Effectiveness of Integrative Medicine Interventions Provided to Patients on Pain Outcomes: via Practice Based Research

> Jeffery Dusek, PhD Director of Research, Connor Integrative Health Network February 8, 2019



Pain Burden in the United States

- Pain affects an estimated 100 million adults in the United States.¹
- Annual cost related to pain in the US is estimated to be between \$560 to \$635 billion.^{1,2}
- 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.¹
- In 2012, there were 50 times more opioid prescriptions than the rest of the world combined,³ reflecting a persistent national epidemic associated with 130 deaths daily.⁴

Sources:

⁴⁻ hhs.gov. Help, resources and information: national opioids crisis; the opioid epidemic in numbers. 2018; https://www.hhs.gov/opioids/ Accessed January 6, 2019



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.



BEDSIDE

Human Clinical Research

Controlled Observational Studies Phase 3 Clinical Trials

PRACTICE

Clinical Practice

Delivery of Recommended Care to the Right Patient at the Right Time Identification of New Clinical Questions and Gaps in Care



BENCH

Basic Science Research

Preclinical Studies Animal Research

BEDSIDE

Human Clinical Research

Controlled Observational Studies Phase 3 Clinical Trials



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PRACTICE

Clinical Practice

Delivery of Recommended Care to the Right Patient at the Right Time Identification of New Clinical Questions and Gaps in Care



Practice-Based Research



Practice-Based Research



Cleveland | Ohio

Practice-Based Research



- Research that occurs in the office, clinic or hospital, where patients generally receive clinical care.
- Method to study the interventions as they are routinely delivered clinically.

Advantages?

- Examine whether interventions with proven <u>efficacy</u> are truly <u>effective</u> and sustainable when provided in real-world setting
- Captures data on representative patients who are receiving representative treatments
- Possible to assess utility of an intervention provided by clinicians with a broad range of training and expertise
- Possible to obtain clinically detailed, patient-level data



Disadvantages?

- Limited ability to infer causality given the lack of randomization
- Data collection may be performed by clinicians who may lack specialized research training
- Electronic health record is a clinical tool and not designed for research purposes

- Integrative Medicine provided at Abbott Northwestern Hospital (ANW)
 - Acute pain

- BraveNet Practice Based Research Network (PBRN)
 - Chronic Pain



Effectiveness of Integrative Medicine

Integrative Medicine (IM) provided at Abbott Northwestern Hospital

- 630 bed tertiary care hospital
- Penny George Institute (PGI) started providing IM services in 2003
 - > ~10,000 IM sessions annually (circa 2016)
 - > IM services are provided at no cost to patient
 - > Average 31 minutes per session
 - > 1.5 sessions per patient per hospital admission



IM Care and Practitioners (circa 2016)

- Patients receive individualized IM care including:
 - Acupuncture, acupressure
 - therapeutic medical massage, reflexology
 - mind/body therapies (e.g. relaxation response)
 - energy healing (e.g. Reiki, healing touch)
 - music therapy
 - > aromatherapy
- 15 practitioners (11.5 FTEs)
 - ➢ 6.3 FTE massage therapists
 - > 3.5 FTE acupuncturists
 - > 0.9 FTE music therapist
 - > 0.8 FTE Nursing

Penny George Institute: IM Process

- Physician or nurse referrals via EPIC electronic health record (EHR)
 > Acupuncture must be referred by MD
- Triage Meeting of IM providers
- EHR review by IM provider
- IM Treatment Session (conducted within 24-36 hrs)
 - Intake
 - Baseline data collection (e.g., pain, anxiety, nausea, coping)
 - IM therapy provided
 - Follow-up data collection
- IM provider documents the baseline and follow-up results in EHR



EPIC- specialized flowsheet

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Impact of IM on Pain Management

- Participants: 1837 patients hospitalized between January 1, 2008 and June 30, 2009.
- Measurements: Pretreatment and post-treatment pain scores on a verbal numeric rating scale (0 to 10).
- Results: Most patients (66%) had not previously received any integrative services.
- The average reduction in pain was 1.9 points and the average percentage in pain reduction was 55%.
- No differences across clinical populations (due to small sample size).

Source: Dusek JA, Finch M, Plotnikoff GA, Knutson L. The Impact of Integrative Medicine on Pain Management in a Tertiary Care Hospital. J Pat Safety 2010; 6(1):48-51.

Unanswered Questions...

- Is the 1.9 unit decrease reproducible ?
- Which patients receive IM?
- Does pain relief differ by IM therapy?
- Does pain relief differ by clinical population?
- Might specific therapies effect greater pain relief in certain clinical populations?
- Is IM cost effective in pain population?
- What is the duration of pain relief?
- Does concurrent use of opioids influence pain relief in the IM patients?



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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: Awardee Organization: DUSEK, JEFFERY A 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. 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) guantitatively 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.



- Aim 1: Understand selection of patients and IM therapies (n=~6,000 admissions)
- Aim 2: Examine the effects of therapies on <u>immediate change in</u> pain (n=~6,000 admissions)
- Aim 3: Examine the effects on <u>duration of pain management</u> (n=~3,575 admissions)



Update on Status of NIH R01

- Initial database: 7/09 to 12/12
 - Electronic Health Record (EHR) flowsheet developed
 - > Focus on certain clinical populations.
 - Total joint replacement, oncology, and cardiology.
 - ➤Cost analysis

Acupuncture in the Emergency Dept.
 Observational proof of concept
 Pilot RCT

- Study data collection: 7/12 to 12/14
 - Databases undergoing additional analyses.
 - Presentations & manuscripts: 2018 & 2019.

Joint Replacement: Pain Analysis

Pre- to post-IM therapy percent decrease in pain scores

Any Treatment	No.	1,977
	Unit Decrease in Pain	-1.91 (-45.2%)
	95% CI	(1.83-1.99)
	p-value	<0.001

Joint Replacement: Pain Analysis

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Any Treatment	No.	1,977
	Unit Decrease in Pain	-1.91 (-45.2%)
	95% CI	(1.83-1.99)
	p-value	<0.001
Day 1	No.	1,259
	Unit Decrease in Pain	-1.79 (-38.8%)
	95% CI	(1.69 – 1.89)
	p-value	<0.001
Day 2	No.	718
	Unit Decrease in Pain	- 2.14 (59.9%)
	95% CI	(2.01 – 2.26)
	p-value	<0.001

Source: Crespin DJ, Griffin KH, Johnson JR, Miller C, Finch MD, Rivard RL, Anseth S, Dusek JA. Acupuncture Provides Short-Term Pain

Relief for Patients in a Total Joint Replacement Program. Pain Med. 2015 Jun;16(6):1195-203.

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Oncology: Pain and Anxiety Analysis

Pre- to post-IM therapy change in pain and anxiety scores

No. Pain Observations	1,514	
% Change in Pain	-46.9	
p-value	<0.001	
No. Anxiety Observations	1,074	
% Change in Anxiety	-56.1	
p-value	<0.001	

Source: Johnson JR, Crespin DJ, Haven KM, Finch MF, Dusek JA. Effects of Integrative Medicine on Pain and Anxiety Among Oncology Inpatients. J Natl Cancer Inst Monogr. 2014 Nov;2014(50):330-7.



Cardiovascular: Pain and Anxiety Analysis

Pre- to post-IM therapy percent decrease in pain and anxiety scores

No. Pain Obs		5,981
	% Decrease in Pain	-46.5
	95% CI	(45.5 - 47.4)
	p-value	<0.001
No. Anxiety Obs		3,109
	% Decrease in Anxiety	-54.8
	95% CI	(53.7 – 55.9)
	p-value	<0.001

Source: Johnson JR, Crespin DJ, Griffin KH, Finch MD, Rivard RL, Baechler CJ, Dusek JA. The effectiveness of integrative medicine interventions on pain and anxiety in cardiovascular inpatients: a practice-based research evaluation. BMC Complement Altern Med. 2014 Dec 13;14:486.



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 2730 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 <u>cost</u> 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.

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 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 posttreatment 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 use?
 - > Yes: 62% were discharged from ED w/o any additional pain meds.
 - 25% received an opioid and 13% received a NSAID

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Publications

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

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

Daniel J. Crespin, MSPH,* Kristen H. Griffin, MA, MPH,[†] Jill R. Johnson, PhD, MPH,[†] Cynthia Miller, RN, LAc,[‡] Michael D. Finch, PhD,[§] Rachael L. Rivard, BS,[†] Scott Anseth, MD,[†] and Jeffery A. Dusek, PhD[†]

DOI:10.1093/jncimonographs/Igu030

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BMC Complementary & Alternative Medicine

Open Access

RESEARCH ARTICLE

The effectiveness of integrative medicine interventions on pain and anxiety in cardiovascular inpatients: a practice-based research evaluation

Jill R Johnson¹, Daniel J Crespin², Kristen H Griffin¹, Michael D Finch³, Rachael L Rivard¹, Courtney J Baechler¹ and Jeffery A Dusek¹

Abstract

Background: Pain and anxiety occurring from cardiovascular disease are associated with long-term health risks. Integrative medicine (M) therapies reduce pain and anxiety in small samples of hospitalized cardiovascular patie within andomized controlled trials; however, practice-based effectiveness research has been limited. The goal of the study is to evaluate the effectiveness of IM interventions (i.e., bodywork, mind-body and energy therapies and traditional Chrines medicine) on pain and anxiety measures across as cardiovascular population.

Methods: Retrospective data obtained from medical records identified patients with a cardiovascular ICD-9 cod admitted to a large Midwestern hospital between 7/1/2009 and 12/31/2012. Outcomes were changes in patient-reported pain and anxiety, strete before and after IM treatments based on a numeric scale (0-10).

Results: Of 57295 hospital cardiovascular admissions, 6589 (11.5%) included IM. After receiving IM therapy patients averaged a 465% (evalue <0.001) decrease in pain and a 54,8% (evalue <0.001) decrease in naru. There was no difference between treatment modalities on pain reduction; however, mind-body and energ therapies (p-value < 0.01), traditional Chinese medicine (p-value < 0.01, and combination therapies (p-value < 0.01), were more effective at reducing anxiety than bodywork therapies. Each additional year of age reduced the od of neceving any IM therapy by two percent (DR 0.98 p-value < 0.01) and females had 96% (OR 1.96, p-value < 0.01) higher odds of neceving any IM therapy compared to males.

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



ORIGINAL ARTICLE

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

Pain Medicine Advance Access published February

Pain Medicine 2016; 0: 1–10 dol: 10.1093/pm/pnv114 Jeffery A. Dusek, PhD¹, Kristen H. Griffin, MA, MPH¹, Michael D. Finch, PhD², Rachael L. Rivard, MPH¹, and David Watson, PhD²

Effects of Integrative Medicine on Pain and Anxiety Among Oncology Inpatients

Jill R. Johnson, Daniel J. Crespin, Kristen H. Griffin, Michael D. Finch, Jeffery A. Dusek

Correspondence to: Jill R. Johnson, PhD, MPH, Penny George Institute for Health and Healing, 800 East 28th Street, MR 33540, Minneapolis, MN 55407-3799 (email: Jill Johnson3 # allina.com)

- Background Few studies have investigated the effectiveness of integrative medicine (IM) therapies on pain and anxiety among oncology inpatients.
- Methods Retrospective data obtained from electronic medical records identified patients with an oncology international Classification of Disease-9 code who were admitted to a larger Midwateren hospital between July 1, 2009 and December 31, 2012. Outcomes were dhange in patient-reported pain and anxiety, rated before and after individual Mit metament sessions, using a numeric scale (0–10).
- Of 10.948 hospital admissions over the study period, 1031 (17%) included IM therapy. Older patients had reduced odds of receiving any IM therapy (odds ratio (0.5); 0.93, 95%; confidence interval (95%; CI = 0.3 0€) 0.968; and females had 63%; (OR: 103, 95%; CI = 1.381 to 1.921) higher odds of receiving any IM therapy compared with males. Moderate (OR: 10.7, 95%; CI = 1.381 to 1.221) major odds of receiving any IM therapy compared with males. Moderate (OR: 10.7, 95%; CI = 1.381 to 1.221), major (OR: 3.64, 95%; CI = 2.881 to 4.355), and extreme (OR: 5.96, 95%; CI = 4.71 to 7.56) illness twerity were significantly associated with higher odds of receiving IM therapy, patients averaged a 46.9%; (95%; CI = 4.61%; to 6.80%; *P*_<.0011 reduction in pain and a 6.61%; 69%; CI = 6.10%; to 68.0%; *P*_<.0011 reduction in an and a 56.1%; 69%; CI = 6.21%; to 68.0%; *P*_<.0011 reduction in an and a 56.1%; 69%; CI = 6.21%; to 68.0%; *P*_<.0011 reduction in an axiely, Biodynovik and traditional Chinese Medicine therapies were observed.</td>
- Cenclusiens IIM services to oncology inpatients resulted in substantial decreases in pain and anxiety. Observational studies using electronic medical records provide unique information about real-word utilization of IM. Future studies are warranted and should explore potential synergy of opioid analgesics and IM therapy for pain control.

J Natl Cancer Inst Monogr 2014;50:330-337

Pain is a common, often debilitating symptom of cancer and a The evidence base for integrative oncology among inpatients

Original Research Article Acceptability, Adap

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

Adam S. Reinstein, MAOM, L.Ac.,* Lauren O. Erickson, MS,* Kristen H. Griffin, MA, MPH,* Rachael L. Rivard, BS,* Christopher E. Kapsner, MD,^{*}Michael D. Finch, PhD,[‡] and Jeffery A. Dusek, PhD*

*Integrative Health Research Center, Penny George Institute for Health and Healing, Allina Health, Minneapolis, Minnesota: ¹Emergency Department, Abbott Northwestern Hospital, Minneapolis, Minnesota: ¹Medical Industry Leadership Institute, Carlson School of Management, University of Minnesota, Minneapolis, Minnesota, USA

Correspondence to: Adam S. Reinstein, MAOM, L.Ac., Perny George Institute for Health and Healing, 800 East 28th Street, MR 30540, Minneapolis, MN 55407-3799, USA. Tel: (612) 863-8404; Fax: (612) 863-9769; E-mail: adam.reinstein@allina.com.

■ Funding sources: This work was partially supported by the National Center for Complementary & Alternative Bodicine of the National Institutes of Health (grant number R01 47006518-01 to JD). The work was also supported by the Abbott Northwestern Hospital Foundation, the Rob and Kris Johnson Family Foundation and the Orning 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 acuupuncture 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-retrospective in the setting and 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 accupatchure, 279 of whom were approached by the acupancturist during their ED visit. Consent for acupancture was obtained from 89% (248279). 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 acupancture session, the average decrease of 2.37 points (95% CI: 1.02, 2.83) was not different (p > 0.05) than the mean decrease of 2.68 points for those receiving analgesics (95% CI 2.13, 315). The average pre-anx-

University Hospitals Accountable Care Organization

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

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 Pilot RCT: Flow





Acupuncture in ED Pilot RCT: Outcomes

Would patients (pain >=4) enroll?

- Yes: 78% of patients enrolled. (46/59)
- <u>Subjects were randomized to either AQ (n=23) or Usual Care (n=23)</u>
 - 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) post-pain: -3.0 (SD 2.51) ED discharge: -2.71 (SD 1.86) 30-day: -5.28 (SD 3.0)

Usual Care:

pre-pain: 7.91 (SD 1.41) post-pain: -1.56 (SD 2.37) ED discharge: -2.53 (SD 2.27) 30-day: -3.41 (SD 4.0).

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



Update on Status of NIH R01

- Initial database: 7/09 to 12/12
 - Electronic Health Record (EHR) flowsheet developed
 - ➢ Focus on certain clinical populations.
 - Total joint replacement, oncology, and cardiology.
 - ➤Cost analysis

▶ Proof of concept: acupuncture in the Emergency Dept.

- Study data collection: 7/12 to 12/14
 - Databases undergoing additional analyses.
 - Presentations & manuscripts: 2018 & 2019.



- Aim 1: Understand selection of patients and IM therapies
- Aim 2: Examine the effects of therapies on <u>immediate change in</u> <u>pain</u>
- Aim 3: Examine the effects on <u>duration of pain management</u>



• Collect six post-IM therapy pain scores:

- 30 minutes
- 1, 2, 3, 4 and 5 hours





Specialized database

A Therapy Interview Tracker

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Specialized database

A Therapy Interview Tracker

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Specialized database

A Therapy Interview Tracker

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





• IM therapies

- Reduce short-term pain and anxiety 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.
 - 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.



Practice Based Research: Integrative Medicine

- Integrative Medicine provided at Abbott Northwestern Hospital (ANW)
 - Acute pain

- BraveNet Practice Based Research Network (PBRN)
 - Chronic Pain



About BraveNet

- BraveNet is the only national practice-based research network of IM
- Currently comprised of 15 leading Integrative Medicine clinics plus VAMC (3 sites)
- 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



pain

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

Ruth Q. Wolever, PhD1* Nikita S. Goel, MS2 Rhonda S. Roberts, MSPH3 Karen Caldwell, PhD4 Benjamin Kligler, MD⁵ Jeffery A. Dusek, PhD⁶ Adam Perlman, MD⁷ Rowena Dolor, MD⁸ and Donald I. Abrams, MD9

Donald I Abrams^{1*}, Rowena Dolor², Rhonda Roberts², Constance Pechura³, Jefferv Dusek⁴, Sandi Amoils⁵, Steven Amoils⁵, Kevin Barrows¹, Joel S Edman⁶, Joyce Frye⁷, Erminia Guarneri⁸, Ben Kligler⁹, Daniel Monti⁶, Myles Spar¹⁰ and Ruth Q Wolever¹¹



Patients Receiving Integrative Medicine Interventions Effectiveness Registry

NCT 01754038



Cleveland | Ohio

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^{1*}, Donald I. Abrams², Rhonda Roberts³, Kristen H. Griffin¹, Desiree Trebesch¹, Rowena J. Dolor³, Ruth Q. Wolever^{4,5}, M. Diane McKee⁶ and Benjamin Kligler⁷



- 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



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



Final PRIMIER Participants Recruited by Site





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

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





- 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.
 - 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



Practice-based Research



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


2016 NIH, NCCIH Systematic Review

SYMPOSIUM ON PAIN MEDICINE



CrossMark

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

> > Mavo Clin Proc. 2016:91(9):1292-1306



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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]



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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

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. 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.

Questions and Answers

