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How initial perceptions of the effectiveness of mind and body complementary and integrative health therapies influence long-term adherence in a pragmatic trial

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Abstract

Objective: Beliefs and perceptions about pain intervention effectiveness when initiating a therapy may influence long-term engagement. This study examines how early perceived effectiveness of complementary and integrative health therapies impacts long-term engagement in a pragmatic trial context.

Participants: Veterans with chronic musculoskeletal pain participating in a pragmatic trial of provider-delivered complementary and integrative health therapies (acupuncture, chiropractic care, or massage therapy) used alone compared to combining those therapies with self-care therapies (yoga, Tai Chi/Qigong, or meditation). This analysis focuses on 1713 participants using self-care therapies at baseline.

Setting: 18 Veterans Healthcare Administration Medical Facilities.

Design: Prospective cohort study.

Methods: Predictors of total self-care complementary and integrative health therapy sessions over a 6-month assessment period were assessed using linear regression to determine how strongly perceptions of initial therapy effectiveness was associated with total utilization. Perception of initial therapy effectiveness was assessed at study entry across four domains (pain, mental health, fatigue, and general well-being).

Results: In total, 56% (1032/1713) of Veterans reported a positive perceived effectiveness of their recent complementary and integrative health therapy use at study initiation. Older individuals and those using meditation were more likely to report early positive perceptions. Mean number of therapy sessions over the 6-month study was 11 (range 1 to 168). Early positive perceptions had a small effect on overall use, increasing mean sessions by 2.5 (1.3 to 3.6). Other factors such as recent physical therapy use and distance to primary care explained more variation in total utilization.

Conclusions: Pragmatic pain trials should examine factors associated with engagement across assigned treatment protocols, especially if any of the treatment protocols being tested are sensitive to long-term engagement.

Keywords: patient adherence; chronic pain; musculoskeletal pain veterans health; mind-body therapies; complementary therapies.

Introduction

Trials testing non-pharmacological behavioral interventions to treat chronic pain depend heavily on patient engagement with the intended treatment assignment to ensure that inferences about the assigned treatments are valid. Traditional explanatory trials try to achieve high engagement and adherence through protocols and methods which extend beyond normal clinical practice. These include enrollment processes in which engagement expectations are presented to potential trial participants who then agree to try to be adherent to treatment assignment

expectations including follow-up visits and collection of study measures.^{1–4} This can result in study populations comprised of participants who are motivated to adhere to their treatment assignment, as individuals who are not interested in the trial requirements do not agree to enroll in the trial.^{5–8} Pragmatic trials testing interventions as they are delivered to patients in real-world settings can face challenges if there is confirmation bias, ceiling effects, or other systematic biases among the enrolled populations.⁷ In pragmatic trials, factors such as beliefs and perceptions of effectiveness of treatments may lead to imbalances

among intervention assignment groups over time, biasing findings especially if long-term participation is associated with outcomes.⁹ Participants with positive expectations may exaggerate benefits, while those with negative expectations may report unfavorable outcomes or dropout early before the intervention can become effective.¹⁰ In the context of interventions which cannot be blinded, such as many non-pharmacological pain treatments including yoga, acupuncture, and chiropractic care, these imbalances have the potential to bias trial results if they are associated with self-reported pain outcomes.^{11–13} This is likely, as pragmatic trial participants who do not believe in the effectiveness of a treatment are likely to participate in fewer treatment sessions than those who have favorable perceptions of the treatment's effectiveness.

Funding from the 2016 Comprehensive Addiction and Recovery Act (CARA) directed the Veterans Health Administration (VHA) to develop an approach to address opioid misuse and chronic pain among Veterans through the expansion of complementary and integrative health (CIH) therapies.¹⁴ These included provider-delivered approaches such as acupuncture, massage therapy, and chiropractic care, as well as self-care therapies including yoga, Tai Chi/Qigong, and mindfulness meditation practices. Expanding CIH therapies is one component of VHA's broader Whole Health System of Care which focuses on building a foundation for healthcare upon understanding the life meaning, aspirations, and purpose of each Veteran. The Whole Health System aims to empower and equip Veterans to take charge of their health and live their life to the fullest, as defined by them.¹⁵ Each of VHA's 18 regional networks—Veterans Integrated Service Networks—identified and funded one medical center in their region to serve as a Whole Health flagship site which would hire dedicated CIH staff and expand CIH offerings.

In this manuscript we examine how initial perceptions of the effectiveness of complementary and integrative health (CIH) therapies influence overall engagement with these therapies. This analysis was conducted as part of the Assessing Pain, Patient-reported Outcomes, and Complementary and Integrative Health (APPROACH) Pragmatic Trial study.¹⁶ Multiple studies have demonstrated the efficacy of nonpharmacological approaches on reducing the burden of chronic pain¹⁷, and healthcare systems are now working to increase patient access to nonpharmacological therapies. The focus of the APPROACH study is on understanding the effectiveness of healthcare systems encouraging patients to engage in self-care therapies in addition to provider-delivered CIH therapies which healthcare systems are more oriented to offering. Patients at the 18 Whole Health flagship sites who were interested in CIH were encouraged to use provider-delivered therapies either alone or in combination with self-care therapies. Our analysis focuses on a subgroup of APPROACH participants who were using self-care therapies at the start of APPROACH, and seeks to define how initial perceptions of the effectiveness of these therapies were associated with dose and duration of continued engagement in their use over a 6-month assessment period.

Methods

This prospective cohort study focuses on participants in the APPROACH study who utilized self-care CIH therapies (ie, yoga, Tai Chi/Qigong, and meditation practices) at the time of entry into the study. The full protocol for the APPROACH

study is described elsewhere.¹⁸ The study is registered with ClinicalTrials.gov ID NCT05097521.

Participants

Beginning in March 2021, Veterans at the 18 Whole Health flagship sites with a history of chronic pain¹⁹ who were newly initiating a CIH therapy and had no utilization of those therapies in the prior 6 months were identified in the VHA electronic health record as potentially eligible for the APPROACH study. Between March 2021 and April 2023, 15 608 such Veterans were identified and approached to participate in a quality improvement survey about their experience with CIH.²⁰ Overall, 7123/15 608 (45.6%) Veterans participated.²⁰ In order to understand how initial perceptions of self-care therapy effectiveness influences continued use of self-care therapies, we focused on a subgroup of 1713 responders eligible for the APPROACH study who reported using a self-care CIH therapy at baseline and who completed follow-up surveys at 1, 3, and 6 months which captured overall CIH therapy use during the 6-month study period. Utilization of these data was approved by the VHA Central Institutional Review Board Study #18–01, IRBNet #1613612.

CIH therapy utilization

VHA electronic medical record and community care billing data were reviewed for utilization of the six forms of CIH therapies prioritized by VHA at the Whole Health flagship study sites (acupuncture, massage therapy, chiropractic care, Tai Chi/Qigong, yoga, and meditation). Review of community care billing data ensured that services delivered through non-VHA clinics and paid for by VHA were captured.^{21,22} Additionally, coding practices for therapies without traditional CPT/billing codes were used to fully capture CIH therapy utilization within the electronic medical record, including participation in yoga, Tai Chi/Qigong, and meditation sessions offered by VHA.^{22,23}

Data from the electronic medical record was supplemented with self-reported survey responses from the CIH Experience Survey detailing use of therapies outside the VHA system such as (1) therapies paid for by other insurance or out-of-pocket by Veterans, and (2) Veterans' use of virtual CIH therapies such as online yoga classes.²⁰ The survey asked Veterans detailed questions about use of each CIH therapy covering the prior 4-week period at the 1 month survey time point, and an 8-week window at each of the survey's 3- and 6-month time periods. While electronic medical record and claims data were extracted for the full 24-week post-baseline period, survey data cover the majority (20 weeks) of this period.²⁰

During this period patients may have used self-care CIH therapies in-person or through a variety of virtual care formats. These included virtual sessions guided online by an instructor, or self-guided recordings patients used and completed on their own. Because the study was initiated during the COVID-19 pandemic, in-person protocols varied across the 18 medical center locations over the study period, especially for group classes. Notably, all medical centers participating in the APPROACH study reported pivoting to offering self-care CIH therapies in some format to patients at the start of the pandemic.

Early perceptions of effectiveness of initial CIH therapy utilization

The CIH Experience Survey was conducted electronically, first asking patients if they had recently used any of the six

types of CIH therapies, then asking additional details about use of each of the therapies they indicated.²⁰ Included in the baseline survey were the Patient Global Impression of Change (PGIC) measures recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) committee.²⁴ The language of the PGIC measure was adapted by inserting specific CIH therapies responders indicated they used in the item stem, eg, “Since doing <Insert each CIH therapy> recently, have you seen changes in your pain?” with ratings from “much better” to “much worse” on a five-item Likert scale.²⁰ Four domains were assessed including pain, mental health, fatigue, and general well-being. If patients reported participating in two therapies, those specific therapies were combined in the stem, for example, “Since doing yoga and meditation recently, have you seen changes in your pain?” If more than two therapies were reported, the stem read as “Since doing these activities recently, have you seen changes in your pain?”

Other covariates

Education, marital status, and chronicity of musculoskeletal chronic pain²⁵ were assessed in the baseline survey. Additional data was extracted from the electronic health record at the time of the baseline survey including location of chronic pain¹⁹, history of eleven common chronic conditions in addition to pain²⁶,

current smoking status^{27,28}, recent use of related services including physical therapy, pain clinic services²⁹, mental health services, and other Whole Health services^{22, 30,31}, each Veteran’s race and ethnicity, service connection and disability status, and distance³² from their home to the nearest primary care clinic. The 11 common chronic conditions in addition to chronic pain included seven of the Elixhauser conditions²⁶ (obesity, diabetes, hypertension, COPD, cardiac arrhythmias, rheumatoid arthritis, and history of solid tumor without metastasis), and four additional conditions common among Veterans (insomnia, obstructive sleep apnea, alcohol abuse, and drug abuse).

Statistical analysis

We constructed a composite variable with Veterans indicating positive perceptions of self-care CIH therapy effectiveness at baseline based on reporting “slightly better” or “much better” for any of the four domains (pain, mental health, fatigue, general well-being) assessed using the PGIC measures. Figure 1 is an UpSet plot³³ describing the joint frequency of improvement across all four domains for patients who reported improvement in at least one domain. Baseline demographic and clinical characteristics of patients with positive perceptions of improvement were compared with those who did not report any improvement (Table 1). Standardized mean differences were calculated to estimate differences in demographic and clinical characteristics

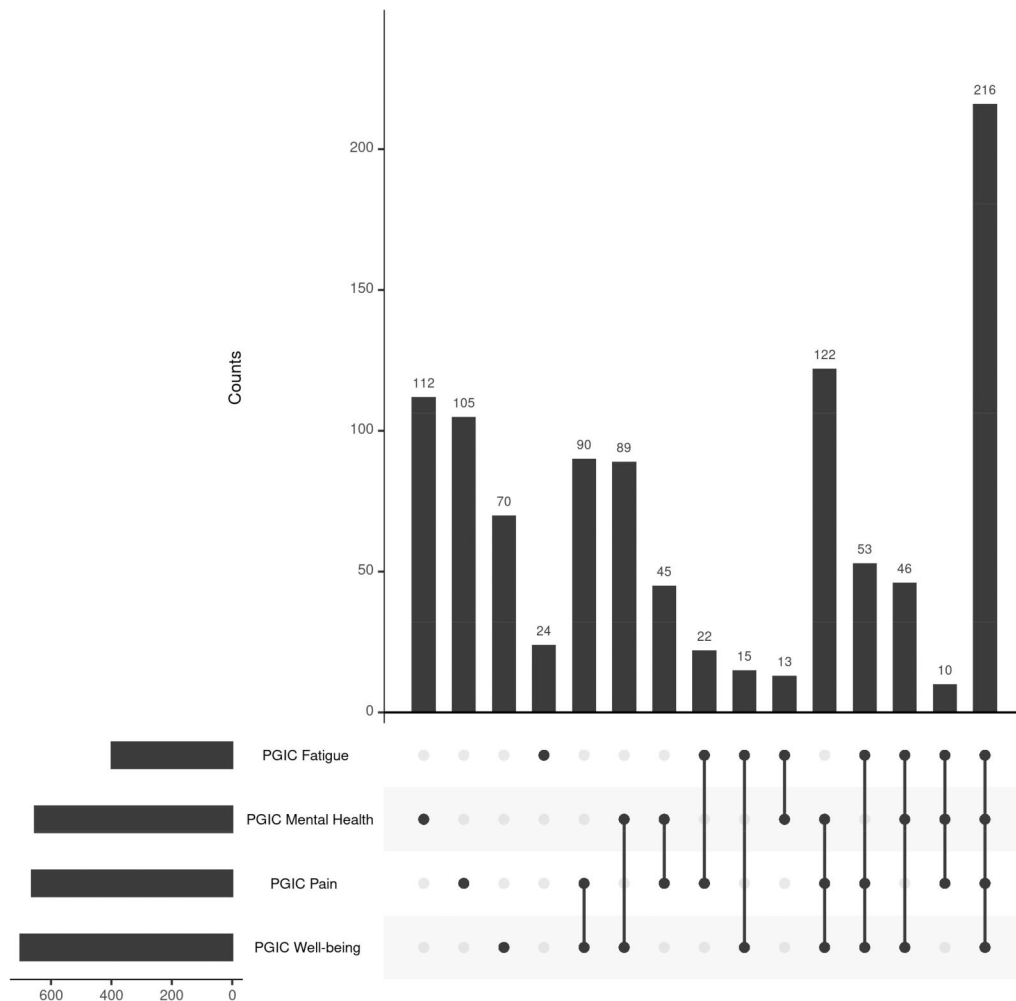


Figure 1. Distribution of positive perceptions among the 1032/1713 (60%) participants who indicated having a positive perception at baseline associated with initial CIH therapy use across at least 1 of the 4 domains of Patient Global Impression of Change.

Table 1. Study cohort demographics and clinical characteristics.

Characteristic	Overall <i>n</i> = 1713	Perceived CIH Effectiveness at Baseline <i>n</i> = 1032	No Perceived CIH Effectiveness at Baseline <i>n</i> = 681	SMD
Initial CIH Therapy at study entry ^a				
Tai Chi/Qigong, <i>n</i> (%)	574 (34)	315 (31)	259 (38)	-0.16
Meditation, <i>n</i> (%)	1329 (78)	833 (81)	496 (73)	0.19
Yoga, <i>n</i> (%)	792 (46)	490 (47)	302 (44)	0.06
Age, mean (SD)	55 (13)	54 (13)	56 (13)	-0.13
Unknown	1	0	1	
Sex (Female), <i>n</i> (%)	486 (28)	301 (29)	185 (27)	0.04
Race, <i>n</i> (%)				0.19
American Indian or Alaska Native	21 (1.2)	14 (1.4)	7 (1.0)	
Asian	18 (1.1)	12 (1.2)	6 (0.9)	
Black or African American	388 (23)	209 (20)	179 (26)	
Multiple Races	22 (1.3)	13 (1.3)	9 (1.3)	
Native Hawaiian or other Pacific Islander	20 (1.2)	13 (1.3)	7 (1.0)	
Race unknown, declined, or missing	108 (6.3)	55 (5.3)	53 (7.8)	
White	1136 (66)	716 (69)	420 (62)	
Ethnicity, <i>n</i> (%)				0.02
Hispanic or Latino	172 (10)	102 (9.9)	70 (10)	
Not Hispanic or Latino	1455 (85)	880 (85)	575 (84)	
Ethnicity unknown, declined, or missing	86 (5.0)	50 (4.8)	36 (5.3)	
Marital status, <i>n</i> (%)				0.05
Married/in relationship	1142 (67)	698 (68)	444 (65)	
Single/divorced/separated/widowed	571 (33)	334 (32)	237 (35)	
Education, <i>n</i> (%)				0.17
High school or less	190 (11)	94 (9.1)	96 (14)	
Some college	738 (43)	445 (43)	293 (43)	
College graduate or higher	784 (46)	493 (48)	291 (43)	
Unknown	1 (<0.1)	0 (0)	1 (0.1)	
Distance to VAMC (miles), <i>n</i> (%)				0.03
≤2	143 (8.3)	89 (8.6)	54 (7.9)	
>2 ≤ 15	1000 (58)	600 (58)	400 (59)	
>15	447 (26)	269 (26)	178 (26)	
Unknown	123 (7.2)	74 (7.2)	49 (7.2)	
Service connected %, <i>n</i> (%)				0.10
<50	446 (26)	286 (28)	160 (23)	
≥50	1267 (74)	746 (72)	521 (77)	
Smoking status, <i>n</i> (%)				0.09
Current smoker	373 (22)	224 (22)	149 (22)	
Former smoker	565 (33)	355 (34)	210 (31)	
Never smoker	770 (45)	449 (44)	321 (47)	
Unknown	5 (0.3)	4 (0.4)	1 (0.1)	
Total chronic conditions ^b , mean (SD)	3.68 (1.95)	3.56 (1.93)	3.87 (1.98)	-0.16
Mental health conditions				
Anxiety	1004 (59)	594 (58)	410 (60)	-0.05
Depression	1081 (63)	622 (60)	459 (67)	-0.15
PTSD, <i>n</i> (%)	972 (57)	570 (55)	402 (59)	-0.08
Mental health service, prior 30 days, <i>n</i> (%)	594 (35)	346 (34)	248 (36)	-0.06
Type of chronic pain				
Back pain	1214 (71)	745 (72)	469 (69)	0.07
Joint pain	1336 (78)	793 (77)	543 (80)	-0.07
Neck pain	641 (37)	390 (38)	251 (37)	0.02
Musculoskeletal chest	212 (12)	116 (11)	96 (14)	-0.09
Fibromyalgia	111 (6.5)	70 (6.8)	41 (6.0)	0.03
Other pain	635 (37)	378 (37)	257 (38)	-0.02
Pain clinic visit, prior 30 days, <i>n</i> (%)	263 (15)	154 (15)	109 (16)	-0.03
Whole health use, prior 30 days, <i>n</i> (%)	342 (20)	220 (21)	122 (18)	0.09
Physical therapy use, prior 30 days, <i>n</i> (%)	508 (30)	308 (30)	200 (29)	0.01

^a Not mutually exclusive; patients may have used more than one CIH therapy.

^b Subset of Elixhauser¹³.

Abbreviations: CIH = complementary and integrative health; MSK Chest Pain = musculoskeletal chest pain; PTSD = post-traumatic stress disorder; SD = standard deviation; SMD = standardized mean differences.

between patients reporting early perceived effectiveness associated with CIH use at baseline and those who did not report any improvement with initial CIH use. Standardized mean differences for non-categorical variables were calculated as the mean difference scaled by the sample variances. For categorical

variables, an extension of the standardized mean difference based on the Mahalanobis distance was used.³⁴ Differences between exposure groups on binary and categorical variables can also be easily assessed by directly comparing reported counts/percentages. Total self-care CIH therapy utilization of

Table 2. Post-baseline total 6-month utilization of Yoga, Tai Chi/Qigong, and mindfulness practices.

	Overall <i>n</i> = 1713	Perceived CIH Effectiveness at Baseline <i>n</i> = 1032	No Perceived CIH Effectiveness at Baseline <i>n</i> = 681
All Mind and Body CIH Therapy Sessions Combined (<i>n</i>)			
Mean	11	12	10
Median	9	9	7
25th percentile	5	6	3
75th percentile	14	14	12
Minimum	1	1	1
Maximum	168	168	81
Yoga			
Mean	3	2	3
Median	0	0	0
25th percentile	0	0	0
75th percentile	4	3	5
Minimum	0	0	0
Maximum	93	93	72
Meditation			
Mean	6	6	5
Median	6	6	4
25th percentile	3	3	1
75th percentile	9	9	8
Minimum	0	0	0
Maximum	74	74	29
Tai Chi/Qigong			
Mean	2	2	2
Median	0	0	0
25th percentile	0	0	0
75th percentile	2	1	2
Minimum	0	0	0
Maximum	62	52	62

yoga, Tai Chi/Qigong, and mindfulness meditation were summed across the 6-month study period (Table 2). To estimate how baseline perceptions of CIH effectiveness and other demographic and clinical characteristics influenced total utilization of self-care CIH modalities, we fit a linear regression model with total number of self-care CIH sessions as the outcome and an indicator for positive perceptions of effectiveness as the primary exposure of interest (model 1).³⁵ Additional covariates described in the *Other Covariates* section were included primarily as adjustment factors.

We also examined whether positive perceptions of CIH therapy effectiveness at baseline were associated with high use of self-care CIH modalities using a logistic regression model. In this model, an indicator for whether the individual was in the highest 75th quartile of self-care CIH utilization was the outcome and an indicator for positive perceptions of effectiveness at baseline was the exposure of interest, with adjustment made for the covariates described in the *Other Covariates* section (model 2). This level was selected to have a group size of at least 25% of our sample. Notably, there is no current consensus on what level of dose or duration is considered “high use” for the CIH therapies we evaluated.^{8,36–38}

Based on the linear regression model (model 1), we estimated variable importance as the difference between the R^2 from the full model and the R^2 from the model that excluded that variable.³⁹ Sensitivity analysis was performed using a negative binomial regression model, adjusting for the same set of covariates as in the linear regression model. We calculated 95% confidence intervals for this variable importance measure using the

nonparametric bootstrap with 10 000 replications. All analyses were conducted in R version 4.1.1 using the `gtsummary`⁴⁰, `tidyverse`⁴¹, and `targets`⁴² R packages.

Results

Among the 1713 participants reporting baseline use of self-care CIH therapies, 28% were female, mean age was 55 years, 78% reported having joint pain, 71% having back pain, 37% having neck pain, and 47% reporting additional types of pain including musculoskeletal chest pain or fibromyalgia (Table 1). Meditation practice was the most commonly used self-care CIH therapy, with 78% of participants indicating its use at study entry; 46% reported using yoga, and 34% reported using Tai Chi/Qigong.

A total of 1032/1713 (60%) reported their baseline CIH therapy use was associated with improvement in at least one domain, while the remaining 681 (40%) patients reported no improvement in any domain (Table 2). Patients who reported improvements with baseline CIH therapy use, and those who did not, were similar across most demographic and clinical characteristics with the exception that older patients, white patients, and patients with higher levels of education were more likely to report initial improvements associated with CIH use at baseline (Table 1). Notably, patients using meditation practices were more likely to report early improvements with CIH therapy use at baseline, while patients using Tai Chi/Qigong were least likely to report early improvements.

Total self-care CIH therapy used during the 6-month follow-up period varied. Participants used a mean of 11 sessions, with patients in the lowest 25th quartile of utilization using five sessions and patients in the highest 75th quartile using 14 (Table 2). The maximum number of sessions reported was 168 over the 6-month follow-up period.

Overall, recent use of physical therapy at baseline was the strongest factor influencing overall CIH therapy utilization, with Veterans reporting recent physical therapy use going on to use an average of 4.09 (95% CI 2.83 to 5.35) more self-care CIH therapy sessions than Veterans without recent use of physical therapy (Table 3 and Figure 2). Age was the second-strongest predictor, with each additional year of age associated with an increase in mean CIH therapy use of 0.13 (0.08 to 0.18) sessions (Table 3 and Figure 2). Having a positive perception of baseline CIH therapy effectiveness was the third-most important factor associated with overall CIH therapy utilization. However, the absolute strength of the association was quite small. Patients who reported a positive perception of baseline CIH therapy effectiveness went on to use an average of 2.5 (1.3 to 3.6) more CIH therapy sessions compared to Veterans who did not report any improvements at baseline (Table 3). We report the top 10 factors observed to have any association with subsequent CIH therapy use in Table 3, noting that the absolute strength of these factors on CIH therapy utilization was quite small (Figure 2).

Factors associated with total utilization were similar to factors associated with likelihood of high CIH use (14 or more CIH sessions) from model 2. One notable difference was that distance to the nearest VHA facility with a primary care clinic was not as strongly associated with high use of CIH as it was with total number of sessions.⁴³ Recent physical therapy use remained the strongest factor, increasing the likelihood that a participant would meet the high CIH use criteria during the 6-month follow-up period by a factor of 2.32 (1.81 to 2.97).

Table 3. Multivariable regression models of factors associated with CIH therapy utilization over the six-month study period.

Factor	Model 1: Total CIH Utilization Mean Difference in Total No. of Sessions (95% CI); P-value	Model 2: Likelihood of High CIH Therapy Utilization ^a Odds Ratio (95% CI); P-value
Early improvements with CIH therapy at baseline	2.5 (1.3–3.6); <.001	1.28 (1.01–1.62); .046
Age (years)	0.13 (0.08–0.18); <.001	1.03 (1.02–1.04); <.001
Distance to nearest primary care location (miles)		
≤2	<i>Reference</i>	<i>Reference</i>
>2 to ≤15	–2.1 (–4.2 to 0.10); .040	0.96 (0.63–1.48); .9
>15	–2.7 (–4.9 to –0.46); .018	1.06 (0.68–1.69); .8
PT utilization within 30 days of baseline	4.1 (2.8–5.3); <.001	2.32 (1.81–2.97); <.001
Whole health utilization within 30 days of baseline	–2.2 (–3.6 to –0.76); .003	0.66 (0.48–0.89); .007
Mental health service within 30 days of baseline	1.3 (0.03–2.5); .045	1.34 (1.03–1.72); .026
Female sex	1.8 (0.46–3.2); .009	1.40 (1.06–1.84); .019
Race		
White	<i>Reference</i>	<i>Reference</i>
Race unknown, declined, or missing	–1.4 (–4.0 to 1.1); .3	0.88 (0.49–1.52); .7
Black or African American	0.13 (–1.3 to 1.6); .9	0.96 (0.72–1.28); .8
Multiracial	–3.5 (–8.4 to 1.5); .2	0.16 (0.01–0.81); .080
Asian	–4.2 (–9.6 to 1.3); .14	0.17 (0.01, 0.85); .086
American Indian or Alaskan Native	–1.0 (–6.1 to 4.0); .7	1.56 (0.56–4.04); .4
Native Hawaiian or Other Pacific Islander	–2.7 (–7.8 to 2.5); .3	0.41 (0.06–1.48); .2
Ethnicity		
Not Hispanic or Latino	<i>Reference</i>	<i>Reference</i>
Hispanic or Latino	–0.85 (–2.8 to 1.1); .4	0.73 (0.47–1.12); .2
Ethnicity unknown, declined, or missing	0.87 (–1.9 to 3.6); .5	0.84 (0.44–1.52); .6
Education		
Four-year college or higher	<i>Reference</i>	<i>Reference</i>
High school or less	–1.6 (–3.5 to 0.25); .090	0.64 (0.42–0.97); .042
Some college	–0.33 (–1.5 to 0.88); .6	1.03 (0.81–1.33); .8
Unknown	–6.1 (–29 to 17); .6	0.00; >.9
Service-connected percentage (%)		
<50	<i>Reference</i>	<i>Reference</i>
≥50	1.1 (–0.26 to 2.4); .11	1.21 (0.92–1.61); .2
Pain type		
Back pain	–0.47 (–1.7 to 0.78); .5	0.87 (0.67–1.13); .3
Joint pain	0.30 (–1.1 to 1.7); .7	1.07 (0.81–1.43); .6
Neck pain	–0.71 (–1.9 to 0.46); .2	0.99 (0.78–1.26); >.9
Musculoskeletal chest pain	–0.85 (–2.5 to 0.85); .3	0.88 (0.62–1.25); .5
Fibromyalgia pain	1.8 (–0.49 to 4.1); .12	0.97 (0.60–1.54); >.9
Other pain	0.60 (–0.62 to 1.8); .3	1.25 (0.97–1.60); .084

^a High CIH Therapy Utilization is defined based on the overall top 75th percentile of users with at least 14 self-care CIH therapy sessions over the follow-up period. Abbreviation: CI = Confidence Interval.

Patients who reported a positive perception of baseline CIH therapy effectiveness were 1.28 (1.01 to 1.62)-times more likely to meet the high CIH use criteria.

The relative importance of having a positive perception of CIH effectiveness at baseline, and each additional adjustment factor, on long-term CIH use is described in Figure 2. The ranking of the variables is based on the amount of variance, calculated by R^2 , each variable explains from the multivariate linear regression model (Model 1). Recent physical therapy use at study entry was the most important factor ($R^2 = 0.027$), with age being the 2nd strongest factor associated with overall CIH use. Positive perception of the initial effectiveness CIH was ranked third, however, its association with variation in overall CIH use was small ($R^2 = 0.011$). Results of the sensitivity analysis using negative binomial regression produced similar rankings of the most influential factors, although the exact order of ranking of variables with low relative importance did vary.

Discussion

Pragmatic trials of pain interventions are necessary to guide real-world policies concerning how to help patients as part of

routine care and to inform efficient investment and utilization of resources. Pain outcomes, including the primary outcome of the APPROACH study, are a comparison of self-reported differences across treatment groups. In practice, patients get to choose in which therapies they engage, which will be informed by their prior experiences and perceptions on how well the therapy can help them manage symptoms. In this analysis we observed that although there was a relationship between early perceptions of CIH therapy effectiveness and overall engagement, the strength of this association was much lower than we had hypothesized; overall, early perceptions of CIH effectiveness did not strongly influence how many CIH therapy sessions patients participated in during the follow-up period.

Testing alternative approaches to pain treatments as part of routine practice in pragmatic trials has the advantage of interpreting results emerging from more realistic and generalizable settings and from a broader range of patients compared to traditional research designs which are often comprised by participants who are interested and willing to engage in randomized assignment to intervention(s).³ Though patient blinding in explanatory trials of nonpharmacological pain management approaches can potentially be

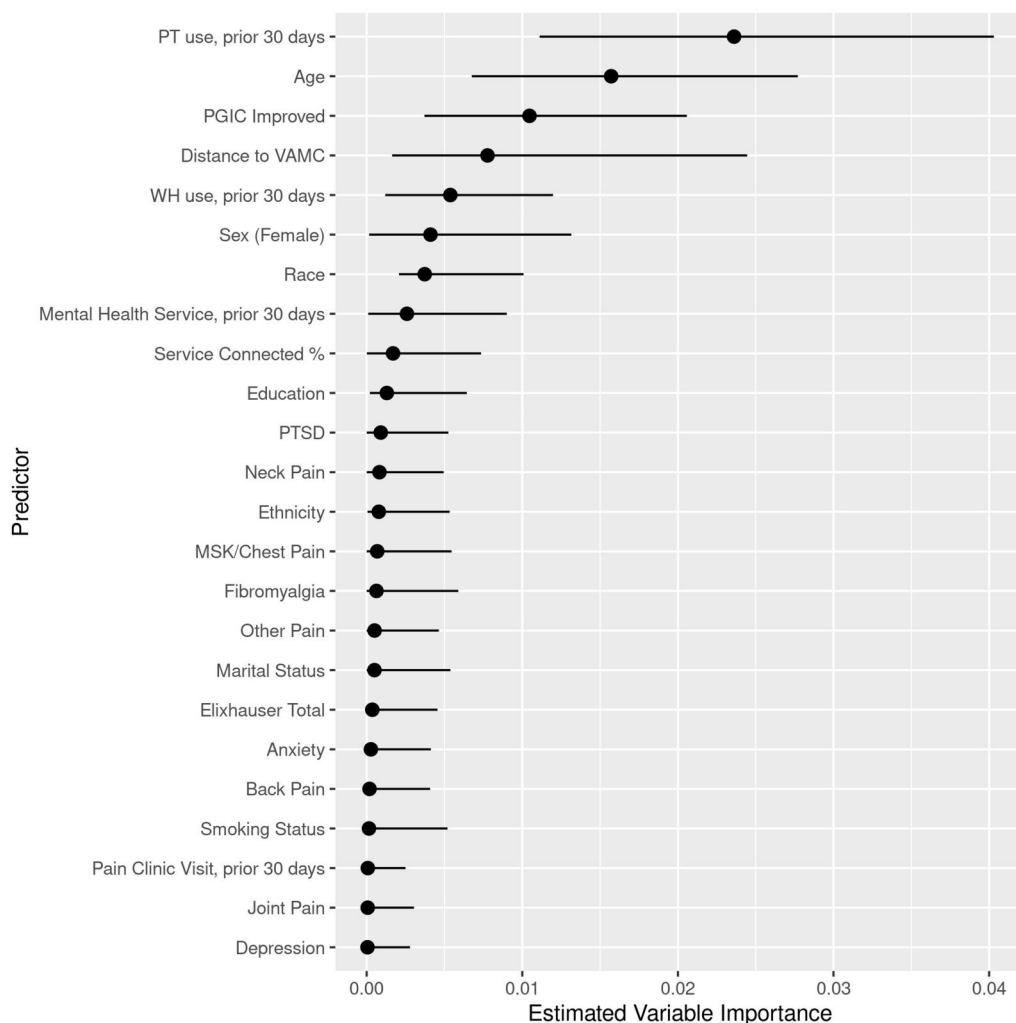


Figure 2. Ranking of factors associated with total CIH therapy utilization from model 1 during the 6-month study period by the absolute reduction in r^2 attributed to removal of the indicated variable from the regression model. Ninety-five percent confidence intervals around estimated variable importance were based on 10 000 bootstrap resamplings.

feasible in some situations, studies in which blinding is not possible may have reduced credibility while also introducing confounding factors such as clear knowledge of which therapy participants have been assigned.^{11, 44} The APPROACH study has the unique opportunity to test the effectiveness of a healthcare system offering self-care CIH therapies in combination with provider-delivered CIH therapies which are more similar to other healthcare services. The pragmatic nature of how these treatments are being offered as part of routine care means that patients may discontinue self-care therapy before participating sufficiently enough for the therapy to be effective. As uptake of CIH therapies by Veterans, and particularly those with chronic musculoskeletal pain, receiving VHA healthcare has significantly increased during VHA expansion of its Whole Health System of Care²¹, it is critical to define whether initial perceptions of effectiveness influence longitudinal utilization.

While patient perception of improvement represented the third-highest relative importance value, it only accounted for a small amount of variance in CIH utilization. A review of 168 trials of yoga explored factors associated with adherence and dropout.⁸ This review observed that many trials had high adherence rates with average overall adherence over

88%, although patient characteristics including age, gender and comorbidity, as well as protocol designs, influenced adherence. A review examining engagement strategies in online mindfulness programs of 19 studies representing over 36 000 individuals describes a range of adherence to mindfulness protocols.³⁷ This review noted that a wide range of engagement and adherence definitions were used across the studies, and observed that poorer psychological well-being at baseline was associated with dropout. This review concluded that more careful assessments of adherence are required in future studies to fully understand the role of adherence in the success of interventions.

Results of our analysis imply that Veterans remain open to trying new or similar therapies despite past experiences. CIH therapies can look different depending on the setting, theoretical perspective, and mode of delivery, which may promote re-engagement with these therapies.^{8, 37} Moreover, a Veteran may lose interest and discontinue a particular CIH therapy due to perceptions of non-improvement, especially if there are multiple sources of friction with continued participation. For instance, a Veteran with perceived non-improvement with yoga may be more likely to discontinue if there is a need to drive a significant amount of time to and from class.

Conversely, Veterans may identify other reasons for continuing to engage in CIH such as comradery and social connection, highlighting a complex relationship between perceived benefits and other factors with engagement in CIH therapies, especially when considering tradeoffs with ease of at-home therapies vs. unique factors associated with in-person therapies.⁴⁵

In addition, although the effect was small, a change in 2.5 sessions of any CIH therapy is potentially meaningful as it reflects more than a 20% increase in engagement associated with perceived effectiveness. Evaluations of costs associated with pain management programs highlight that low-cost efforts to increase engagement are critical.³⁸ These findings support that addressing perceived effectiveness at baseline when offering self-care therapies and targeting adherence efforts based on initial perceptions may be a low-cost way to tailor and encourage ongoing engagement, especially to those patients—including the over 40% in our analysis who reported they did not perceive the therapies to be effective—who are at higher risk of discontinuing.

A review of pragmatic trials in contexts other than pain highlighted the importance of standardizing treatment protocols to ensure valid inference.^{8,11,36–38,46} While providers at the 18 medical centers in the APPROACH study encouraged continued engagement in self-care CIH therapies, standardizing these therapies is challenging. Therefore, the focus of the APPROACH study was on testing these therapies as they would be delivered and standardized in routine practice. One critical aspect of standardization of CIH therapies is around dose and intensity or frequency of utilization. These data provide important insights into typical patterns of CIH therapy use in real-world contexts, which include the expanded offerings through apps, self-guided recordings, virtual groups, YouTube, and other online tools.

An additional lesson from this analysis is on the potential implications of including important confounders that may lead to imbalance in treatment arms or in engagement in care within treatment arms as highlighted in a recent review of real-world pain treatment evaluations.⁴⁷ Although data analysis for the APPROACH study is ongoing and primary outcomes are not yet available, unmeasured differences in early perceptions of care is a potentially important factor likely to influence long-term self-report pain outcomes.^{48,49} Notably, with about half of patients in the self-care arm reporting favorable early perceptions and half not reporting any initial benefit, we will be able to compare how this aligns with the comparison group of provider-delivered therapies only. One of the core hypotheses of the APPROACH study is that self-care CIH therapies help engage patients in having a role in reducing interference from pain and improving self-efficacy and pain outcomes, as provider-delivered therapies may reinforce the concept that pain needs to be “fixed” by “external” repair or agents.^{48–55} The collection of baseline perceptions allows the APPROACH study to directly assess the role of perceptions of CIH therapies not only on engagement in those therapies but also on longer-term outcomes and mechanisms. Our ability to insert specific CIH therapies which patients indicated they had recently used through the electronic survey format is a novel approach attempting to connect specific beliefs with specific treatment components, and provides a potential model for future studies.

Limitations include how we defined perceptions of initial improvement. By including individuals with improvement on any of the 4 PGIC indicates, we are including Veterans who

improved on only one or two indicators in the improved group. However, results indicate this is a small group, and most Veterans reported improvement in at least three indicators (Figure 1). Patients participating in the pragmatic study and this analysis were identified as newly initiating one of the six priority CIH therapies. These patients were not randomly assigned to the therapy that led to their entry into the study. There were many potential pathways to their initiation of therapy such as responding to postings about newly available therapies at their medical center, referral from a primary care or pain clinic provider, or word of mouth from other Veterans, among others. Additionally, although electronic medical records were assessed to identify patients newly initiating a CIH therapy with no indication of use in the prior 6 months, this assessment was based only on information captured in the electronic medical record. Some patients may have been using self-care therapies outside of VHA.²⁰ For these individuals, responses to the PGIC measures may have included perceptions of their prior use of CIH therapies as well as perceptions about their recent utilization of the self-reported therapies. Sex was assessed using information from the electronic medical record and only included categories for male and female, and future studies should incorporate gender identity.

This real-world pragmatic study demonstrated that there is considerable variation in utilization of self-care CIH therapies when offered and encouraged by healthcare systems for management of chronic pain. Surprisingly, initial perceptions of perceived benefit of the therapies, which are typically not measured, were not a strong factor in predicting long-term adherence in this large study. Underlying structures such as distance and ease of access, and co-occurring utilization of physical therapy were more strongly associated with longitudinal use of self-care CIH therapies.

Data availability

The United States Department of Veterans Affairs (VA) places legal restrictions on access to Veteran’s health care data, which includes both identifiable and de-identified data, and sensitive patient information. The datasets generated and analyzed in this study are derived from the Veterans Health Administration (VHA) Corporate Data Warehouse and stored in the Patient-Centered Wellbeing Measure and Health Data Repository, which is managed by VA Puget Sound. The analytic data sets used for this project are not permitted to leave the data repository and VA firewall without a Data Use Agreement (DUA). This limitation is consistent with other studies based on VA data. However, VA data are made freely available to investigators behind the VA firewall with an approved VA study protocol. The programming code generated by this study is available to facilitate reproducibility of study findings by supporting the extraction and transformation of identical data from VA data sources. Study authors can make the programming code available upon request. For more information about data access within VA, please visit <https://www.virec.research.va.gov> or contact the VA Information Resource Center (VIREC) at VIREC@va.gov.

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