# Use of Heat and Cold Therapy is Associated with Decreased Pain Treatment Utilization and Opioid Consumption: A Retrospective Quasi-Experimental Study

*This study found that patients who received heat-cold therapy, relative to those who did not, had greater reductions in specialty pain care utilization and risky opioid use, pointing to benefits of heat-cold therapies to health care systems as a result of reductions in costly care utilization and higher-risk opioid prescribing.*


Travis I. Lovejoy, PhD, MPH [1,2,3,4]
David C. Cameron, MPH [1,3]
Robert L. Handley, PhD [3]
Crystal Lederhos Smith, PhD [5]
Sterling M. McPherson, PhD [5]

[1] Department of Psychiatry, Oregon Health & Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97239, USA

[2] School of Public Health, Oregon Health & Science University, 3181 SW Sam Jackson Park Rd, Portland, OR 97239, USA

[3] Center to Improve Veteran Involvement in Care, VA Portland Health Care System, 3710 SW U.S. Veterans Hospital Rd, Portland, OR 97239, USA

[4] VA Office of Rural Health Veterans Rural Health Resource Center, VA Portland Health Care System, 3710 SW U.S. Veterans Hospital Rd, Portland, OR 97239, USA

[5] Elson S. Floyd College of Medicine, Washington State University, 412 E. Spokane Falls Blvd, Spokane WA 99202, USA

Correspondence:
Travis I. Lovejoy
VA Portland Health Care System, 3710 SW U.S. Veterans Hospital Rd, Mail Code: R&D 66, Portland, OR 97239, USA
Tel : 1-503-220-8262 x57744
Email : travis.lovejoy@va.gov



Number of Tables: 2
Number of Figures: 3
Number of References: 42



## ABSTRACT

**Background:** Body-surface heat and cold therapies are non-pharmacologic pain treatments purported to have pain-reducing benefits but have received limited attention for chronic pain syndromes in the scientific literature. The purpose of this study was to examine the potential clinical and health systems benefits of heat and cold therapy.

**Methods:** Patients were 2,182 patients receiving medical care through the United States Veterans Health Administration who received a heat-cold therapy device and 2,182 propensity score-matched control patients. Clinical encounters, pain pharmacy data, and pain self-ratings were extracted from the electronic health record in the year prior to and following receipt of a device or the equivalent dates for matched control patients. Mixed effects regression and random effects growth modeling compared changes in pain treatment utilization and pain intensity, respectively, between heat-cold therapy treatment patients and matched controls.

**Results:** In the year following device receipt, treatment patients, relative to matched control patients, had greater reductions in days of high-dose opioid therapy use and co-use of opioids and benzodiazepines. In addition, treatment patients had fewer encounters with pain specialty care, including physical therapy, occupational therapy, physical medicine and rehabilitation, and interdisciplinary pain clinics. Treatment patients and matched controls did not experience differential changes in pain intensity, which on average remained relatively constant.

**Conclusions:** While associations identified in this observational study cannot establish causal conclusions, there seem to be benefits of heat and cold therapy use to the health system as a result of decreased utilization of costly specialty pain care and risky opioid use.



**Key Words:** chronic pain, cold therapy, heat therapy, quasi-experimental, veterans

## Introduction

Growing recognition of the limitations of long-term opioid therapy for chronic non-cancer pain (Krebs et al., 2018) has highlighted the importance of non-pharmacologic approaches in pain treatment regimens (Becker et al., 2018). These treatments are varied and may include psychological and behavioral therapies (e.g., Cognitive Behavioral Therapy for Chronic Pain), exercise and movement therapies (e.g., yoga), and manual therapies (e.g., chiropractic), to name a few. Body-surface cold therapy, while predominantly used to reduce post-operative pain and inflammation (Adkas et al., 2021; Fernandes et al., 2019; Ozkan & Cavdar, 2021; Quinlan et al., 2017) and pain related to muscle soreness (Wang et al., 2021), is a non-pharmacologic treatment that has shown pain-reducing benefits for chronic low back pain and knee osteoarthritis, as has its counterpart superficial heat therapy (Ariana et al., 2022; French et al., 2006; Tao & Bernacki, 2005). Heat therapy has also been shown to improve strength, flexibility and activities of daily living in patients with chronic low back pain (Freiwald et al., 2018; Friewald et al., 2021).

Heat and cold therapies benefit resource-limited health care systems, as most devices require a relatively low one-time cost and can be self-administered by patients within the home as part of their pain self-management plan. In addition, these pain self-management tools may, for some patients, obviate the need for more expensive specialty pain care and ongoing analgesic pharmacotherapy. Despite their potential, few studies have characterized the benefits of heat and cold therapy for patients with heterogenous chronic pain syndromes.

The purpose of this retrospective quasi-experimental cohort study was to examine the potential clinical and health systems benefits of patient-administered heat and cold therapy. Our primary hypothesis was that patients with chronic musculoskeletal pain who received heat and cold therapy would evidence decreased use of opioid therapy compared to a sample of matched control patients who did not receive heat and cold therapy. Secondarily, we hypothesized that patients who received heat and cold therapy, relative to matched controls, would also have lower utilization of specialty pain care, decreased use of potentially hazardous opioid therapy (i.e., high-dose opioid therapy and co-use of opioids and benzodiazepines), decreased use of non-opioid analgesic pharmacotherapy, and decreased pain intensity

## Methods

This study was approved by the United States Department of Veterans Affairs (VA) Portland Health Care System Institutional Review Board (IRB) and was granted a waiver of informed consent to access patient medical records by the responsible IRB. All procedures followed were in accordance with the ethical standards of the Institutional Review Board and with the Helsinki Declaration of 1975, as revised in 1983.

## Study Design

This is a retrospective cohort study design that compares pain pharmacotherapy, pain treatment utilization, and pain intensity outcomes between patients who received a heat and cold therapy device and matched patients who did not.

## Heat and Cold Therapy

The ThermaZone® thermal therapy device utilizes thermoelectric technology to provide point-of-contact cooling and heating therapy. Several body site-specific pads are available, including ankle, knee, hip, back, elbow, and shoulder. Patients place device pads on body sites where they experience pain, and temperature-regulated water circulates through the device and to the pad, providing consistent, localized heat or cold therapy. The pads range in temperature from 1 to 52 degrees Celsius, and temperatures are self-monitored and controlled by the patient. The VA began utilizing these devices for patients in 2014 for the treatment of chronic pain.

## Standard Pain Care

In the current study, standard pain care followed the VA's stepped model of pain care (Kerns et al., 2011) that builds on a foundation of patient education for pain self-management approaches (e.g., exercise, mindfulness, relaxation, social support). Most patients with chronic pain will adequately manage pain using these self-management approaches. However, some patients require more intensive care. Within the VA, stepped-up treatment engages primary and specialty care services—such as physical therapy, pharmacy, complementary and integrative health (CIH) approaches, mental health, substance use—and, when indicated, may elevate treatment to interdisciplinary pain teams or tertiary pain centers. In this retrospective quasi-experimental cohort study, treatment patients received a heat and cold therapy device and utilized standard of care, while control patients received standard of care only.

## Sample Selection

Eligible patients (1) were at least 18 years of age, (2) had a musculoskeletal pain diagnosis in the VA electronic health record in the year prior to device receipt (or over the same dates for a treatment patient's matched control), and (3) were enrolled in VA health care over the 24-month observation period. Patients with a diagnosis of cancer (other than non-melanoma skin cancer) in the VA electronic health record in the year prior to device receipt and death during the study period were excluded.

Treatment patients received a heat and cold therapy device from the VA between January 1, 2017 and December 31, 2018. At the time the study was initiated, these were the years over which complete data on heat and cold therapy devices were available to the study team. To identify a sample of control patients, we used the VA Corporate Data Warehouse and propensity score matching procedures to identify a matched sample similar in demographic and clinical characteristics to treatment patients. The Corporate Data Warehouse is a data repository that provides comprehensive information contained in electronic medical records for all VA patients. For this study, the use of propensity score matching procedures reduces the likelihood of confounding biases due to underlying differences between patients who do and do not receive a heat and cold therapy device. For any given treatment patient, we restricted the pool of potential control patients to those who received care at the same VA facility. This resulted in a control population of 1,150,149 patients.

We next modeled the probability that a patient would receive a heat and cold therapy device using logistic regression. Predictor variables were measured in the year prior to device receipt and included variables associated with target outcomes of pain treatment utilization and analgesic pharmacotherapy receipt, as recommended by Brookhart and colleagues (2006). These included: age, birth sex, race, ethnicity, VA service connected disability status, medical comorbidity, receipt of medications for opioid use disorder, pain diagnoses, mental health diagnoses, and substance use disorder diagnoses (Edlund et al., 2010; Kaur et al., 2007; Meghani & Cho, 2009; Morasco et al., 2010; Nielsen et al., 2015; Quinn et al., 2017).

The resulting propensity scores (i.e., predicted probabilities) were used to match treatment patients 1:1 with control patients using a nearest neighbor matching algorithm

(Rubin, 1973). This procedure matches a control patient with the "closest" propensity score to that of the corresponding treatment patient. We required an exact match on VA facility (i.e., treatment patients and their matched controls needed to have received care from the same VA facility). Standardized differences were then used to assess covariate balance between the matched groups (Rosenbaum & Rubin, 1985), and kernel density plots of propensity scores tested for sufficient overlap (Ho et al., 2007). The Online Supplemental Digital Content Table lists, for each variable in the propensity model, the differences between patients who did and did not receive a device in the full sample of N=1,152,331 patients (i.e., 1,150,149 candidate control patients plus 2,182 treatment patients), and the matched sample of N=4,364 patients (2,182 matched control patients plus 2,182 treatment patients).

## Study Variables

We defined the index date as the date the heat and cold therapy device was released to treatment patients or the same date for a treatment patient's matched control. Data were extracted from the VA Corporate Data Warehouse for treatment and control patients over a 24-month period—12 months prior to, through 12 months following the index date. We chose this study window to emulate a clinical trial with a 12-month follow-up period. Collecting data in the 12 months prior to treatment initiation allowed us to adjust for covariates and provide greater precision to our findings, as is recommended for observational study designs (Steiner et al., 2010).

## Independent variable

Treatment condition was defined dichotomously as receipt versus non-receipt of a heat and cold therapy device.

## Dependent variables

The primary outcome was the number of days of opioid use in the 12 months following the index date. In addition, we characterized the number of days in the 12 months post-index date that patients received the following: (1) high-dose opioid therapy, defined as ≥ 50 mg morphine equivalent (MME) daily dose, (2) concurrent opioid and benzodiazepine prescriptions, and (3) non-opioid analgesic pharmacotherapy (e.g., non-steroidal anti-inflammatory drugs, acetaminophen, muscle relaxants). All prescription data were based on medication fills obtained from pharmacy records. Four additional treatment utilization outcomes included: (1) number of physical therapy visits, (2) number of occupational therapy visits, (3) number of physical medicine and rehabilitation visits, and (4) number of interdisciplinary pain clinic visits (including interventional pain medicine).

Within the VA, pain intensity ratings are collected as part of routine care. Patients rate their current pain on a numeric scale of 0 ("no pain") to 10 ("worst possible pain"). For the current study, we computed pain intensity trajectories using all available electronic health record-derived pain intensity score data for each patient in the 12 months prior to and 12 months following the index date.

## Covariates

Covariates were extracted from the electronic health record and evaluated in the year prior to the index date, unless otherwise noted. They included age at the index date, self-reported birth sex, self-reported race and ethnicity, service connected disability status (which is disability granted to veteran patients as a result of military service-related traumas or injuries), medical comorbidity as calculated by the Charlson Comorbidity Index (Charlson et al., 1987), and diagnoses of opioid use disorder, alcohol use disorder, other substance use disorder, mood disorder, post-traumatic stress disorder, other anxiety disorder, psychotic disorder, neuropathic pain, and headache pain. All diagnoses were coded as either "yes" if identified in the electronic health record as a focus of treatment during any clinical encounter in the year prior to the index date or "no" if not identified as a focus of treatment.

In addition, we identified the number of days patients had been living with pain, defined as the number of days from the first pain diagnosis available in a patient's medical record to the index date. Finally, number of pain-related surgeries (i.e., surgeries that had one or more pain diagnoses associated with the clinical encounter) and average pain intensity were computed in the pre- and post-index date evaluation periods and included as model covariates.

## Statistical analyses

For the four pharmacotherapy and four non-pharmacologic treatment utilization outcomes, we tested the fit of linear models and several models with count distributions using the Bayesian Information Criterion (Long & Freese, 2014). Count distributions included the Poisson distribution, zero-inflated Poisson distribution, negative binomial distribution, and zero-inflated negative binomial distribution. With one exception (days of high-dose opioid use), a negative binomial distribution best fit the data. For days of high-dose opioid use, a Gaussian distribution best fit the data.

Eight separate mixed effects regression analyses compared the change in each outcome from the 12-month pre-index period to the 12-month post-index period between treatment and control patients by testing the Time X Treatment interaction. This approach statistically accounts for any observed pre-treatment differences in model outcome variables. Statistics for the main effects of time and treatment are also presented. In order to reduce bias, models controlled for covariates specified previously.

For the outcome of pain intensity score, we used random effects growth modeling (Muthen & Muthen, 2017) to quantify both fixed and random effects of pain intensity at the index date (i.e., the model intercept), which estimates pain at the time of treatment initiation, and change in pain in the 12 months following the index date (i.e., the model slope), which characterizes the 12-month trajectory of pain intensity ratings. The model included piecewise components of pain score trajectories in the 12 months prior to the index date and in the 12 months following the index date. We explored several types of change for the 12-month post-index date period of observation—including quadratic and cubic change. A linear model for change in pain over time fit the data best based on the Bayesian Information Criterion and parsimony of model parameters (Hedeker & Gibbons, 2006). We report estimates of change in pain over time in monthly intervals for ease of interpretation. However, models used all individual pain scores rather than computing monthly pain score averages when more than one pain score was available within a month, as has been suggested in previous studies (Dobscha et al., 2015). This makes optimal use of all the available data. We regressed both random effects (intercept and slope) onto the set of covariates described previously.

This study utilized data available in patients' electronic health records over the 24-month observation period. Thus, missing data were not germane to this study. We used an alpha level of 0.05 for all inferential analyses. Treatment utilization and pharmacotherapy outcome analyses were performed in Stata Version 16.1 (College Station, TX). Random effects growth modeling of pain score trajectories was performed using Mplus Version 8.8 (Los Angeles, CA).

## Results

Table 1 presents sample characteristics of treatment patients (N=2,182) and matched control patients (N=2,182). On average, patients were middle-aged, predominantly male birth sex, with approximately 2/3 of the sample identifying as white, non-Hispanic. Mental health comorbidities were common, with over 40% of the sample having diagnoses of a mood disorder and/or post-traumatic stress disorder. Nearly all patients (90%) were service connected through the VA for an injury or trauma sustained during, or as a result of, military service. Among this sample of patients with chronic musculoskeletal pain, a small proportion had comorbid neuropathic pain (8%) or headache (14%). The mean duration of days living with chronic pain in the overall sample was 3416 days (SD = 2016 days) or approximately 9.4 years.

**Table 1.** Baseline characteristics of treatment and matched control patients in the 12-month pre-treatment period

| Variable | Total Sample N = 4,364 % (N) or Mean (SD) | Treatment Patients n = 2,182 % (N) or Mean (SD) | Matched Controls n = 2,182 % (N) or Mean (SD) |
|---|---|---|---|
| **Demographic Characteristics** | | | |
| Age | 54.11 (14.80) | 53.77 (13.75) | 54.44 (15.78) |
| Male Birth Sex | 81.19 (3543) | 80.93% (1766) | 81.44% (1777) |
| Race | | | |
| White | 67.99% (2967) | 68.33% (1491) | 67.64% (1476) |
| Black or African American | 16.70% (729) | 17.64% (385) | 15.77% (344) |
| Asian | 1.08% (47) | 1.33% (29) | 0.82% (18) |
| Native Hawaiian or Other Pacific Islander | 1.28% (56) | 1.10% (24) | 1.47% (32) |
| American Indian or Alaska Native | 1.33% (58) | 1.01% (22) | 1.65% (36) |
| Unknown | 11.62% (507) | 10.59% (231) | 12.65% (276) |
| Ethnicity | | | |
| Hispanic | 24.86% (1085) | 21.13% (461) | 28.60% (624) |
| Not Hispanic | 71.86% (3136) | 76.21% (1663) | 67.51% (1473) |
| Unknown | 3.28% (143) | 2.66% (58) | 3.90% (85) |
| **VA Service-Connected Disability** | 90.35% (3943) | 89.18% (1946) | 91.52% (1997) |
| **Clinical Characteristics** | | | |
| Charlson Comorbidity Score | 0.85 (1.41) | 0.87 (1.38) | 0.83 (1.44) |
| Opioid Use Disorder Diagnosis | 2.84% (124) | 3.12% (68) | 2.57% (56) |
| Alcohol Use Disorder Diagnosis | 7.72% (337) | 7.33% (160) | 8.11% (177) |
| Other Substance Use Disorder Diagnosis | 4.88% (213) | 4.22% (92) | 5.55% (121) |
| PTSD Diagnosis | 34.83% (1520) | 36.53% (797) | 33.13% (723) |
| Other Anxiety Disorder Diagnosis | 20.99% (916) | 22.09% (482) | 19.89% (434) |
| Psychotic Disorder Diagnosis | 1.74% (76) | 1.60% (35) | 1.88% (41) |
| Depressive Disorder | 41.84% (1826) | 43.35% (946) | 40.33% (880) |
| Average Pain Intensity | 3.80 (2.49) | 4.40 (2.30) | 3.09 (2.52) |
| Neuropathic Pain Diagnosis | 369 (8.46%) | 275 (12.60%) | 94 (4.31%) |
| Headache Pain Diagnosis | 607 (13.91%) | 436 (19.98%) | 171 (7.84%) |
| **Musculoskeletal Pain Diagnosis** | | | |
| Foot/Ankle | 17.35% (757) | 17.69% (386) | 17.00% (371) |
| Knee | 22.75% (993) | 23.83% (520) | 21.68% (473) |
| Hip | 7.15% (312) | 8.30% (181) | 6.00% (131) |
| Arm/hand | 3.12% (163) | 3.30% (72) | 2.93% (64) |
| Shoulder | 17.21% (751) | 18.19% (397) | 16.22% (354) |
| Low Back | 61.11% (2667) | 62.79% (1370) | 59.44% (1297) |
| Neck | 17.80% (777) | 20.62% (450) | 14.99% (327) |

## Changes in Analgesic Pharmacotherapy

Table 2 presents statistics for the main effects of Time and Treatment, as well as the Time X Treatment Interactions for the 4 pharmacotherapy outcome variables and 4 specialty pain treatment utilization variables. Days of opioid use, high-dose opioid use (defined as greater than 50 MME daily dose), and co-use of opioids and benzodiazepines decreased across all patients from the pre- to post-treatment period (see Table 2 Main Effects of Time). However, treatment patients decreased high-dose opioid use (Time x Treatment Interaction = 3.24 [1.03-5.44]; see Figure 1, Panel B) and use of concurrent opioids and benzodiazepines (Time x Treatment Interaction = 0.76 [0.69-0.84]; see Figure 1, Panel C) to a greater extent than matched control patients. For any opioid use (Figure 1, Panel A), both treatment and matched control patients had comparable reductions in days of opioid use (Time X Treatment Interaction = 0.98 [0.92-1.03]). Finally, both treatment and control patients evidenced increased use of non-opioid analgesic pharmacotherapies (Main Effect of Time IRR = 1.03 [1.00-1.06]); however, treatment patients had greater utilization of these medications in the follow-up period (Time X Treatment Interaction = 0.95 [0.91-1.00]; see Figure 1, Panel D).

## Changes in Non-pharmacologic Pain Treatment Utilization

As shown in Table 2 and Figure 2, treatment patients decreased utilization of non-pharmacologic pain treatments following receipt of the device to a greater extent than matched control patients for the four pain treatment utilization outcomes (see Table 2 Time X Treatment Interactions and Figure 2 Panels A-D). Number of Occupational Therapy, Physical Therapy, and Pain Clinic visits declined for treatment patients (Figure 2, Panels A-C), while increasing slightly for matched control patients. For Physical Medicine and Rehabilitation visits (Figure 2, Panel D), both treatment patients and matched control patients decreased utilization over time (Main Effect of Time IRR = 0.78 [95% CI = 0.69-0.88]), but this occurred to a greater extent for treatment patients (Time X Treatment Interaction = 1.16 [1.00-1.33]).

## Changes in Pain Intensity

As shown in Figure 3, across all treatment and control patients, pain decreased on average by an estimated 0.02 points per month (95% Confidence Interval = -0.03, -0.01, $p < 0.01$), or 0.24 points over the 12-month post-index date follow-up period. There were no statistically significant differences between treatment and control patients in pain changes over the follow-up period (B = -0.02 [-0.05, 0.01], p = 0.15).

**Table 2.** Changes in pain treatment utilization between treatment patients and matched control patients

| Outcome | Time | | Treatment | | Time X Treatment | |
|---|---|---|---|---|---|---|
| | IRR with 95% CI | p-value | IRR with 95% CI | p-value | IRR with 95% CI | p-value |
| Number of Physical Therapy Visits | 1.06 (0.97, 1.16) | 0.19 | 2.26 (2.06 – 2.48) | <0.01 | 1.13 (1.01 – 1.27) | 0.03 |
| Number of Occupational Therapy Visits | 1.07 (0.93, 1.23) | 0.32 | 2.27 (1.99 – 2.59) | <0.01 | 1.27 (1.07 – 1.50) | 0.01 |
| Number of Physical Medicine & Rehabilitation Visits | 0.82 (0.73, 0.92) | <0.01 | 2.42 (2.15 – 2.72) | <0.01 | 1.23 (1.07 – 1.40) | <0.01 |
| Number of Interdisciplinary Pain Clinic Visits | 1.20 (1.07, 1.34) | <0.01 | 3.35 (2.99 – 3.75) | <0.01 | 1.43 (1.26 – 1.63) | <0.01 |
| Days on Opioid Therapy | 0.74 (0.72, 0.77) | <0.01 | 2.23 (2.09 – 2.38) | <0.01 | 0.99 (0.94 – 1.04) | 0.57 |
| Days on High-Dose Opioid Therapy * | -1.57 (-2.60, -0.54) | <0.01 | 9.67 (6.04 – 13.31) | <0.01 | 3.36 (1.32 – 5.40) | <0.01 |
| Days Co-Prescribed Opioids and Benzodiazepines | 0.45 (0.42 – 0.48) | <0.01 | 7.06 (6.36 – 7.83) | <0.01 | 0.81 (0.75 – 0.88) | <0.01 |
| Days on Non-Opioid Analgesic Pharmacotherapy | 1.03 (0.99 – 1.06) | 0.10 | 1.50 (1.41 – 1.60) | <0.01 | 0.97 (0.93 – 1.02) | 0.23 |

**Note:** Models control for age at index date, birth sex, race, ethnicity, service connected disability status, medical comorbidity as measured by the Charlson Comorbidity Index, substance use disorder diagnoses, mental health diagnoses, and pain diagnoses.

* Model specified a Gaussian distribution. Statistics represent a beta coefficient with 95% confidence interval.

## Discussion

Patients with musculoskeletal pain who received a heat and cold therapy device, relative to matched control patients, evidenced overall decline in specialty pain treatment utilization. One possible explanation for this finding is that patients who utilized the device may have had their pain adequately managed and thus required less specialty pain care. However, the absence of clinically significant changes in pain intensity over time suggests that pain intensity alone did not account for the observed changes in pain treatment utilization. We were unable to measure constructs of pain interference or functioning, which may be better predictors of functional restoration, as these data are not routinely collected within the VA health care system. Future replication studies could help to elucidate these findings by including measures of pain interference and functioning.

An alternative explanation for this study finding is that heat and cold therapy devices may empower patients to improve pain self-management, resulting in use of fewer health care resources. In stepped models of pain care, such as those implemented in the VA (Kerns et al., 2011), pain self-management forms the foundation of an overall pain management plan. Similar to other pain self-management practices such as transcutaneous electrical nerve stimulation, home exercise programs, and stress reduction activities, among others, patients are educated on the administration of heat and cold therapy and empowered to use this self-management approach to reduce pain and improve functioning. A growing body of literature points to the importance of patient empowerment in reducing low-value care within health systems—i.e., care that provides little benefit to patients but that may incur unnecessary costs to patients and/or health systems (Akesson et al., 2022; Chen et al., 2016; Scott et al., 2021). Future studies should prospectively examine the impact of improved pain self-management and patient empowerment on reducing specialty pain care.

If in fact heat and cold therapy devices are associated with decreased utilization of specialty pain care, this could be a tremendous cost-savings to health systems, as it would save on higher-cost specialty pain care. Though overall declines in specialty pain care utilization observed in patients who received a heat and cold therapy device was modest, representing less than one visit per patient on average, the impact of these reductions in a large health care system such as the VA can be profound. The VA serves over 9 million patients annually, and an estimated 65% of patients experience chronic pain, representing over 5.8 million patients (Nahin, 2017). In resource-limited healthcare settings, small reductions in high-cost care utilization could be of great value in that health systems could offset costs associated with treating chronic pain without compromising quality of care or key clinical outcomes. This study, however, did not include a cost analysis. Future studies should incorporate formal cost analyses to quantify cost offsets that may result from decreased specialty pain treatment utilization.

Patients in this study who received heat and cold therapy did not evidence clinically meaningful reductions in pain intensity over time, defined as reductions in pain intensity of 1.3 to 1.8 on the 0-10 numeric rating scale (Bahreini et al., 2020; Suzuki et al, 2020). This finding is consistent with prior work that demonstrates relatively stable pain intensity self-ratings longitudinally by patients with chronic pain diagnoses (McPherson et al., 2018), when assessed in the context of usual clinical care. This finding, however, is inconsistent with prior literature that demonstrates pain-reducing benefits of heat and cold therapy for low back pain and knee osteoarthritis (Ariana et al., 2022; French et al., 2006; Tao & Bernacki, 2005). In the current study, pain intensity ratings were derived from the electronic health record during routine outpatient clinical encounters and not at the time heat and cold therapy was administered, as has been done in prior trials (Ariana et al., 2022; French et al., 2006; Tao & Bernacki, 2005). In addition, pain location was not specified at the time of pain ratings, and it is possible that patients may have been endorsing pain in areas of the body that had not been treated by heat and cold therapy. We did not examine within patient variability in pain intensity ratings in the current study (i.e., the range of an individual patient's pain scores over time), which has been shown to vary considerably (McPherson et al., 2018). While average pain intensity ratings in the current study did not change, an

examination of within patient variability warrants further examination, as a narrowing of pain intensity ratings can be perceived, by patients, as demonstrable improvement and has been associated with improved physical and psychological outcomes (Andrews et al., 2012). Furthermore, pain intensity is but one patient-reported outcome, and it does not characterize physical or emotional functioning that can be captured with more comprehensive validated measures, some of which are recommended outcomes in pain clinical trials (Dworkin et al., 2005).

Finally, study findings point to reductions in all forms of opioid use across both treatment and control patients. Data from the Veterans Health Administration and in the U.S. more generally point to downward trends in opioid prescribing during the study period (Gellad et al., 2017), likely due to increased use of risk mitigation approaches such as routine urine drug screens and reviewing U.S. prescription drug monitoring databases (Lin et al., 2017), which are databases housed at the state level that show prescribing of controlled substances, including opioids and benzodiazepines, by all U.S. health system providers within a state. Implementation of these practices has been associated with declines in higher risk opioid prescribing (Lin et al., 2017). Findings from the current study further point to associations of reduced higher risk opioid use among patients treated with heat and cold therapy. In the full sample of patients, reductions in days of opioid use, high-dose opioid use, and co-use of opioids and benzodiazepines were observed across all patients, with greater reductions observed in high-dose opioid use and co-use of opioids and benzodiazepines among patients who received heat and cold therapy. Experimental studies have found that the endogenous opioid system is implicated in pain relief and that this system is activated by heat and cold therapies (Sirucek et al., 2021). Differential reductions in higher risk opioid use among patients who received heat and cold therapy devices in the current study may be associated with endogenous opioid activation, though this was not specifically measured. It is also unclear if heat and cold therapy was provided by clinicians in the context of opioid taper or other risk mitigation efforts, or if patients reduced higher risk opioid use of their own volition. Prior research has identified both patient- and clinician-initiated reasons for opioid taper and discontinuation (Lovejoy et al., 2017). While a thorough explication of opioid dose reduction was beyond the scope of this study, future qualitative work could help explain potential benefits of heat and cold therapy in the context of analgesic pharmacotherapy utilization, including opioid medications.

This study has several limitations beyond those discussed previously. Patients in the treatment and control groups evidenced some differences in outcome variables at the index date. We attempted to control for potential known biases using (1) a quasi-experimental study design and propensity score matching procedures and (2) statistical procedures that control for patient demographic and clinical characteristics, as well as pre-treatment values of all outcome variables. However, this observational study is not able to control for all known and unknown confounds, and a randomized controlled trial is needed to make claims of causality.

Second, this is a United States veteran sample and contained a low proportion of women, relative to the general patient population of persons living with chronic pain. Results may thus not generalize to other non-VA settings or patient populations. Third, medication prescription dispensing, this study's estimate for pharmacotherapy utilization, does not necessarily equate to medication use. Finally, we were unable to measure the extent to which patients utilized the device and thus used device receipt as a proxy measure of utilization. However, we are unable to determine if frequency and duration of device use is related to study outcomes.

Despite its limitations, this study is one of the first to examine associations between heat and cold therapy with specialty pain treatment and analgesic pharmacotherapy use in a diverse patient population. While the retrospective quasi-experimental cohort study design does not allow us to draw causal inferences about the efficacy of the device, we have greater confidence in the study findings after methodologically and statistically controlling for known confounds. Future trials that employ experimental designs will advance our understanding of the clinical and health systems benefits of heat and cold therapy for general musculoskeletal pain syndromes.

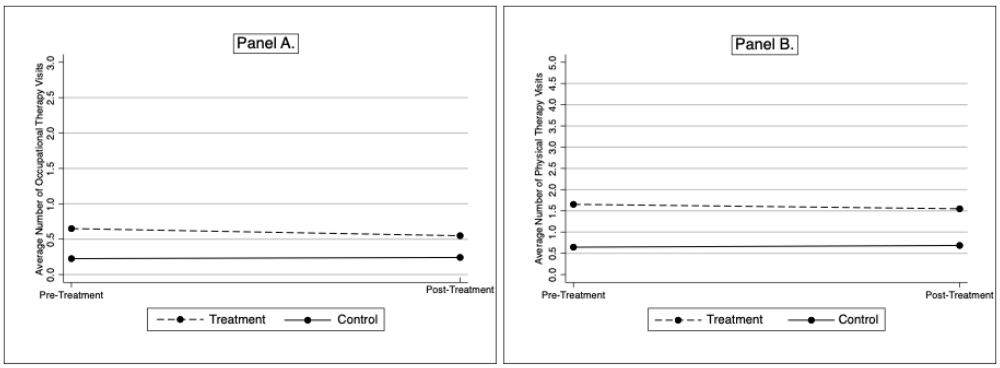
## Funding Source

This study was supported with funds from the Ohio Opioid Abuse, Prevention and Treatment Technology Initiative, a program of Ohio Third Frontier, a part of the larger Ohio Department of Development. The funds were granted to Innovative Medical Equipment, LLC and provided to Dr. Lovejoy to conduct the study. Neither the sponsor nor Innovative Medical Equipment, LLC had a role in study design; analysis, collection, and interpretation of data; writing of the report; and decision to submit the article for publication. The content and opinions in this manuscript are those of the authors and do not represent the content or opinions of the Ohio Department of Development, State of Ohio, Innovative Medical Equipment, LLC, the United States Department of Veterans Affairs, or the United States Government.

## Disclosure

Dr. Lovejoy reports a contract from Innovative Medical Equipment, LLC, the maker of ThermaZone®, during the conduct of the study; grants from the VA Health Services Research & Development, grants from the VA Office of Rural Health, grants of the National Center for Complementary and Integrative Health, and grants from the National Institute on Drug Abuse, outside the submitted work. Dr. McPherson reports and discloses that he is a founding principal of Attenuex, LLC and a scientific advisor to Managed Health Connections, LLC and Appiture, LLC. This technology work is distinct from the device being reported in this manuscript. All remaining authors have nothing to disclose.

**Figure 1 (Panels A-D).** Average change in non-pharmacologic pain treatment over time in treatment and matched control patients.



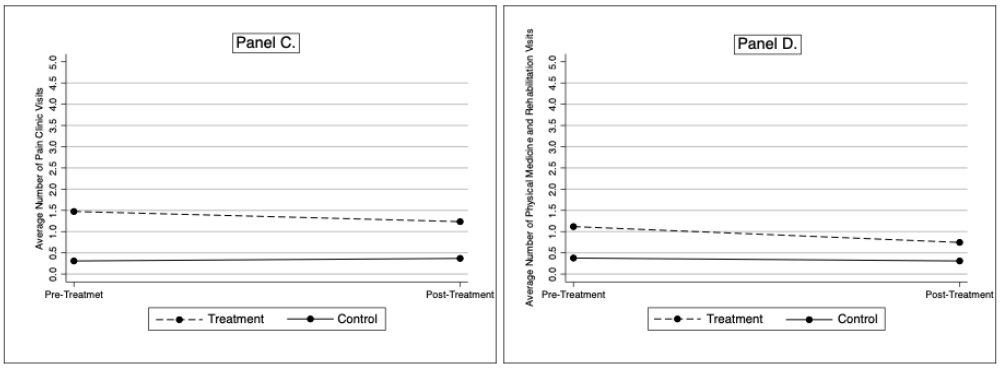
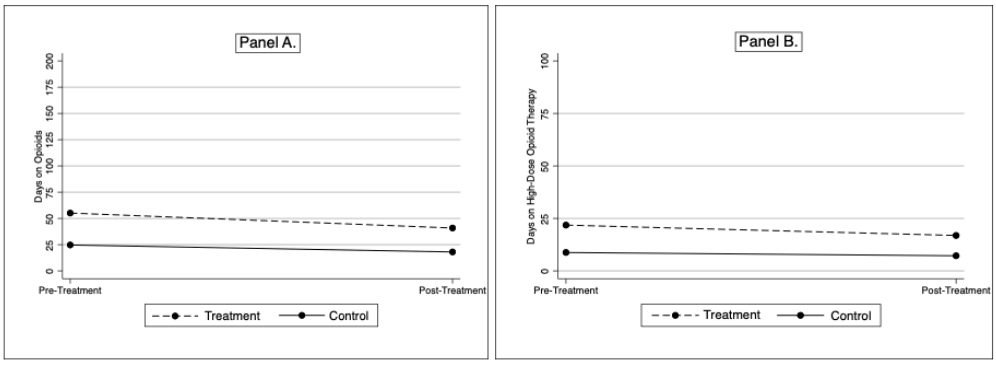




**Figure 2 (Panels A-D).** Average change in pharmacologic pain treatment over time in treatment and matched control patients



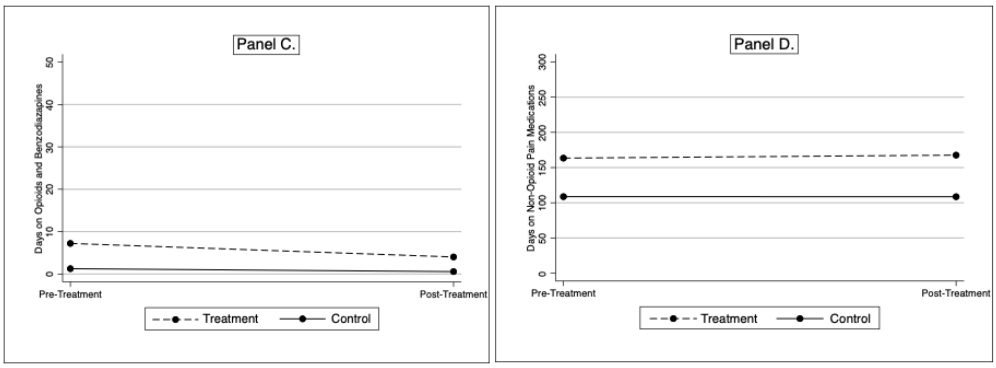
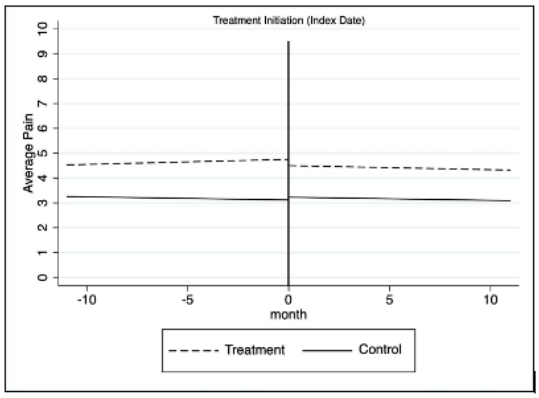



**Figure 3.** Average change in pain intensity over time in treatment patients and matched control patients.



## References


Akesson, K. S., Sunden, A., Fagerstrom, C., Pawlikowska, T., & Hansson, E. E. (2022). Enablement and empowerment among patients participating in a supported osteoarthritis self-management programme – a prospective observational study. BMC Musculoskeletal Disorders, 23, 555. doi: 10.1186/s12891-022-05457-9.

Andrews, N. E., Strong, J., & Meredith, P. J. (2012). Activity pacing, avoidance, endurance, and associations with patient functioning in chronic pain: A systematic and meta-analysis. Archives of Physical Medicine and Rehabilitation, 93, 2109-121. doi: 10.1016/j.apmr.2012.05.029.

Ariana, M., Afrasiabifar, A., Doulatabad, S. N., Mosavi, A., & Behnammoghadam, M. (2022). The effect of local heat therapy versus cold rub gel on pain and joint functions in patients with knee osteoarthritis. Clinical Nursing Research, 31, 1014-1022. doi: 10.1177/10547738211035502.

Atkas, Y. Y., Durgun, H., & Durhan, R. (2021). Cold therapy and the effects on pain and physiological parameters in patients recovering from spine surgery: A randomized prospective study. Complementary Medicine Research, 28, 31-39. doi: 10.1159/000508029.

Bahreini, M., Safaie, A., Mirfazaelian, H., & Jalili, M. (2020). How much change in pain score does really matter to patients? The American Journal of Emergency Medicine, 38, 1641-1646. doi: 10.1016/j.ajem.2019.158489

Becker, W. C., DeBar, L. L., Heapy, A. A., Higgins, D., Krein, S. K., Lisi, A., Makris, U. E., & Allen, K. D. (2018). A research agenda for advancing non-pharmacological management of chronic musculoskeletal pain: Findings from a VHA state-of-the-art conference. Journal of General Internal Medicine, 33, 1-15. doi: 10.1007/s11606-018-4345-6.

Bookhart, M. A., Schneeweiss, S., Rothman, K. J., Glynn, R. J., Avorn, J., & Sturmer, T. (2006). Variable selection for propensity score models. American Journal of Epidemiology,163, 1149-1156. doi: 10.1093/aje/kwj149.

Charlson, M. E., Pompei, P., Ales, K. L., & MacKenzie, C. R. (1987). A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. Journal of Chronic Diseases, 40, 373-383. doi: 10.1016/0021-9681(87)90171-8.

Chen, J., Mullins, C. D., Novak, P., & Thomas, S. B. (2016). Personalized strategies to activate and empower patients in health care and reduce health disparities. Health Education and Behavior, 43, 25-34. doi: 10.1177/1090198115579415.

Dobscha, S. K., Morasco, B. J., Kovas, A. E., Peters, D. M., Hart, K., & McFarland, B. H. (2015). Short-term variability in outpatient pain intensity scores in a national sample of older veterans with chronic pain. Pain Medicine, 16, 855-865. doi: 10.1111/pme.12643.

Dworkin, R. H., Turk, D. C., Farrar, J. T., Haythornthwaite, J. A., Jensen, M. P., Katz, N. P., Kerns, R. D., Stucki, G., Allen, R. R., Bellamy, N., Carr, D. B., Chandler, J., Cowan, P., Dionne, R., Galer, B. S., Hertz, S., Jadad, A. R., Kramer, L. D., Manning, D. C.,…Witter, J. (2005). Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain, 113, 9-19. doi: 10.1016/j.pain.2004.09.012

Edlund, M. J., Martin, B. C., Devries, A., Fan, M., Braden, J. B., & Sullivan, M. D. (2010). Trends in use of opioids for chronic non-cancer pain among individuals with mental health and substance use disorders: The TROUP study. Clinical Journal of Pain, 26, 1-8. doi: 10.1097/AJP.0b013e3181b99f35.

Fernandes, I. A., Armond, A. C. V., & Falci, S.G.M. (2019). The effectiveness of the cold therapy (cryotherapy) in the management of inflammatory parameters after removal of mandibular third molars: A meta-analysis. International Archives of Otorhinolaryngol,23, 221-228. doi: 10.1055/s-0039-1677755.

Freiwald, J., Hoppe, M. W., Beermann, W., Krajewski, J., & Baumgart, C. (2018). Effects of supplemental heat therapy in multimodal treated chronic low back pain patients on strength and flexibility. Clinical Biomechanics, 57, 107-113. doi: 10.1016/j.clinbiomech.2018.06.008.

Freiwald, J., Magni, A., Fanlo-Mazas, P., Paulino, E., de Medeiros, L. S., Moretti, B., Schleip, R., & Solorino, G. (2021). A role for superficial heat therapy in the management of non-specific, mild-to-moderate low back pain in current clinical practice: A narrative review. Life, 11, 780. doi: 10.3390/life11080780.

French, S. D., Cameron, M., Walke, B. F., Reggars, J. W., & Esterman, A.J. (2006). Superficial heat or cold for low back pain. The Cochrane Database of Systematic Reviews, 2006, CD004750. doi: 10.1002/14651858.CD004750.pub2.

Gellad, W. F., Good, C. B., & Shulkin, D. J. (2017). Addressing the opioid epidemic in the United States: Lessons from the Department of Veterans Affairs. JAMA Internal Medicine, 177, 611-612. doi: 10.1001/jamainternmed.2017.0147.

Hedeker, D., & Gibbons, R. D. (2006). Longitudinal data analysis. Vol. 451. Hoboken, NJ: John Wiley & Sons.

Ho, D. E., Imai, K., King, G., & Stuart, E. A. (2007). Matching as nonparametric preprocessing for reducing model dependence in parametric causal inference. Political Analysis, 15, 199-236. https://gking.harvard.edu/files/abs/matchp-abs.shtml

Kaur, S., Stechuchak, K. M., Coffman, C. J., Allen, K. D., & Bastian, L. A. (2007). Gender differences in health care utilization among veterans with chronic pain. Journal of General Internal Medicine, 22, 228-233. doi: 10.1007/s11606-006-0048-5.

Kerns, R. D., Philip, E. J., Lee, A. W., & Rosenberger, P. H. (2011). Implementation of the Veterans Health Administration National Pain Management Strategy. Translational Behavioral Medicine, 1, 635-643. doi: 10.1007/s13142-011-0094-3.

Krebs, E. E., Gravely, A., Nugent, S., Jensen, A. C., DeRonne, B., Goldsmith, E. S., Kroenke, K., Bair, M. J., & Noorbaloochi, S. (2018). Effect of opioid vs nonopioid medications on pain-related function in patients with chronic back pain or hip or knee osteoarthritis pain: The SPACE randomized clinical trial. Journal of the American Medical Association, 319, 872-882. doi: 10.1001/jama.2018.0899.

Lin, L. A., Bohnert, A. S. B., Kerns, R. D., Clay, M. A., Ganoczy, D., & Ilgen, M. A. (2017). Impact of the Opioid Safety Initiative on opioid-related prescribing in veterans. Pain, 158, 833-839. doi: 10.1097/j.pain.0000000000000837.

Long, J. S., & Freese, J. (2014). Regression models for categorical dependent variables using Stata. 3rd ed. College Station, TX: Stata Press.

Lovejoy, T. I., Morasco, B. J., Demidenko, M. I., Meath, T. H. A., Frank, J. W., & Dobscha, S. K. (2017). Reasons for discontinuation of long-term opioid therapy in patients with and without substance use disorders. Pain, 158, 526-534. doi: 10.1097/j.pain.0000000000000796.

McPherson, S. M., Smith, C. L., Dobscha, S. K., Morasco, B. J., Demidenko, M. I., Meath, T. H. A., & Lovejoy, T. I. (2018). Changes in pain intensity after discontinuation of long-term opioid therapy for chronic noncancer pain. Pain, 159, 2097-2104. doi: 10.1097/j.pain.0000000000001315.

## References (continued)


Meghani, S. H., & Cho, E. (2009). Self-reported pain and utilization of pain treatment between minorities and nonminorities in the United States. Public Health Nursing, 26, 307-316. doi: 10.1111/j.1525-1446.2009.00785.x.

Morasco, B. J., Duckart, J. P., Carr, T. P., Deyo, R. A., & Dobscha, S. K. (2010). Clinical characteristics of veterans prescribed high doses of opioid medications for chronic non-cancer pain. Pain, 151, 625-632. doi: 10.1016/j.pain.2010.08.002.

Muthen, L. K., & Muthen, B.O. (2017). Mplus User's Guide, Version 8. Los Angeles, CA: Muthen & Muthen.

Nahin, R. L. (2017). Severe pain in veterans: The effect of age and sex, and comparisons with the general population. The Journal of Pain, 18, 247-254. doi: 10.1016/j.jpain.2016.10.021.

Nielsen, S., Lintzeris, N., Bruno, R., Campbell, G., Larance, B., Hall, W., Hoban, B., Cohen, M. L., & Degenhardt, L. (2015). Benzodiazepine use among chronic pain patients prescribed opioids: associations with pain, physical and mental health, and health service utilization. Pain Medicine, 16, 356-366. doi: 10.1111/pme.12594.

Ozkan, B., & Cavdar I. (2021). The effect of cold therapy applied to the incision area after abdominal surgery on postoperative pain and analgesic use. Pain Management Nursing, 22, 775-782. doi: 10.1016/j.pmn.2021.03.007.

Quinlan, P., Davis, J., Fields, K., Madamba, P., Colman, L., Tinca, D., & Drake, R.C. (2017). Effects of localized cold therapy on pain in postoperative spinal fusion patients: A randomized controlled trial. Orthopedic Nursing, 36, 344-349. doi: 10.1097/NOR.0000000000000382.

Quinn, P. D., Hur, K., Chang, Z., Krebs, E. E., Bair, M. J., Scott, E. L., Rickert, M. E., Gibbons, R. D., Kroenke, K., & D'Onofrio, B. M. (2017). Incident and long-term opioid therapy among patients with psychiatric conditions and medications: A national study of commercial health care claims. Pain, 158, 140-148. doi: 10.1097/j.pain.0000000000000730.

Rosenbaum, P. R., & Rubin, D. B. (1985). Constructing a control group using multivariate matched sampling methods that incorporate the propensity score. The American Statistician, 39, 33-38. https://doi.org/10.2307/2683903

Rubin, D. B. (1973). Matching to remove bias in observational studies. Biometrics, 29, 159-183. https://doi.org/10.2307/2529684

Scott, I. A., Elshaug, A. G., & Fox, M. (2021). Low value care is a health hazard that calls for patient empowerment. The Medical Journal of Australia, 215, 101-103. doi: 10.5694/mja2.51168.

Sirucek, L., Price, R. C., Gandhi, W., Hoeppli, M., Fahey, E., Qu, A., Becker, S., & Schweinhardt, P. (2021). Endogenous opioids contribute to the feeling of pain relief in humans. Pain, 162, 2821-2831. doi: 10.1097/j.pain.0000000000002285

Steiner, P. M., Cook, T. D., Shadish, W. R., & Clark, M. H. (2010). The importance of covariate selection in controlling for selection bias in observational studies. Psychological Methods, 15, 250-267. doi: https://doi.org/10.1037/a0018719

Suzuki, H., Aono, S., Inoue, S., Imajo, Y., Nishida, N., Funaba, M., Harada, H., Mori, A., Matsumoto, M., Higuchi, F., Nakagawa, S., Tahara, S., Ikeda, S., Izumi, H., Taguchi, T., Ushida, T., & Sakai, T. (2020). Clinically significant changes in pain along the pain intensity numerical rating scale in patients with chronic low back pain. PLoS One, 15, e0229228. doi: 10.1371/journal.pone.0229228

Tao, X. G., & Bernacki, E. J. (2005). A randomized clinical trial of continuous low-level heat therapy for acute muscular low back pain in the workplace. Journal of Occupational and Environmental Medicine, 47, 1298-1306. doi: 10.1097/01.jom.0000184877.01691.a3.

Wang, Y., Li, S., Zhang, Y., Chen, Y., Yan, F., Han, L., & Ma, Y. (2021). Heat and cold therapy reduce pain in patients with delayed onset muscle soreness: A systematic review and meta-analysis of 32 randomized controlled trials. Physical Therapy in Sport, 48, 177-187. doi: 10.1016/j.ptsp.2021.01.004.