - Acupuncture:
    - pre-pain: **8.18** (SD 1.62)
    - diff at post-pain: **-3.0** (SD 2.51)
    - diff at ED discharge: **-2.71** (SD 1.86)
    - diff at 30-day: **-5.28** (SD 3.0)
  - Usual Care:
    - pre-pain: **7.91** (SD 1.41)
    - diff at post-pain: **-1.56** (SD 2.37)
    - diff at ED discharge: **-2.53** (SD 2.27)
    - diff at 30-day: **-3.41** (SD 4.0).

Source: Presented at International Congress on Integrative Medicine & Health, Baltimore MD (May 2018). Article in preparation.



Pain Medicine 2015; 16: 1195-1203  
Wiley Periodicals, Inc.

THE JOURNAL OF ALTERNATIVE AND COMPLEMENTARY MEDICINE  
Volume 00, Number 00, 2018, pp. 1-7  
© Mary Ann Liebert, Inc.  
DOI: 10.1089/acm.2017.0203

# JACM

## Acupuncture Provides Short-Term Pain Relief for Patients in a Total Joint Replacement Program

Pain Medicine Advance Access published February 25, 2016

Pain Medicine 2016; 0: 1-10  
doi: 10.1093/pm/pnv114

### Original Research Article

## Acceptability, Adaptation, and Clinical Outcomes of Acupuncture Provided in the Emergency Department: A Retrospective Pilot Study

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Kristen H. Griffin, MA, MPH,<sup>†</sup>  
Jill R. Johnson, PhD, MPH,<sup>†</sup> Cynthia Miller, RN, LAc,  
Michael D. Finch, PhD,<sup>§</sup> Rachael L. Rivard, BS,<sup>†</sup>  
Scott Anseth, MD,<sup>||</sup> and Jeffery A. Dusek, PhD<sup>†</sup>

Adam S. Reinstein, MAOM, L.Ac.,\* Lauren O. Erickson, MS,\* Kristen H. Griffin, MA, MPH,\* Rachael L. Rivard, BS,\* Christopher E. Kapsner, MD,<sup>†</sup> Michael D. Finch, PhD,<sup>§</sup> and Jeffery A. Dusek, PhD\*

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Funding sources: This work was partially supported by the National Center for Complementary & Alternative Medicine of the National Institutes of Health (grant number R01 AT006518-01 to JD). The work was also supported by the Abbott Northwestern Hospital Foundation, the Rob and Kris Johnson Family Foundation and the Penny George Institute Foundation.

Conflicts of interest: The authors declare no conflicts

Design. Observational, retrospective pilot study.

Setting. Abbott Northwestern Hospital ED, Minneapolis, MN.

Methods. Retrospective data was used to identify patients receiving acupuncture in addition to standard medical care in the ED between 11/1/13 and 12/31/14. Feasibility was measured by quantifying the utilization of acupuncture in a novel setting and performing limited tests of its efficacy. Patient-reported pain and anxiety scores were collected by the acupuncturist using an 11-point (0-10) numeric rating scale before (pre) and immediately after (post) acupuncture. Efficacy outcomes were change in pain and anxiety scores.

Results. During the study period, 436 patients were referred for acupuncture, 279 of whom were approached by the acupuncturist during their ED visit. Consent for acupuncture was obtained from 89% (248/279). A total of 182 patients, who had a pre-pain score >0 and non-missing anxiety scores, were included in analyses. Of the 52% (94/182) who did not have analgesics before or during the acupuncture session, the average decrease of 2.37 points (95% CI: 1.92, 2.83) was not different ( $p > 0.05$ ) than the mean decrease of 2.68 points for those receiving analgesics (95% CI 2.21, 3.15). The average pre-anx-

ORIGINAL ARTICLE

## Cost Savings from Reducing Pain Through the Delivery of Integrative Medicine Program to Hospitalized Patients

Jeffery A. Dusek, PhD<sup>1</sup>, Kristen H. Griffin, MA, MPH<sup>1</sup>, Michael D. Finch, PhD<sup>2</sup>,  
Rachael L. Rivard, MPH<sup>1</sup>, and David Watson, PhD<sup>2</sup>

ARTICLE

## Assessing the Impact of Acupuncture on Pain, Nausea, Anxiety, and Coping in Women Undergoing a Mastectomy

Jessica Quinlan-Woodward, RN, BSN, Autumn Gode, MS, APRN, CNS,  
Jeffery A. Dusek, PhD, Adam S. Reinstein, LAc, MAOM, Jill R. Johnson, PhD, MPH,  
and Sue Sendelbach, PhD, APRN, CNS, FAHA, FAAN

# Conclusions

- **IM therapies: Current State**
  - Reduce short-term pain among various inpatients.
  - Longer-term pain relief is exhibited across clinical populations.
  - Reduce hospital costs for pain inpatients responding to IM.
  - Are well liked by providers and patients (Emergency department) with potential impact on pain intensity.
  
- **Future studies are warranted and could explore:**
  - Multi-site, feasibility of AQ in the ED is next step.
  - Definitive study of AQ in ED is final goal.
  - Multi-site studies of inpatient IM is needed!
  - Potential synergy of opioid analgesics and IM therapy.
  - Longer-term effects of IM on pain and anxiety.
  - Optimal cost effectiveness delivery of IM therapy for inpatients and ED.
  - Biological mechanisms of action.

# Collaborators and Funding Source

- Jon Christianson PhD, Economist
  - Michael Finch PhD, Methodologist
  - Rachel Rivard, Biostatistician
  - Alison Kolste, Study Coordinator
  - Kristen Griffin MA, MPH, Scientific Advisor
  - Adam Reinstein MaOM, LAc Acupuncturist
  
  - Pamela Jo Johnson PhD, Co-Investigator
  - Jill Johnson PhD, Epidemiologist
  - Desiree Trebesch MA, Study Coordinator
  - Kelly McBride LAc, Acupuncturist
  - Dan Crespin, Methodologist
  - Robert Jones, Senior Research Assistant
  - Caitlin Dreier, Research Assistant
  - Stephanie Wallerius, Research Assistant
  - Nichole Janssen, Research Assistant
  - Sirri Ngwa, Research Assistant
- The project was partially supported by grant R01 AT006518 from the National Center for Complementary and Integrative Health (NCCIH) to JD.

## Poll Question #2

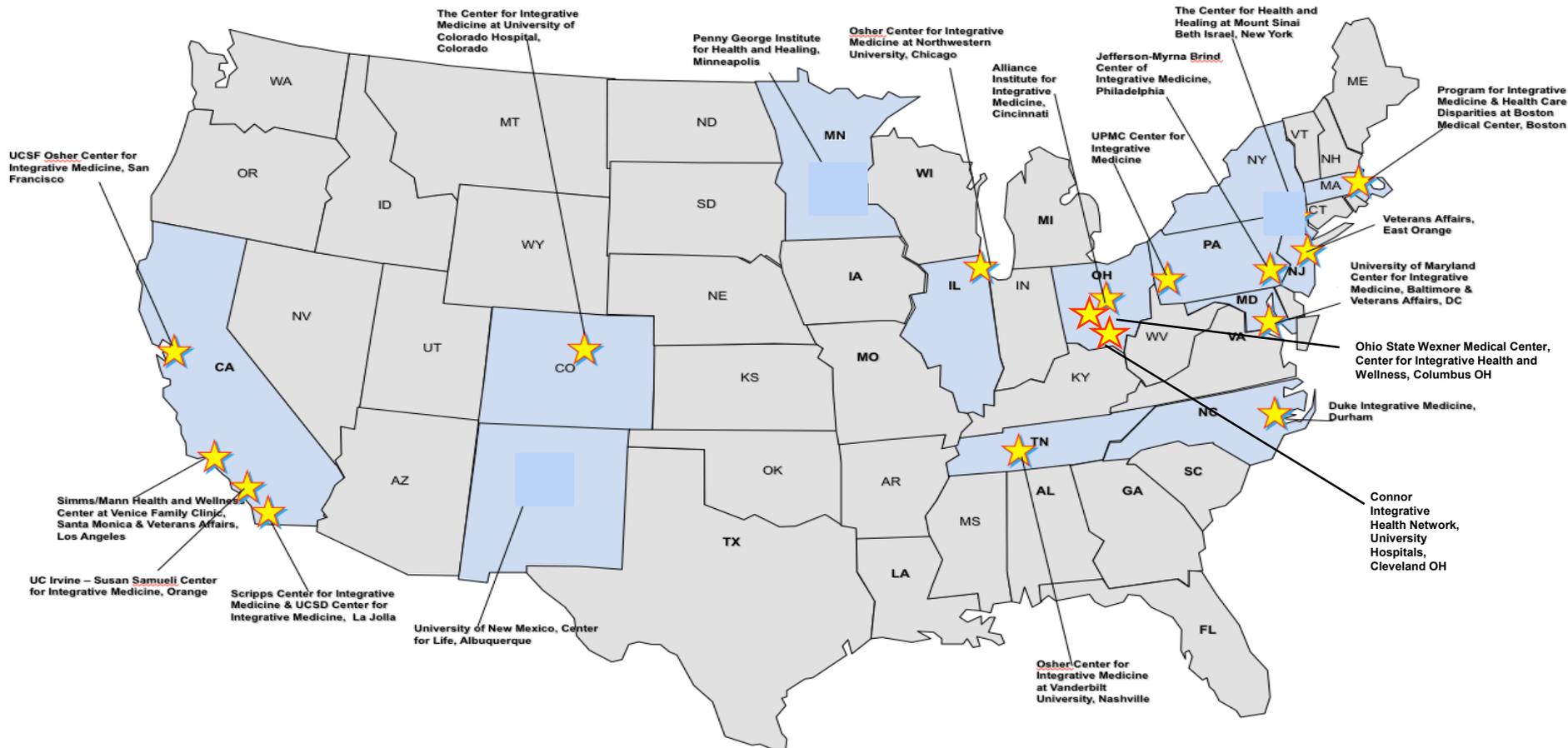
- Which best describes your research experience?
  - have not done research
  - have collaborated on research
  - have conducted research myself
  - have applied for research funding
  - have led a funded research grant

# Questions and Answers

# About BraveNet

- BraveNet is the only national practice-based research network of IM
- Currently comprised of 15 leading Integrative Medicine clinics plus VAMC (2 sites: EO and GLA)
- Founded in 2007
- Expanded in two waves of enrollment from 8 initial member sites
- Expansion focus:
  - Ethnic, racial, and economic diversity
  - Actively funded researchers
  - Geographic range

# BraveNet Member Clinics



# BraveNet Publications

## ORIGINAL RESEARCH

### PATIENTS SEEK INTEGRATIVE MEDICINE FOR PREVENTIVE APPROACH TO OPTIMIZE HEALTH

Ruth Q. Wolever, PhD,<sup>1,\*</sup> Donald I. Abrams, MD,<sup>2</sup> Benjamin Kligler, MD,<sup>3</sup> Jeffery A. Dusek, PhD,<sup>4</sup> Rhonda Roberts, MSPH,<sup>5</sup> Joyce Frye, DO, MBA, MSCE,<sup>6</sup> Joel S. Edman, DSc,<sup>7</sup> Steve Amoils, MD,<sup>8</sup> Elizabeth Pradhan, PhD,<sup>6</sup> Myles Spar, MD, MPH,<sup>9,10</sup> Tracy Gaudet, MD,<sup>1</sup> Erminia Guarneri, MD,<sup>11</sup> Peter Homel, PhD,<sup>3</sup> Sandra Amoils, MD,<sup>8</sup> Roberta A. Lee, MD,<sup>3</sup> Brian Berman, MD,<sup>6</sup> Daniel A. Monti, MD,<sup>7</sup> and Rowena Dolor, MD, MHS<sup>5</sup>

## ORIGINAL RESEARCH

### INTEGRATIVE MEDICINE PATIENTS HAVE HIGH STRESS, PAIN, AND PSYCHOLOGICAL SYMPTOMS

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## Brief Report

### Characteristics of Cancer Patients Presenting to an Integrative Medicine Practice-Based Research Network

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Integrative Cancer Therapies  
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DOI: 10.1177/1534735414537876  
ict.sagepub.com  


Abrams et al. *BMC Complementary and Alternative Medicine* 2013, 13:146  
<http://www.biomedcentral.com/1472-6882/13/146>

 **BMC**  
Complementary & Alternative Medicine

## RESEARCH ARTICLE

## Open Access

### The BraveNet prospective observational study on integrative medicine treatment approaches for pain

Donald I. Abrams<sup>1\*</sup>, Rowena Dolor<sup>2</sup>, Rhonda Roberts<sup>3</sup>, Constance Pechura<sup>3</sup>, Jeffery Dusek<sup>4</sup>, Sandi Amoils<sup>5</sup>, Steven Amoils<sup>3</sup>, Kevin Barrows<sup>1</sup>, Joel S. Edman<sup>6</sup>, Joyce Frye<sup>7</sup>, Erminia Guarneri<sup>8</sup>, Ben Kligler<sup>9</sup>, Daniel Monti<sup>6</sup>, Myles Spar<sup>10</sup> and Ruth Q. Wolever<sup>11</sup>

## Patients Receiving Integrative Medicine Interventions Effectiveness Registry

NCT 01754038

# Study Protocol published

Dusek et al. *BMC Complementary and Alternative Medicine* (2016) 16:53  
DOI 10.1186/s12906-016-1025-0

BMC Complementary and  
Alternative Medicine

STUDY PROTOCOL

Open Access



## Patients Receiving Integrative Medicine Effectiveness Registry (PRIMIER) of the BraveNet practice-based research network: study protocol

Jeffery A. Dusek<sup>1\*</sup>, Donald I. Abrams<sup>2</sup>, Rhonda Roberts<sup>3</sup>, Kristen H. Griffin<sup>1</sup>, Desiree Trebesch<sup>1</sup>, Rowena J. Dolor<sup>3</sup>,  
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# PRIMIER Overview

- Prospective, non-randomized, observational evaluation conducted at all BraveNet clinical sites.
- Participants complete patient-reported outcome measures at enrollment, 2, 4, 6, 12 months.
- Extractions from participants' health records include
  - IM services received
  - ICD diagnostic codes
  - CPT codes

# PRIMIER OBJECTIVES

- PRIMARY To evaluate the change in patient-reported outcomes (PROs: quality of life, mood and stress) over time
- SECONDARY To evaluate PROs differ by baseline characteristics (e.g. demographics, clinical condition, pain interference or IM intervention sought)
- TERTIARY To evaluate whether specific IM interventions differentially impact PROs over time.

# PRIMIER DATA COLLECTION: Self-reported

- Enrollment Date
- Patient Demographics
- PROMIS-29
- PROMIS Perceived Stress Scale (PSS-4)
- Patient Activation Measure © (PAM)
- Primary Conditions and Symptoms
- IM Services Utilized
- New patient status

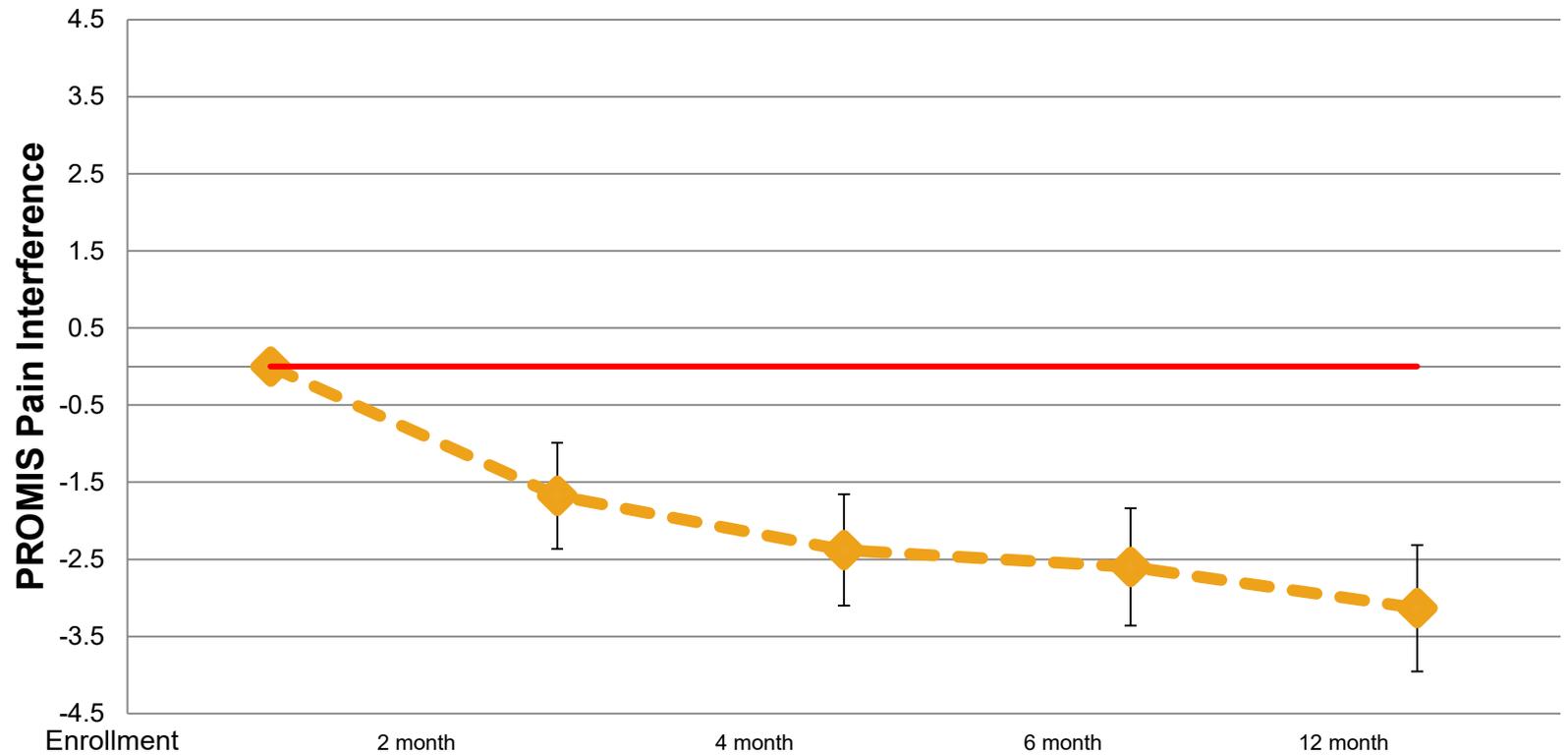
<b><u>Pain Interference</u></b>						
<b>In the past 7 days...</b>		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
PAININ9	How much did pain interfere with your day to day activities? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ22	How much did pain interfere with work around the home? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ31	How much did pain interfere with your ability to participate in social activities? .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
PAININ34	How much did pain interfere with your household chores? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

# Chronic Pain Cohort: Enrollment

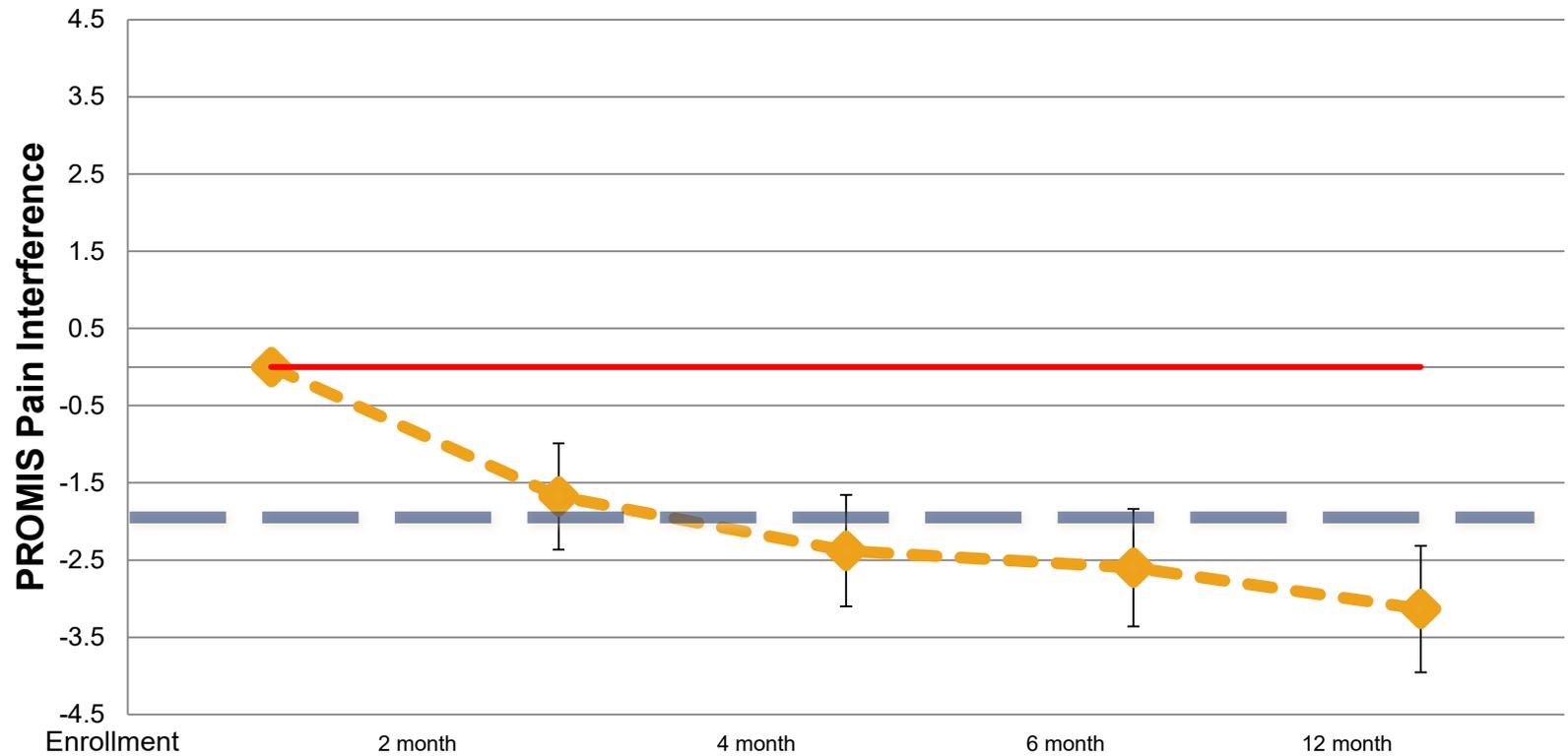
- Report pain (4 or greater on a scale of 0 to 10) for 3 months or longer (n=969)
- Participants with at least 2 surveys completed
- Participants with complete EMR data

Cohort	Baseline	2 Months	4 Months	6 Months	12 Months
Chronic Pain	969	693	559	490	421

# Pain Interference: Change Over Time



# Pain Interference: Change Over Time



# Conclusions

- PRIMIER Chronic pain cohort achieved important reductions in pain interference.
- Future PRIMIER analyses will identify:
  - Which IM therapies are associated with the best pain relief (e.g. acupuncture).
  - Optimal dose of IM therapies for pain reduction

# Summary: Practice-Based Research

- Practice based research provides invaluable information for the field of complementary and integrative health
  - Research, clinical practice and operations.
- Answers derived from this research can be used in various ways
  - Inform future randomized trials
  - Uncover best clinical practice
  - Optimize operations