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Authors

Rodgers-Melnick, Samuel Srinivasan, Roshini Rivard, Rachael et al.

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Samuel N. Rodgers-Melnick, MPH, MT-BC^{1,2}, Roshini Srinivasan, RYT^{1,3}, Rachael L. Rivard, MPH^{1,4}, Francoise Adan, MD, ABIHM^{1,5}, and Jeffery A. Dusek, PhD^{6,7}

Abstract

Background: Patients seeking integrative health and medicine (IHM) modalities often present with multiple physical and psychological concerns. Research supports IHM's effectiveness for addressing symptoms over longer time periods. However, few studies have evaluated immediate outpatient effects.

Objective: This study describes pre-encounter patient-reported outcome (PRO) clusters and examines the immediate clinical effectiveness of IHM modalities on pain, stress, and anxiety among outpatients with moderate-to-severe symptoms.

Methods: A retrospective review was conducted of encounters among adults presenting to outpatient acupuncture, chiropractic, massage, integrative medicine consultation, or osteopathic manipulation treatment between January 2019 and July 2020. Encounters were included if patients reported pre-encounter pain, stress, or anxiety ≥4 on a numeric rating scale (NRS). Outcome analyses included random effects for patient and provider using a mixed model.

Results: Across 7335 clinical encounters among 2530 unique patients (mean age: 49.14 years; 81.0% female; 75.9% White; 15.8% Black/African American), the most common pre-encounter PRO clusters were pain, stress, and anxiety \geq 4 (32.4%); pain \geq 4 only (31.3%); and stress and anxiety \geq 4 (15.6%). Clinically meaningful single-encounter mean [95% CI] changes were observed across all modalities in pain (-2.50 [-2.83, -2.17]), stress (-3.22 [-3.62, -2.82]), and anxiety (-3.05 [-3.37, -2.73]). **Conclusion:** Patients presenting to outpatient IHM with moderate-to-severe symptoms most often presented with pain, stress, and anxiety \geq 4 on the NRS. Multiple IHM modalities yielded clinically meaningful (\geq 2 unit) immediate reductions in these symptoms. Future research measuring immediate and longitudinal effectiveness is needed to optimize the triage and coordination of IHM modalities to meet patients' needs.

Keywords

integrative medicine, electronic health record, pain, stress, anxiety

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Corresponding Author:

Samuel N. Rodgers-Melnick, MPH, MT-BC, University Hospitals Connor Whole Health 11100 Euclid Avenue, Wearn 548A Cleveland, OH 44106, USA. Email: Samuel.RodgersMelnick@UHhospitals.org



¹Connor Whole Health, University Hospitals of Cleveland, Cleveland, OH, USA

²Department of Population and Quantitative Health Sciences, Case Western Reserve University School of Medicine, Cleveland, OH, USA

³Duke University School of Medicine, Durham, NC, USA

⁴Center for Evaluation and Survey Research, HealthPartners Institute, Minneapolis, MN, USA

⁵Department of Psychiatry, Case Western Reserve University School of Medicine, Cleveland, OH, USA

⁶Department of Medicine, University of California – Irvine, Irvine, CA, USA

⁷Susan Samueli Integrative Health Institute, University of California – Irvine, Irvine, CA, USA

Introduction

Integrative health and medicine (IHM) involves the coordinated combination of conventional medicine (e.g., medication, physical rehabilitation, and surgery) and evidence-based modalities such as acupuncture, massage, and chiropractic care to address the needs of the whole person (body, mind, and spirit). Within IHM, practitioners personalize strategies to patients' unique conditions, needs, and circumstances to best help them regain and maintain optimal health. 3

Patients seeking IHM modalities often present with multiple physical and psychological concerns such as chronic pain. According to the 2019 and 2020 National Health Interview Surveys (NHIS), 20.8% of adults in the United States (US) report chronic pain (i.e., pain on most days or every day during the prior three months).4 In a large cross-sectional study, chronic pain (33.1%), acute pain (9.7%), stress (9.3%), and anxiety (7.7%) were among the top ten most common medical conditions addressed among 4182 patients receiving care at nine IHM clinics within the BraveNet Practice-Based Research Network (PBRN). Patients in this study reported higher levels of perceived stress, pain, and depressive symptoms, and lower levels of health-related quality of life (HRQoL) compared to national norms. Similarly, in a survey of 27,225 patients presenting to their initial IHM encounter, the most common reasons for seeking IHM services included spine/truncal pain (70.5%), extremity pain (8.8%), neurologic conditions (6.8%), other pain (5.4%), and generalized muscle pain (4.0%). Therefore, pain-related complaints appear to be prevalent among patients seeking IHM modalities.

Prior studies have shown that patients seeking care from IHM providers (1) perceive IHM to be safe and effective for addressing their needs; 8-11 (2) do so in response to dissatisfaction with conventional medical providers; 9,10,12 and (3) desire an approach to care that emphasizes the therapeutic relationship and control over their health. Patients within the nine BraveNet PBRN sites reported a desire to "improve health and wellness now to prevent future problems" as their top reason for seeking IHM care (83.9%). However, to demonstrate the immediate impact of IHM modalities on patients' health and wellness, patient-reported outcomes (PROs) must be embedded within clinical practice. 13,14

Multiple studies and systematic reviews support the effectiveness of outpatient IHM modalities for addressing domains including pain^{15,16} and HRQoL¹⁷ over longer periods of time (e.g., 1 month to 1 year). However, relatively fewer studies have evaluated immediate effects of IHM modalities on acute measures of pain, stress, and anxiety, with the majority of studies coming from the inpatient clinical setting. ^{13,18-22} For example, hospitalized adults receiving various IHM modalities (e.g., acupuncture, massage therapy, music therapy, and/or holistic nursing) provided during 2730 hospital admissions reported an average pain reduction of 2.05 units, which was associated with a cost savings of \$898 per admission. ²³ Prior studies of short-term effects of

outpatient IHM have also been limited to investigating single modalities (e.g., acupuncture, ²⁴ yoga, ²⁵ or massage) ²⁶ and reporting symptom presentations individually rather than describing overlapping symptomology (i.e., moderate-to-severe pain, stress, and anxiety vs pain alone).

Understanding immediate post-encounter effects of outpatient IHM modalities on pain, stress, and anxiety is critically important for coordinating optimal delivery of care. While immediate mean changes do not necessarily speak to the overall impact of these modalities on important domains such as pain interference, stress, mood, and HRQoL over the long-term (days and weeks), they are important for several practical and clinical reasons. First, inviting patients to reflect upon their symptoms immediately post-encounter may facilitate important conversations with IHM providers about the comparative impact of specific interventions (e.g., electroacupuncture vs traditional acupuncture or acupressure vs fascial release) and help patients internalize an awareness of the immediate benefits of IHM. 13 Second, reducing patients' immediate symptoms by a meaningful degree following an encounter may increase patient motivation to continue IHM treatment in pursuit of improved health and well-being.5 Finally, understanding single-encounter effects may help providers and patients determine which IHM modalities may best address long-term health goals. Accordingly, the purpose of this study was to (1) describe pre-encounter PRO clusters and (2) examine immediate changes in pain, stress, and anxiety among patients with moderate-to-severe symptoms receiving care at four outpatient IHM clinics.

Material and Methods

Participants and Design

This study is a retrospective review of all encounters among adult patients (ages 18 and older) receiving care at one of four outpatient IHM clinics between January 1, 2019 and July 31, 2020 that met the following criteria: (1) the encounter was for acupuncture, chiropractic, massage, integrative medicine consultation (IMC), or osteopathic manipulation treatment (OMT) and (2) the patient reported at least one pre-encounter PRO ≥4 on a numeric rating scale (NRS) (i.e., moderate-to-severe pain, anxiety, and/or stress)²⁷ with an accompanying post-encounter NRS rating. IHM encounters not meeting these criteria were excluded from the sample.

Setting

University Hospitals (UH) is a non-profit health system in Northeast Ohio serving the needs of more than 1.2 million unique patients annually. UH Connor Whole Health (UHCWH), a team of practitioners embedded within the UH health system, provides approximately 29,000 outpatient IHM treatments among 6000 patients per year. Referrals are not required to receive services, though some patients present

to UHCWH following a referral from another UH provider. At the time of this study (January 2019 to July 2020), acupuncture, chiropractic, IMC, and OMT modalities were eligible for third party reimbursement depending on the nature of the patient's condition and health insurance. Massage therapy services were self-pay. During the study period, UHCWH employed six acupuncturists, 10 massage therapists, four chiropractors, four integrative medicine physicians or physician assistants, and one physician providing OMT within its four outpatient clinics.

Ethics and Permissions

This study was approved by the UH Cleveland Medical Center Institutional Review Board (STUDY20200308) as a retrospective chart review with a waiver of informed consent. This study was conducted in accordance with the Declaration of Helsinki.

Data Collected

Patients presenting to UHCWH between January 2019 and July 2020 were asked to complete an NRS measuring pain, anxiety, and stress immediately before and after their encounters. The NRS is a validated measure for acute pain intensity. It has been widely used within studies of IHM modalities and found to be more reliable than the visual analog scale in clinical trials, especially among patients of low socioeconomic status. Investigators in previous IHM studies have also used the 0-10 NRS to measure anxiety 18,20,21,29 and stress. 19,30

Following appointment check-in, patient service representatives at the front desk presented patients with a preencounter questionnaire. This questionnaire consisted of the statement, "On a scale of 0 to 10 (0 being no pain/stress/ anxiety at all and 10 being the worst pain/stress/anxiety imaginable) how would you rate your pain/stress/anxiety RIGHT NOW? Please circle only one number in each row," and three rows of the integers 0 through 10 with headings and anchors for PAIN (No Pain, Worst Pain), ANXIETY (No Anxiety, Worst Anxiety) and STRESS (No Stress, Worst Stress). Providers were encouraged to review pre-encounter NRS scores prior to initiating treatment. Identical postencounter questionnaires were completed by patients immediately after their IHM encounters and subsequently collected by clinical staff at the conclusion of the encounter. Providers then entered the pre- and post-encounter NRS scores into the electronic health record (EHR). This mode of data collection had previously been investigated by the authors in the context of longitudinal changes in PROs and was implemented here to assess acute changes.¹³

We extracted the following data from all records meeting eligibility criteria: (1) demographic information including age, sex, race, and ethnicity; (2) clinical characteristics including International Classification of Diseases (ICD)-

10 codes for all diagnoses and chief complaints listed in providers' notes; and (3) IHM documentation data including modality (i.e., acupuncture, chiropractic, massage, IMC, or OMT) and PROs (i.e., NRS scores of pain, anxiety, and stress) collected pre- and post-encounter. ICD-10 codes were only available for patients who had at least one encounter with an acupuncturist, chiropractor, physician, or advanced practice provider. ICD-10 data were not available for patients presenting only to massage therapy as massage therapists were unable to document formal diagnoses within their scope of practice. All data, including full note documentation, were extracted via a single structured query language script from the UH Electronic Data Warehouse. Regular expressions functions including str extract all from the stringr package³¹ and regmatches, gregepr, sub, and gsub from base R version 4.3.0 were used to extract clinical information from the freetext note.

Data Analysis

To summarize patients' primary diagnoses, ICD-10 codes were categorized into Major Expanded Diagnosis Clusters (MEDC). Descriptive statistics were calculated for patient demographics, clinical characteristics, and pre-encounter PROs. To examine immediate changes in PROs overall and by modality, we adjusted for multiple sessions on the same patient using a mixed model, including a random effect for patient and another random effect for IHM provider. This approach allowed for summarized mean NRS scores, 95% confidence intervals (CI), and rates of clinically significant changes to control for the effect of multiple encounters from a proportion of high-utilizing patients^{32,33} as well as any provider-specific effects. Conducting formal tests comparing NRS changes between IHM modalities was beyond the scope of this study and inappropriate given the high variability in patient presentation and intervention delivery.

Prior studies of IHM modalities have defined NRS reductions ≥2 units as clinically significant. ^{19,24,34} Thus, we reported adjusted counts and percentages of NRS reductions ≥2 units in defining clinical significance in the current study. We extracted data from clinical narratives, analyzed descriptive statistics, and generated plots using R Version 4.3.0 and RStudio Version 2023.06.0 + 421. ³⁵ The mixed model was generated using SAS software, Version 9.4 of the SAS System for Windows (Cary, NC).

Results

Sample

Between January 2019 and July 2020, there were 7335 encounters among 2530 patients reporting at least one pre-encounter PRO ≥4 with an accompanying postencounter PRO. These 7530 included encounters for

acupuncture (37.5%), massage (36.4%), chiropractic (16.2%), IMC (9.1%), and OMT (.7%). At the provider level within this sample of 7335 encounters, a median (IQR) of 287 (103.5 - 513.5) treatments were provided per provider. A median of 129 (54.5 - 189) patients were seen per provider.

Demographics, Chief Complaints, and Utilization

Table 1 summarizes demographics, chief complaints, and utilization characteristics. Patients (mean age: 49.14 ± 15.22 at first encounter) were mostly White (75.9%) or Black/ African American (15.8%), non-Hispanic (87.0%), and female (81.0%). More than half of patients reported a chief complaint of pain (60.6%) at some point during the study, with specific pain complaints located in the back (33.9%), neck (25.5%), and shoulder (25.5%). Other common chief complaints included tension (19.7%), stress (19.3%), anxiety (16.2%), and headache/migraine (10.2%). Median [IQR] encounter engagement among patients was 1 [1 – 3] encounters, with patients fitting eligibility criteria engaging in a range of 1 to 42 encounters. Almost half of the sample engaged in massage (45.8%) followed by acupuncture (34.3%), chiropractic (17.4%), IMC (15.1%), and OMT (1.8%).

Clinical Characteristics

Supplemental Table 1 summarizes the MEDCs among 1577 (62.3%) patients who attended at least one IHM encounter that was not massage. Common MEDCs included musculoskeletal (79.1%), general signs and symptoms (52.8%), neurologic (48.0%), psychosocial/mental health (27.7%), and administrative (e.g., lab abnormalities, preventive care) (25.5%).

Pre-encounter Patient-Reported Outcomes

Supplemental Table 2 summarizes mean and 95% CI for PRO scores adjusted for multiple encounters per patient overall and by modality. Across all 7335 encounters in which patients reported at least one pre-encounter PRO \geq 4 and a complete post-encounter PRO, 5434 (74.1%) were among patients who reported pre-encounter pain \geq 4 (mean [95% CI] = 5.65 [5.54, 5.77]); 4694 (64.0%) were among patients who reported pre-encounter stress \geq 4 (5.89 [5.80, 5.97]); and 3805 (51.9%) were among patients who reported pre-encounter anxiety \geq 4 (5.71 [5.61, 5.82]). Figure 1 presents a Venn diagram of the intersections between unadjusted rates of pre-encounter pain, stress, and anxiety \geq 4. Among 7335 encounters, the most common pre-encounter PRO clusters were pain, stress, and anxiety \geq 4 (32.4%); pain \geq 4 only (31.3%); and stress and anxiety \geq 4 (15.6%).

Immediate Effects of IHM

Supplemental Table 2 and Figures 2-4 summarize the immediate effects of IHM modalities after adjusting for

Table 1. Demographics, Chief Complaints, and Utilization.

Variable	N = 2530
Patient age (years), mean ± SD	49.14 ± 15.22
Patient age (years), median [range]	49.00 [18.00, 95.00]
Sex, n (%)	
Female	2049 (81.0%)
Male	481 (19.0%)
Race, n (%) ^a	
White	1921 (75.9%)
Black/African American	399 (15.8%)
Declined, missing, or unknown	145 (5.7%)
Other race/Multi-racial	37 (1.5%)
Asian	24 (.9%)
American Indian	4 (.2%)
Ethnicity, n (%)	
Non-Hispanic	2202 (87.0%)
Declined, missing, or unknown	262 (10.4%)
Hispanic or Latino	66 (2.6%)
Pain complaint, n (%)	1534 (60.6%)
Back pain complaint, n (%)	858 (33.9%)
Neck pain complaint, n (%)	645 (25.5%)
Shoulder pain complaint, n (%)	645 (25.5%)
Tension complaint, n (%)	498 (19.7%)
Stress complaint, n (%)	488 (19.3%)
Anxiety complaint, n (%)	411 (16.2%)
Headache/migraine complaint, n (%)	259 (10.2%)
Total treatments, median [IQR]	I [I, 3]
Total treatments, range	I – 42
Received massage, n (%)	1158 (45.8%)
Received acupuncture, n (%)	869 (34.3%)
Received chiropractic, n (%)	440 (17.4%)
Received IMC, n (%)	382 (15.1%)
Received OMT, n (%)	45 (1.8%)

^aRace, including multi-racial, is reported exactly as it was entered into the EHR: Abbreviations: EHR, electronic health record; IMC, integrative medicine consult; IQR, interquartile range; OMT, osteopathic manipulation treatment; SD, standard deviation.

multiple encounters per patient. When combining all encounters with moderate-to-severe pre-encounter PRO patients reported clinically (i.e., ≥ 2 unit) mean [95% CI] reductions in pain (-2.50 [-2.83, -2.17), stress (-3.22 [-3.62, -2.82]), and anxiety (-3.05 [-3.37, -2.73]). The largest mean immediate changes in PROs were observed among massage encounters, with patients reporting reductions in pain (-3.07 [-3.24, -2.89]), stress (-4.02 [-4.21, -3.83]), and anxiety (-3.64 [-3.85, -3.42]). In contrast, the smallest mean immediate changes in PROs were observed among IMC encounters, with patients reporting smaller reductions in pain (-.52 [(-.90, -.13]), stress (-1.35 [-...])1.78, -.92), and anxiety (-1.35 [(-1.82, -.88])).

In examining rates of PRO reductions (estimate [95% CI]) across all encounters, 69.5% [68.1%, 71.0%] reported pain reduction \geq 2 units, 82.6% [81.4%, 83.9%] reported stress reduction \geq 2 units, and 80.7% [79.2%,

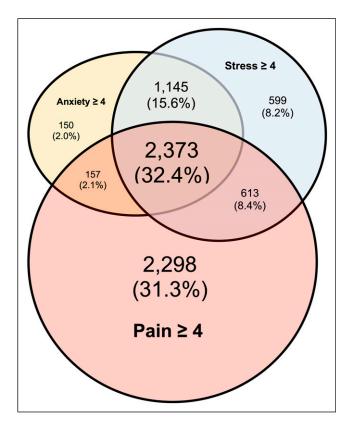


Figure 1. Patient-Reported Outcome Clusters Venn diagram representing the count and percentage of encounters falling into moderate-to-severe PRO thresholds for pre-encounter pain, stress, and anxiety.

82.2%] reported anxiety reduction ≥2 units. Like the mean changes, the highest rates of PRO change at each threshold were observed among massage encounters while the lowest rates were observed among IMC encounters.

Discussion

The purpose of this study was to (1) describe preencounter PRO clusters and (2) examine the immediate clinical effectiveness of IHM modalities on acute measures of pain, stress, and anxiety among patients with moderate-to-severe symptoms receiving IHM. Among 7335 encounters for acupuncture, massage, chiropractic, IMC, or OMT in which patients reported at least one preencounter PRO ≥4 on the NRS, nearly one-third (32.4%) presented with co-occurring pain, stress, and anxiety ≥ 4 . This finding is consistent with the prior BraveNet PBRN study where pain, stress, and anxiety were among the top ten most common medical conditions addressed.⁵ From a neurobiological perspective, the co-occurrence of stress and anxiety with chronic pain may be a result of dysfunction within the functional and structural connectivity of the neural circuits that govern sensory, emotional, and cognitive functions.³⁶ Scioli-Salter and colleagues³⁷ proposed that high rates of co-occurring chronic pain and conditions such as post-traumatic stress disorder (PTSD) may be explained by shared pathophysiological mechanisms such as (1) stress-stimulated increases in peripheral and central nervous system levels of neuropeptide Y and GABAergic neuroactive steroids and (2) dysregulation of the opioid, endocannabinoid, and immune systems in chronic pain and PTSD.

Most clinical encounters (74.1%) within this sample were among patients reporting moderate-to-severe pre-encounter pain ≥4. This finding is consistent with a prior cross-sectional study in which pain conditions were the most common reasons for seeking IHM services. Furthermore, prior analyses of National Health Interview Survey data have demonstrated increased odds (adjusted odds ratio [95% CI]) of using IHM among (1) adults with limiting low back pain as compared to non-limiting low back pain $(1.1 [1.0 - 1.2]);^{38}$ (2) adults with severe migraine and recurring headache as compared to recurring headache alone (3.36 [2.08, 5.43]);³⁹ and (3) adults with arthritis and joint pain as compared to no joint pain (2.08 [1.46, 2.96]). 40 Given the prevalence of acute pain among individuals engaging in IHM and its association with increased odds of engagement in IHM, it is critically important for IHM centers to collect PROs related to pain at baseline and over time to assess effectiveness.

PROs are of vital importance in healthcare delivery, and their use is now becoming mandated by The Centers for Medicare & Medicaid Services within oncology⁴¹ and joint arthroplasty.⁴² PROs demonstrate whether symptoms and/or HRQoL are improving (or not) in response to treatment; ^{13,14} facilitate shared care and decision making with the healthcare system; ⁴³ and can improve rates of patient satisfaction. ⁴³ Collecting PROs is also essential within practice-based research for evaluating the effectiveness of IHM modalities across healthcare systems. ^{13,28,30,44}

In the context of this study, collecting acute NRS measures of pain, stress, and anxiety may have helped providers tailor the delivery of IHM modalities to a given patient's immediate needs. As NRS measures were integrated within routine care, providers reviewed the pre-encounter measures and used them to inform their overall assessment of patients' symptoms and guide their clinical decisions. For example, chiropractors within the clinic used the pain NRS in conjunction with the Oswestry Disability Index to help determine patients' pain disability at the initial visit and track changes in pain outcomes over time.

Patients within this study reported clinically meaningful reductions in pain, stress, and anxiety that are comparable to or exceed reductions observed in prior studies of inpatient IHM. However, direct comparisons to prior studies are challenging given differences in IHM modalities, timing of PRO collection, number of PROs collected, and preintervention PRO thresholds applied (e.g., none, ≥ 1 , or ≥ 4). Nevertheless, the overall observed mean reductions in

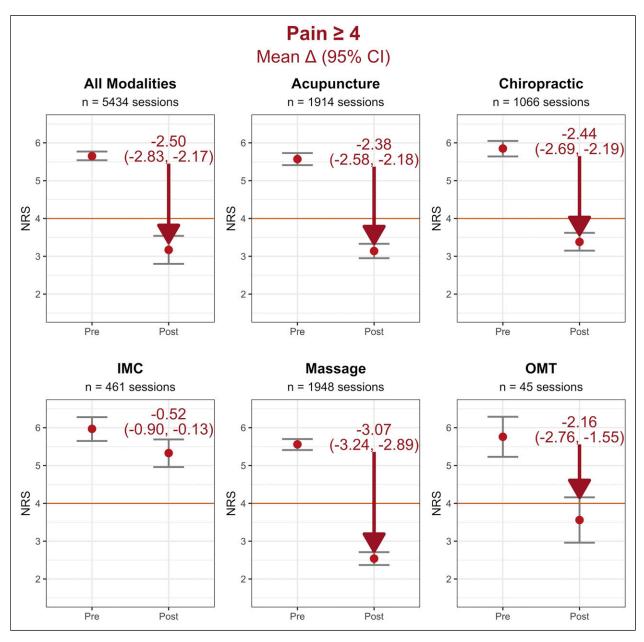


Figure 2. Immediate Changes in Pain Intensity Overall and By Modality Red dots represent means, while error bars represent 95% confidence intervals after adjusting for the random effects of patient and provider. The downward arrow represents the magnitude of the immediate change in PRO scores from pre-to post-encounter. The orange line at 4 represents the threshold for at least moderate pain rated 4/10 on the numeric rating scale. Abbreviations: Δ , change; IMC, integrative medicine consultation; NRS, numeric rating scale; OMT, osteopathic manipulation treatment.

pain (2.50 units), stress (3.22 units), and anxiety (3.05 units) were similar to findings from a recent study of inpatient music therapy within community hospitals in which patients reporting pre-session PROs ≥4 on the NRS also reported clinically meaningful single-session reductions in pain (2.04 units), stress (3.48 units), and anxiety (2.80 units). Mean pain reduction observed within this sample was also similar to prior observational studies of inpatient IHM among patients reporting any pain ≥1 including studies of various IHM modalities (i.e., acupuncture, massage, holistic nursing,

and music therapy) among 2730 hospitalized adults (2.05 units),²³ post-surgical acupuncture among 1977 adults undergoing hip or knee replacement surgery (1.91 units),²² and combination aromatherapy among 2444 hospitalized adults (3.43 units).²¹

When comparing findings from this study to other outpatient studies of IHM among adults with acute and/or chronic pain, patients' reported mean reductions in pain with chiropractic (2.44 units) were slightly lower than reductions at 1 month in response to chiropractic care observed

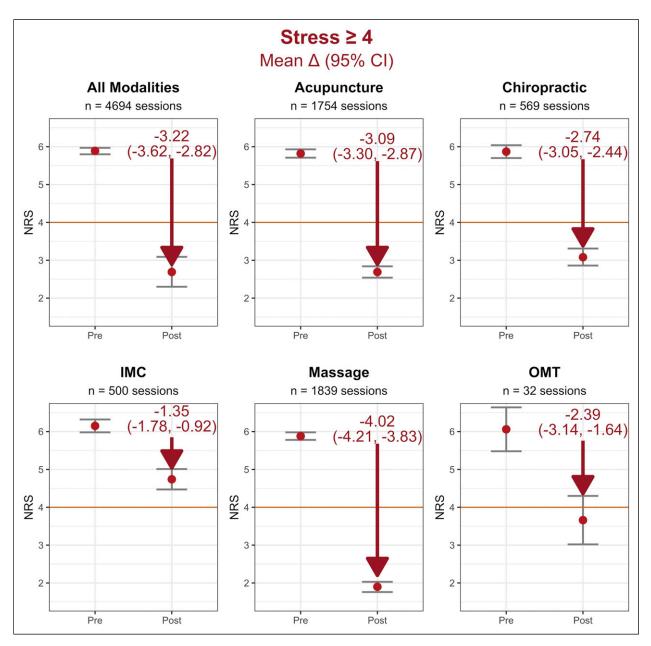


Figure 3. Immediate Changes in Stress Overall and By Modality Red dots represent means, while error bars represent 95% confidence intervals after adjusting for the random effects of patient and provider. The downward arrow represents the magnitude of the immediate change in PRO scores from pre-to post-encounter. The orange line at 4 represents the threshold for at least moderate stress rated 4/10 on the numeric rating scale. Abbreviations: Δ , change; IMC, integrative medicine consultation; NRS, numeric rating scale; OMT, osteopathic manipulation treatment.

among 79 patients with acute low back pain (2.98 units)⁴⁶ and higher than reductions at 1 month among 44 patients with chronic low back pain (1.31 units).⁴⁷ Patients' reported immediate reductions in pain with acupuncture (2.38 units) were similar to reductions at 24 hours among 117 active duty military, dependents, and retirees with acute and chronic pain receiving acupuncture (2.5 units).⁴⁸

Finally, in comparing our results to those from observational studies of IHM among adults with cancer receiving acupuncture, we observed greater mean reductions in pain (2.38 units) and anxiety (2.87 units) than those reported by Miller and colleagues²⁴ (N=68, mean pain reduction 1.90 units, mean anxiety reduction .90 units) and Thompson and colleagues⁴⁹ (N=87 for pain, mean pain reduction: 1.39 units, N=85 for anxiety, mean anxiety reduction: 1.26 units). We also observed massage encounters resulting in greater mean reductions in pain (3.07 units) and anxiety (3.64 units) than those reported by Lopez and colleagues²⁶ (N=168, mean pain reduction: 1.55 units, mean anxiety reduction: 1.34 units). However, it is important to note that

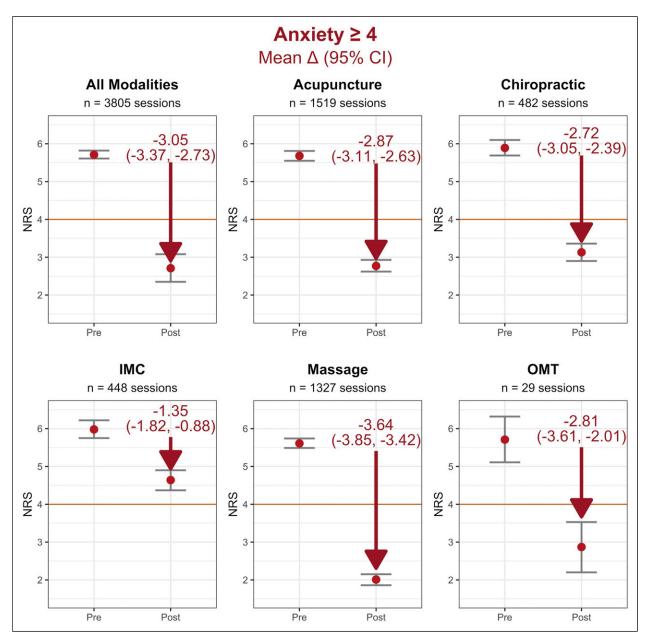


Figure 4. Immediate Changes in Anxiety Overall and By Modality Red dots represent means, while error bars represent 95% confidence intervals after adjusting for the random effects of patient and provider. The downward arrow represents the magnitude of the immediate change in PRO scores from pre-to post-encounter. The orange line at 4 represents the threshold for at least moderate anxiety rated 4/10 on the numeric rating scale. Abbreviations: Δ , change; IMC, integrative medicine consultation; NRS, numeric rating scale; OMT, osteopathic manipulation treatment.

these studies within oncology did not apply a pre-encounter PRO threshold of ≥4 and thus included patients who did not have moderate-to-severe symptoms as was the case in the current study.

Although the current study did not formally compare singleencounter PRO changes between IHM modalities using statistical tests, numerical differences were apparent – particularly the higher reductions observed within massage encounters relative to the lower reductions observed within IMC encounters. Massage therapy may be unique in yielding large immediate reductions in pain, stress, and anxiety given the characteristics of the intervention (e.g., continuous hands-on massage techniques provided over 30 to 60 minutes). In contrast, IMC encounters include physical exams, verbal assessments in which patients discuss their health concerns, clinical referrals to IMH modalities, and discussions of ways to implement therapeutic changes in between appointments over the longer term (rather than during the IMC encounter). Thus, even if stress and anxiety ratings were to decrease during this therapeutic encounter, pain would not be expected to decrease by the same degree observed with hands-on

interventional approaches such as massage. Furthermore, research has shown that the effects of some IHM modalities (e.g., acupuncture and chiropractic) on acute symptoms may become more apparent at 24–72 hours. ⁵⁰ However, to better understand response patterns in the real-world of ambulatory clinics, future longitudinal research with more frequent data collection is needed to compare the effects of various IHM modalities on acute symptoms at various time points (e.g., post-encounter, 24 hours, 1 week, and 1 month).

This study had some notable limitations. First, we did not assess PROs longitudinally across or between IHM encounters, and thus our analysis focused on immediate changes. Second, this study used observational data within a single IHM center without a control or comparison group. To better understand the real-world effectiveness of IHM as compared to conventional care, future observational studies should consider comparing patients who received IHM to propensity-score matched controls who did not receive IHM over the course of treatment. Third, there is a potential for response bias among patients reporting post-encounter PROs as patients may have wanted to please the providers by reporting improved scores. This risk was somewhat mitigated as patients completed their post-encounter evaluations on paper and had the option of dropping off their evaluations to the patient service representatives at the clinic's front desk. Furthermore, the observed symptom reductions within IMC encounters being numerically lower than those observed in response to interventional modalities (e.g., massage and acupuncture) provide some assurance that patients were reporting their symptoms accurately and honestly. Future studies could consider collecting PROs through a mobile device or having research assistants blinded to patients' participation in IHM collect PROs to reduce this risk of bias.⁵¹

Fourth, though NRS measures were presented to patients as part of routine clinical care rather than as part of a formal research study, there is the potential for the Hawthorne effect within this study whereby patients' perception of being observed and measured may have modified their NRS responses. Fifth, this study primary consisted of middle-aged individuals (mean 49.14 years) identifying as female (81.0%) and white (75.9%). This demographic profile does not reflect that of the county where the study took place (30.5% Black/African American), 52 and may not reflect the population of individuals with moderate-to-severe symptoms engaging in IHM modalities nationally.

Finally, this study used single item 0-10 NRS scores rather than more comprehensive instruments for pain, stress, and anxiety. However, more robust measures such as the Patient Reported Outcome Measurement Information System (PROMIS) are often more suited toward capturing outcomes over a period of several days or weeks than capturing outcomes immediately pre- and post-encounter like the NRS. Strengths of this study include the large sample size, diversity of clinical populations, use of real-world EHR data, and the

collection of PROs immediately before and after IHM encounters.

Conclusions

Patients presenting to an outpatient IHM center with moderate-to-severe symptoms most often presented with pain, stress, and anxiety ≥ 4 on the NRS (32.4%) followed by pain ≥ 4 alone (31.2%). The results from this study support the clinically meaningful impact that IHM modalities can have on moderate-to-severe symptoms within a single encounter and add to a growing body of evidence supporting the real-world clinical effectiveness of IHM for pain 15,16 and HRQoL. 17 Multiple IHM modalities yielded clinically meaningful reductions (i.e., ≥ 2 units) in these symptoms within a single encounter. Future research is needed to (1) assess changes in these acute measures and more global HRQoL measures over time, (2) compare outcomes between IHM and a matched comparison group, and (3) utilize PRO data to best triage and dose IHM modalities to optimize care. Future researchers should be encouraged to measure immediate and longitudinal effectiveness as a means of optimizing the triage and coordination of IHM modalities to meet patients' immediate and long-term needs.

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Declaration of Conflicting Interests

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ORCID iDs

Samuel N. Rodgers-Melnick https://orcid.org/0000-0003-0886-253X

Jeffery A. Dusek https://orcid.org/0000-0001-9581-0564

Data Availability Statement

The datasets generated and/or analyzed during the current study are not publicly available due to privacy restrictions as the databases contain information that could compromise the privacy of research participants. However, the de-identified datasets are available from the corresponding author on reasonable request.

Supplemental Material

Supplemental material for this article is available online.

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