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Telehealth and Online Cognitive Behavioral Therapy–Based Treatments for High-Impact Chronic Pain
A Randomized Clinical Trial

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IMPORTANCE Cognitive behavioral therapy (CBT) skills training interventions are recommended first-line nonpharmacologic treatment for chronic pain, yet they are not widely accessible.

OBJECTIVE To examine effectiveness of remote, scalable CBT-based chronic pain (CBT-CP) treatments (telehealth and self-completed online) for individuals with high-impact chronic pain, compared with usual care.

DESIGN, SETTING, AND PARTICIPANTS This comparative effectiveness, 3-group, phase 3 randomized clinical trial enrolled 2331 eligible patients with high-impact chronic musculoskeletal pain from 4 geographically diverse health care systems in the US from January 2021 through February 2023. Follow-up concluded in April 2024.

INTERVENTIONS Participants were randomized 1:1:1 to 1 of 2 remote, 8-session, CBT-based skills training treatments: health coach–led via telephone/videoconferencing (health coach; n = 778) or online self-completed program (painTRAINER; n = 776); or to usual care plus a resource guide (n = 777).

MAIN OUTCOMES AND MEASURES The primary outcome was attaining or exceeding the minimal clinically important difference (MCID) in pain severity score (≥30% decrease; score range, 0-10) on the 11-item Brief Pain Inventory–Short Form from baseline to 3 months; 6 and 12 months from baseline were secondary time points. Secondary outcomes at 3, 6, and 12 months included pain intensity, pain-related interference, PROMIS (Patient-Reported Outcomes Measurement Information System) social role and physical functioning; and patient global impression of change.

RESULTS Among 2331 eligible randomized individuals (mean age, 58.8 [SD, 14.3] years; 1712 [74%] women; 1030 [44%] rural/medically underserved), 2210 (94.8%) completed the trial. At 3 months, the adjusted percentage of participants achieving 30% or greater decrease in pain severity score was 32.0 (95% CI, 29.3-35.0) in the health coach group, 26.6 (95% CI, 23.4-30.2) in the painTRAINER group, and 20.8 (95% CI, 18.0-24.0) in the usual care group. Both intervention groups were significantly more likely to attain an MCID in pain severity compared with control (health coach vs usual care: relative risk [RR], 1.54 [95% CI, 1.30-1.82]; painTRAINER vs usual care: RR, 1.28 [95% CI, 1.06-1.55]), and the health coach program was more effective than the online self-completed painTRAINER program (health coach vs painTRAINER: RR, 1.20 [95% CI, 1.03-1.40]). Statistically significant benefits were observed for both intervention groups vs usual care at 6 and 12 months after randomization for the pain severity outcomes and for other secondary pain and functioning outcomes.

CONCLUSIONS AND RELEVANCE Remote, scalable CBT-CP treatments (delivered either via telehealth or self-completed modules online) resulted in modest improvements in pain and related functional/quality-of-life outcomes compared with usual care among individuals with high-impact chronic pain. These lower-resource CBT-CP treatments could improve availability of evidence-based nonpharmacologic pain treatments within health care systems.

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Supplemental content

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Approximately 8.5% of US adults experience high-impact chronic pain (pain lasting 3 months or longer and accompanied by at least 1 major life or work-related activity limitation).[1,2] High-impact chronic pain is more prevalent among rural populations, who also experience greater pain-related disability, depression, and difficulties accessing health care services compared with those in urban regions.[1,3,4] Cognitive behavioral therapy (CBT) is a widely accepted and effective nonpharmacologic treatment for chronic pain,[5] with benefits among low-literacy, rural populations.[6] Calls for wider implementation of CBT for chronic pain (CBT-CP) recognize that barriers exist at patient, clinician, and health care system levels, notably the paucity of appropriately trained clinicians and their concentration in urban areas.[7-9]

Telehealth and online treatment programs offer ways to increase access to CBT-CP,[7,10-14] and overall use and acceptability of remote services for chronic disease management have increased markedly since the COVID-19 pandemic.[15-17] Prior studies have demonstrated clinically meaningful benefits of telephone-based CBT-CP in the context of multicomponent interventions.[12,18,19] Online CBT-CP programs have also demonstrated effectiveness for reducing pain and pain-related impairment.[14,20,21] Remote treatment is promising for lowering costs; overcoming patient, clinician, and system barriers; and having greater safety compared with pharmacologic pain treatments.[14,20-22]

The RESOLVE randomized clinical trial (RCT) examined the comparative effectiveness of 2 remote interventions for delivering CBT-CP (a health coach–led telephonic/video-conferencing program and a self-completed online program) at improving pain-related outcomes and functioning for patients with high-impact chronic pain, compared with one another and with usual care. As a pragmatically oriented RCT, the study was designed to compare the added value of treatment strategies delivered under routine clinical practice conditions with usual medical care.[23] The study hypothesis was that both remote CBT-CP interventions would result in improved pain-related outcomes compared with usual care.

Key Points

Question How effective are remote, scalable cognitive behavioral therapy skills training programs for chronic pain (CBT-CP) for individuals with high-impact chronic pain?

Findings In this randomized clinical trial that included 2331 participants, both the telephonic/video health coach–led and the online self-completed CBT-CP programs resulted in a significantly greater proportion of participants achieving at least 30% improvement from baseline in pain severity at 3 months compared with usual care. Intervention benefits were sustained at 12 months, and the 3-month outcome was better for those in the health coach group vs the online self-completed program.

Meaning These remote, scalable CBT-CP programs are effective for treating individuals with high-impact chronic pain.

Methods

Study Design and Participants

The RESOLVE RCT was approved by the Vanderbilt University Medical Center institutional review board. A waiver of written informed consent was granted and informed consent was obtained (verbally or electronically) from all participants. This phase 3, comparative effectiveness, parallel-group design RCT randomized patients in equal ratio to 1 of 3 study groups. One group received 8 one-on-one sessions with a health coach via telephone or video conference. The second group self-completed an 8-session, online CBT-CP program (painTRAINER). The health coach and online CBT-CP programs had similar content. The third group (usual care plus) received a mailed copy of the *American Chronic Pain Association Resource Guide to Chronic Pain Management*.[24] The trial protocol is included as Supplement 1 and has been published[25]; the statistical analysis plan is included as Supplement 2. The CONSORT (Consolidated Standards of Reporting Trials) guidelines were followed.[26] Participants were recruited from January 2021 through February 2023. Follow-up occurred from April 2021 to April 2024.

Recruitment occurred at 4 health care systems: (1) Kaiser Permanente Georgia, serving northern Georgia; (2) Kaiser Permanente Northwest, serving Oregon and southwest Washington; (3) Kaiser Permanente Washington, serving Washington and Idaho; and (4) Essentia Health, serving northern Minnesota, eastern North Dakota, and northern Wisconsin. Eligible participants were 18 years or older, English-speaking, receiving care in the health care system for the past year, had internet/telephone access, and met the following clinical criteria based on electronic health record data (ie, *ICD-10-CM* [*International Classification of Diseases, Tenth Revision, Clinical Modification*] codes) and self-report:

1. One or more (Essentia) or 2 or more (Kaiser Permanente) outpatient encounters more than 60 days apart for nonmalignant musculoskeletal pain[27] within the past 360 days
2. High-impact chronic pain determined by the Graded Chronic Pain Scale–Revised[28]
3. Pain score 12 or greater on the PEG (Pain, Enjoyment of Life, General Activity) scale (a 3-item scale assessing pain intensity and interference,[29] scored as sum of items; total range, 0 to 30; higher score indicates worse pain)
4. No surgery encounter for common musculoskeletal pain conditions within the past 60 days
5. No malignant cancer diagnosis (except nonmelanoma skin cancer) within the past 60 days
6. No hospice or palliative care within the past 360 days
7. No CBT, psychoeducation, or behavioral skills training for pain management within the past 6 months or currently/next month
8. No inpatient or intensive outpatient services for substance use disorders currently/next month
9. No planned/scheduled surgery related to pain condition within the next 12 months

Each month during the 26-month recruitment period, sites queried their electronic health record virtual data warehouses to identify potentially eligible patients, who were then

randomly sampled with stratification by urban vs rural/medically underserved residence (based on census tract/geocoded data).[30,31] The monthly sample was mailed a recruitment letter and, if feasible, sent an email approximately 5 days later and followed up with telephone calls. Patients completed the eligibility screening, which assessed for high-impact chronic pain, technology access, and current or planned therapies, either by telephone or via the study website. If eligible, patients completed the informed consent by telephone or web at that time or scheduled a later time to complete the consent. The baseline assessment could be completed following consent either by telephone with research staff or via a Research Electronic Data Capture (REDCap) survey. Further details regarding recruitment are provided in the published protocol.[25]

After completing the baseline assessment, participants were individually randomized in a 1:1:1 ratio, stratified by sex, baseline pain severity score (<7 vs ≥7), clinical site, and rural or medically underserved residency (yes vs no). Within each stratum a random permutated block design was used with random variable block sizes of 3, 6, or 9. The National Institutes of Health (NIH), Helping to End Addiction Long-term (HEAL), Pain Management Effectiveness Research Network statistical and data coordinating center biostatisticians (R.E.T., T.C.C.) developed and implemented the randomization scheme, which was integrated into and occurred within the study's secure, web-based, electronic data capture system at baseline REDCap survey completion. The research staff conducting eligibility assessments and enrollment were blinded to group assignments, as were outcome assessors.

Interventions

All groups could receive pain treatment as usual. Intervention descriptions are provided in Supplement 3 using the TIDieR (Template for Intervention Description and Replication) guideline.[32] The 8-session CBT-CP interventions are based on programs developed[33-38] and refined[39,40] by 2 authors (L.L.D., F.J.K.) in prior studies.

Health Coach Program

The health coach program included 8 sessions of CBT-CP-based skills training provided one-on-one via either telephone or videoconferencing per participant preference. The 12 health coaches had master's-level behavioral health training (without previous training in chronic pain management) and were centrally based at the Kaiser Permanente Northwest and Kaiser Permanente Washington clinical study sites, enabling consistent and efficient supervision and fidelity monitoring. Sessions, scheduled at the participant's convenience, lasted about 45 to 60 minutes, with approximately 1 per week. Participants were asked to complete all 8 sessions within the 12 weeks following randomization.

Online Program

The painTRAINER program is an online, 8-session, CBT-CP-based skills training program that can be accessed free of charge at https://mypaintrainer.org. Each session requires approximately 30 to 45 minutes to complete and provides interactive training in 1 or more evidence-based pain-coping skills. When the RESOLVE study began in 2021, prior efficacy and feasibility studies had demonstrated high acceptability and efficacy of painTRAINER in reducing pain among populations with pain related to osteoarthritis or systemic lupus erythematosus in the rural US[35,41] and Australia.[42] RESOLVE participants self-completed approximately 1 session per week, with all 8 intended to be completed within 12 weeks after randomization. Participants were assisted in registering via an individual onboarding telephone call and had access to the program for the year of study participation. Research staff also provided technical support and outreach to encourage engagement if session completion differed from the recommended completion schedule in prespecified ways (eg, >10 days since the last session was completed or ≥3 sessions completed in 9 days). No treatment content guidance was provided during these contacts.

Usual Care Plus

Participants in this group received a mailed copy of the *American Chronic Pain Association Resource Guide to Chronic Pain Management,* 2020 edition.[24] The guide provides comprehensive information describing a broad range of pain management modalities, such as medications; nutrition; exercise; complementary, alternative, and integrative medicine; and biopsychosocial strategies. The guide aims to inform individuals in making treatment decisions with their clinician and does not advise on treatments.

Main Outcomes and Measures

Primary and secondary outcomes were assessed at baseline (prerandomization) and at 3, 6, and 12 months following randomization. Outcome assessments were completed via online survey (REDCap), by telephone with study staff, or by postal mail, based on participant preference.

Primary Outcome

The primary outcome was attaining or exceeding a minimal clinically important difference (MCID) in pain severity, defined as a 30% or greater decrease in pain score[43] from baseline (prerandomization) to 3 months. Pain severity score, a composite of pain intensity and pain-related interference, was measured by an 11-item version of the Brief Pain Inventory-Short Form (BPI-SF), which has demonstrated reliability and validity.[44-47] The score is the calculated mean of all 11 items; the range is 0 to 10, with a higher score indicating worse pain severity. All 4 items of the pain intensity subscale and at least 4 of the 7 items in the pain-related interference subscale were required to score pain severity. Secondary time points for the primary outcome were 6 and 12 months following randomization.

Secondary Outcomes

Secondary outcomes included attaining or exceeding an MCID (30% improvement in score from baseline) in pain intensity and pain-related interference scores (4-item and 7-item subscales of the BPI-SF, respectively; range, 0-10, with higher scores indicating worse pain intensity or interference).

Additionally, changes in continuous score for pain severity, pain intensity, and pain-related interference were assessed at the 3 follow-up time points from baseline. Social role functioning was assessed using the 4-item Patient-Reported Outcomes Measurement Information System (PROMIS) Ability to Participate in Social Roles 4A,[48] and physical functioning was assessed using the 6-item PROMIS Physical Functioning Short Form 6b. Patient global impression of change was assessed for both pain and overall status using a modified 7-point scale (Guy/Farrar-Patient Global Impression of Change scale).[49,50] See Supplement 4 for secondary outcome ranges and cut points.

Sample Size

The planned sample size of 2331 (777 per group) was designed to have 90% power to detect a difference of 7.5% (1.5 relative risk [RR]) between each intervention group relative to the usual care plus group in the proportion of individuals who attain an MCID in pain severity at 3 months (primary time point). We assumed a 15% usual care outcome rate and 80% retention rate and controlled for multiple comparisons using the Fisher least significant difference method.[51] Power calculations were performed via 10 000 simulations using Modified Poisson regression in R version 3.6.2.[52,53]

Statistical Analysis

The intention-to-treat principle was used for all analyses.[54] For the primary analysis comparing study groups on MCID in pain severity (binary outcome), we applied modified Poisson regression[53] to estimate adjusted RRs and 95% CIs. Generalized estimating equations (GEE) with a working independence correlation matrix and robust sandwich standard errors were used to account for clustering at the highest level (either within-person or within-health coach).[53,55,56] The model included indicators for the intervention groups, time points, and group × time-point interactions to estimate time-specific intervention effects. Adjustment for baseline pain severity, stratification variables (sex, clinical site, and rural/medically underserved residency), and other variables predictive of the outcome (multisite pain and co-occurring mental health condition) was prespecified. Adjusted percent improvement and 95% CI by group for each time point were further estimated by centering covariates with mean values across all participants. Adjusted number needed to treat, defined as 1 divided by the difference in adjusted percent improvement between groups, was also included to guide evaluation of the clinical meaningfulness of these binary outcome findings.

The same modeling structures were applied to secondary outcomes but with added adjustment for the given baseline secondary outcome. For continuous secondary outcomes, linear regression with GEE was applied to estimate within group adjusted means and 95% CIs; between group adjusted mean differences and 95% CIs; and between group adjusted standardized mean differences (SMDs) for all time points. Adjusted SMD is defined as the adjusted mean difference divided by the standard deviation of the change in outcome among the usual care plus group for a given time point[57] (small: 0.2-0.5 SMD, moderate: >0.5-0.8 SMD, large: >0.8 SMD[5]).

Missing outcome data for the primary analysis were addressed in 3 ways: (1) prespecified adjustment; (2) nonignorable pattern mixture imputation among those with at least 1 follow-up time point[58]; and (3) inverse probability of missing weighting to account for individuals with no follow-up measurements (eTables 1-6 and eFigure 2 in Supplement 4). Missing covariate data were imputed using mean imputation.[59] Sensitivity analyses related to missingness were also planned and conducted (eTable 7 in Supplement 4). All analyses were performed using R version 4.4.1[52] on Windows 10, and all statistical tests were 2-sided with $\alpha = .05$.

Results

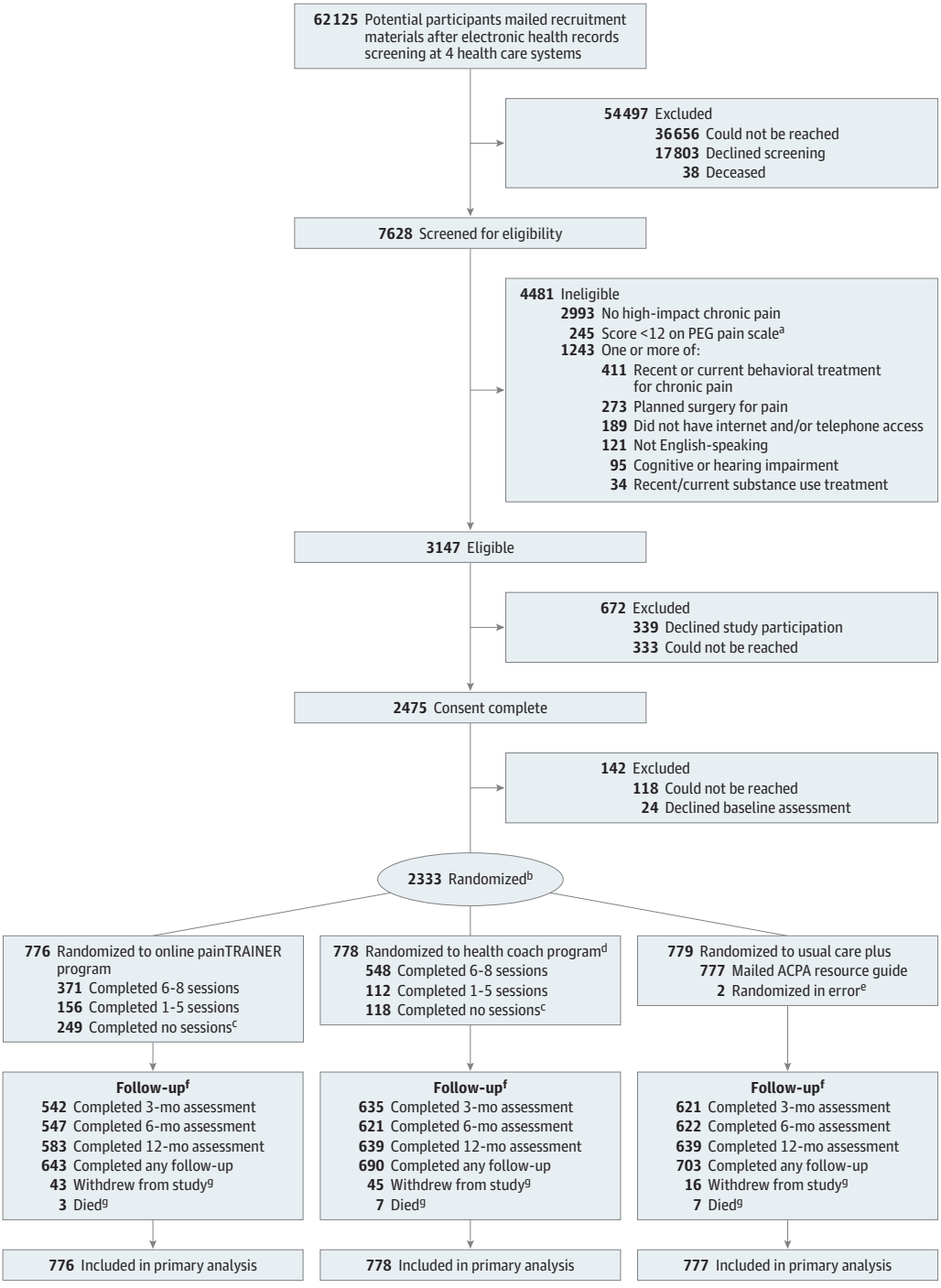
Among 7628 individuals screened for eligibility, 2331 were eligible and randomized; of these, 2210 completed the trial (**Figure 1**). Main reasons for exclusion were failing to meet criteria for high-impact chronic pain (n = 2993) and recent or current behavioral treatment for chronic pain (n = 411). The follow-up assessment completion rate was approximately 6% to 7% lower overall for the painTRAINER group (643 [83%] with any follow-up assessment) than for the other 2 groups (690 [89%] for health coach and 703 [90%] for usual care plus with any follow-up assessment) and 10% lower in painTRAINER than the other 2 groups at the 3-month primary time point (painTRAINER, 70%; health coach, 82%; usual care plus, 80%). Of those randomized to the painTRAINER group, 527 (68%) completed at least 1 session and 371 (43%) completed at least 6 sessions (therapeutic dose). Of those randomized to the health coach group, 660 (85%) received at least 1 session, with 548 (70%) completing at least 6 sessions. See eFigure 1 in Supplement 4 for more detailed session completion data.

Baseline characteristics were similar across groups (**Table 1**), with almost 40% of participants 65 years or older (mean, 58.8 [SD, 14.3] years), 74% women, 75% White non-Hispanic, 44% residing in rural or medically underserved regions of the country, and 33% reporting negative social determinants of health (Supplement 5). Most individuals (73%) had multiple pain-related musculoskeletal conditions (mean, 2.5 [SD, 1.3]), and 25.5% reported high levels (BPI-SF score ≥7) of pain severity. In addition, 47.8% had current depression, defined as a score of 10 or greater on the PHQ-8 (8-item Patient Health Questionnaire Depression Scale); 27.8% had moderate-to-severe anxiety, defined as a score of 10 or greater on the GAD-7 (Generalized Anxiety Disorder 7-Item scale); and 43.3% reported at least moderate sleep disturbance. Long-term opioid treatment (9.6%) was relatively uncommon among those at clinical sites reporting pharmacy dispense information (Supplement 5).

Primary Outcomes

At 3 months the groups differed significantly ($P < .001$) in adjusted percentage of participants who attained or exceeded the MCID in pain severity (usual care plus, 20.8% [95% CI, 18.0%-24.0%]; painTRAINER, 26.6% [95% CI, 23.4%-30.2%]; health

Figure 1. Flow of Participants Through Trial



ACPA indicates American Chronic Pain Association.

[a]Pain, Enjoyment of Life, General Activity (PEG) scale assessing pain intensity and interference, calculated as sum of 3 items (each 0-10; total scale range, 0-30; higher score worse). Eligibility screening was tiered. Individuals without high-impact chronic pain were not asked the PEG questions. Those without PEG score ≥12 were not asked the other questions about behavioral treatment and planned surgery. [b]Randomization stratified by sex (male vs female), clinical site, baseline pain severity score (<7 vs ≥7), and rural/medically underserved residency (yes vs no). [c]Of 249 (painTRAINER): 13 withdrew, 1 became incarcerated, and 2 died; 233 remained in study but 212 could not be reached during the treatment period, 8 no longer interested in intervention, 5 had other health/life issues, 3 did not like intervention services, 3 gave no reason, and 2 did not have time. Of 118 (health coach): 16 withdrew and 1 died; 101 remained in study but 74 could not be reached, 16 did not have time, 3 had other health/life issues, 3 gave no reason, 2 did not like intervention services, 2 no longer interested, and 1 had privacy concerns. [d]Twelve treatment providers delivering intervention; median number of patients treated by each, 69 (IQR, 52-76) (range, 24-110). [e]Did not meet the electronic health records–based eligibility criteria. [f]Patients were assessed at follow-up regardless of number of sessions completed. [g]May have completed follow-up assessment(s) prior to the event and would consequently be counted as having completed any follow-up.

Table 1. Baseline Characteristics of RESOLVE Study Participants by Study Group

Characteristic	No./total (%)		
	painTRAINER (n = 776)	Health coach (n = 778)	Usual care plus (n = 777)
Demographics			
Age, mean (SD), y[a]	58.8 (13.9) [n = 776]	58.8 (14.5) [n = 778]	58.8 (14.3) [n = 777]
Age ≥65 y[a]	291/776 (37.5)	305/778 (39.2)	304/777 (39.1)
Sex[b]			
Female	571/776 (73.6)	572/778 (73.5)	569/777 (73.2)
Male	205/776 (26.4)	206/778 (26.5)	208/777 (26.8)
College degree or higher[c,d]	332/770 (43.1)	347/767 (45.2)	344/770 (44.7)
Not employed[c,d]	400/769 (52.0)	416/771 (54.0)	418/769 (54.4)
Household income <$50 000[c,d]	266/671 (39.6)	217/643 (33.7)	251/681 (36.9)
Married or domestic partnered[c,d]	484/761 (63.6)	512/768 (66.7)	511/771 (66.3)
Race and ethnicity[c,d,e]			
American Indian/Alaska Native	6/751 (0.8)	11/760 (1.4)	11/755 (1.5)
Asian	10/751 (1.3)	6/760 (0.8)	11/755 (1.5)
Black or African American non-Hispanic	119/751 (15.8)	118/760 (15.5)	113/755 (15.0)
Hispanic	21/751 (2.8)	26/760 (3.4)	30/755 (4.0)
Native Hawaiian/other Pacific Islander	1/751 (0.1)	0/760	1/755 (0.1)
White non-Hispanic	573/751 (76.3)	572/760 (75.3)	554/755 (73.4)
≥1 race	21/751 (2.8)	27/760 (3.6)	35/755 (4.6)
Rural/medically underserved residency[a,f]	340/776 (43.8)	345/778 (44.3)	345/777 (44.4)
Any negative social determinant of health[c,d]	261/763 (34.2)	231/766 (30.2)	266/769 (34.6)
Financial resource strain	198/770 (25.7)	170/771 (22.0)	199/771 (25.8)
Housing instability	134/766 (17.5)	101/763 (13.2)	129/767 (16.8)
Food insecurity	116/769 (15.1)	100/773 (12.9)	117/768 (15.2)
Transportation insecurity	57/772 (7.4)	56/774 (7.2)	57/773 (7.4)
Clinical characteristics			
Pain-related symptoms, conditions, and treatment			
Pain severity score ≥7[c,d,g]	195/776 (25.1)	199/778 (25.6)	200/777 (25.7)
Pain duration >5 y[c,d]	532/775 (68.6)	536/778 (68.9)	541/777 (69.6)
Hip, knee, or foot pain[c,d]	494/776 (63.7)	487/778 (62.6)	495/777 (63.7)
Back pain[c,d]	402/775 (51.9)	401/777 (51.6)	422/777 (54.3)
Hand, arm or shoulder pain[c,d]	298/774 (38.5)	301/778 (38.7)	284/777 (36.6)
Neck pain[c,d]	202/776 (26.0)	207/778 (26.6)	213/777 (27.4)
Widespread pain[c,d]	141/775 (18.2)	176/775 (22.7)	143/777 (18.4)
Headache or migraine[c,d]	95/775 (12.3)	131/778 (16.8)	117/777 (15.1)
Abdominal, pelvic, or genital pain[c,d]	58/775 (7.5)	73/777 (9.4)	66/775 (8.5)
Toothache or jaw pain[c,d]	37/776 (4.8)	54/777 (6.9)	52/777 (6.7)
No. of musculoskeletal pain conditions, median (IQR)[a,h]	2.0 (1-3) [n = 776]	2.0 (1-3) [n = 778]	2.0 (1-3) [n = 777]
No. of pain-related health care encounters in past year, median (IQR)[a]	6.0 (3-12) [n = 776]	6.0 (3-13) [n = 778]	6.0 (3-11) [n = 777]
Long-term opioid use[a,i]	43/569 (7.6)	60/566 (10.6)	60/562 (10.7)
Related health conditions			
Anxiety or depression diagnosis[a]	300/776 (38.7)	322/778 (41.4)	343/777 (44.1)
Moderate to severe depression[c,d,j]	373/775 (48.1)	373/777 (48.0)	370/777 (47.6)
Moderate to severe anxiety[c,d,k]	206/774 (26.6)	218/778 (28.0)	224/777 (28.8)
Moderate to severe sleep disturbance[c,d,l]	332/772 (43.0)	331/775 (42.7)	342/772 (44.3)
Substance use disorder diagnosis[a]	31/776 (4.0)	31/778 (4.0)	24/777 (3.1)
Charlson Comorbidity Index, median (IQR)[a,m]	0.0 (0-1.25) [n = 776]	1.0 (0-2) [n = 778]	1.0 (0-2) [n = 777]
Baseline primary outcome			
Pain severity (0-10), mean (SD)[d,g]	5.8 (1.6) [n = 776]	5.9 (1.7) [n = 778]	5.9 (1.6) [n = 777]

(continued)

Table 1. Baseline Characteristics of RESOLVE Study Participants by Study Group (continued)

Characteristic	No./total (%) painTRAINER (n = 776)	Health coach (n = 778)	Usual care plus (n = 777)
Baseline secondary outcome			
Pain intensity (0-10), mean (SD)[d,n]	5.4 (1.6) [n = 776]	5.6 (1.7) [n = 778]	5.5 (1.6) [n = 777]
Pain-related interference (0-10), mean (SD)[d,o]	6.0 (1.9) [n = 776]	6.0 (1.9) [n = 778]	6.1 (1.9) [n = 777]
Moderate to severe limitations in social functioning[c,p]	258/758 (34.0)	283/770 (36.8)	277/765 (36.2)
Moderate to severe limitations in physical functioning[c,q]	563/764 (73.7)	566/770 (73.5)	580/773 (75.0)

[a] Data are from the electronic health record (EHR); diagnoses are based on *International Classification of Diseases, Tenth Revision, Clinical Modification* (*ICD-10-CM*) codes.

[b] Data source was self-reported sex from study survey unless missing and then used sex from EHR.

[c] Missing values are excluded from the denominator.

[d] Data are self-reported.

[e] Race and ethnicity collected as multiple selections via self-report at baseline. Participants that responded as Hispanic (regardless of other responses) were categorized as Hispanic and those that responded with multiple races were recategorized as multiple races.

[f] Rural defined as participant's resident census tract corresponds to US Census 2010 Rural-Urban Commuting Area codes 4, 5, 6, 7, 8, 9 or 10. Medically underserved is defined as participant's resident census tract corresponds to Health Resources and Services Administration–designated primary care or mental health geographic or geographic high needs health professional shortage area.

[g] Pain Severity Score. Based on modified 11-item version of the Brief Pain Inventory–Short Form (BPI-SF). Score is calculated mean of all 11 items; range, 0 to 10, with a higher score indicating worse pain severity.

[h] Based on *ICD-10-CM* diagnoses in past year and includes the following nonmalignant musculoskeletal chronic pain conditions: back pain; neck pain; limb/extremity pain, joint pain, and arthritic disorders; fibromyalgia; headache; orofacial, ear, and temporomandibular disorder pain; musculoskeletal chest pain; general pain.

[i] Long-term opioid therapy use defined as opioid prescription fills indicating 60-day or more supply during 90 days prior to randomization. Data are reported for 3 of the 4 clinical sites. Variable could not be reported for Essentia Health site due to EHR data limitations.

[j] Eight-item Personal Health Questionnaire Depression Scale. Sum of 8 items related to depressive symptoms (each item response, 0-3), with total scale range 0 to 24; higher score indicates greater severity of depressive symptoms. Cut points = 10 (moderate), 15 (moderately severe), and 20 (severe depression).

[k] Generalized Anxiety Disorder 7-Item scale. Sum of 7 items related to anxiety symptoms (each item response, 0-3), with total scale range 0 to 21; higher score indicates greater severity of anxiety symptoms. Cut points = 5 (mild), 10 (moderate), and 15 (severe) levels of anxiety.

[l] Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance–Short Form 6a. Score by summing the 6 items (each item response, 1-5), then converting raw score to standardized T score using the HealthMeasures Scoring Service, with mean of 50 and standard deviation of 10. Higher T score indicates worse sleep disturbance. Score 60 or greater indicates moderate (60-70) to severe (>70) sleep disturbance.

[m] Charlson Comorbidity Index. Based on *ICD-10* diagnosis codes in medical record; algorithm assesses presence of 19 possible comorbid conditions (ie, diabetes, congestive heart failure) and assigns weight for each condition present (1, 2, 3, or 6) based on its potential impact on mortality and health care resource utilization. Score is calculated by summing the individual condition-specific weights. Total score range, 0 to 37; 0 represents no comorbidities, and 1 to 37 the number of comorbid conditions and their severity, with higher score indicating more severe comorbidities.

[n] Pain Intensity Score. Based on 4-item subscale of the BPI-SF. Score is calculated mean of all 4 items; range, 0 to 10, with a higher score indicating worse pain intensity.

[o] Pain-related Interference Score. Based on 7-item subscale of the BPI-SF. Score is calculated mean of 7 items; range, 0 to 10, with a higher score indicating worse pain-related interference.

[p] PROMIS Ability to Participate in Social Roles and Activities–Short Form 4a. Score by summing the 4 items (each item response, 1-5), then converting raw score to standardized T score, using the HealthMeasures Scoring Service, with mean of 50 and standard deviation of 10. Higher T score indicates better ability to participate in social roles and activities. Score 40 or less indicates moderate (40-30) to severe (<30) limitations in ability to participate.

[q] PROMIS Physical Function–Short Form 6b. Score by summing the 6 items (each item response, 1-5), then converting raw score to standardized T score, using the HealthMeasures Scoring Service, with mean of 50 and standard deviation of 10. Higher T score indicates better physical functioning. Score 40 or less indicates moderate (40-30) to severe (<30) limitations in physical functioning.

coach, 32.0% [95% CI, 29.3%-35.0%]) (**Figure 2** and **Table 2**). Participants randomized to either CBT-CP program (painTRAINER or health coach) were more likely than those randomized to usual care plus to show MCID in pain severity (painTRAINER vs usual care plus: RR, 1.28 [95% CI, 1.06-1.55]; health coach vs usual care plus: RR, 1.54 [95% CI, 1.30-1.82]). The health coach group was more likely to show a meaningful improvement in pain severity than the painTRAINER group (health coach vs painTRAINER: RR, 1.20 [95% CI, 1.03-1.40]). The statistically significant differences between each of the CBT-CP programs relative to usual care plus persisted at 6 and 12 months, with RRs similar but attenuated somewhat over time; however, differences between health coach and painTRAINER observed after treatment were no longer significant at 6 and 12 months (Table 2).

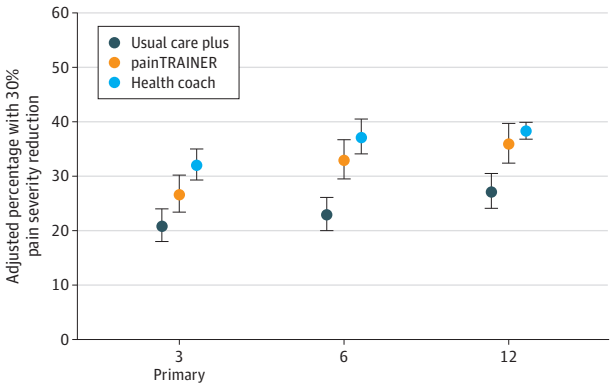
Secondary Outcomes

Overall patterns for secondary outcomes were similar to those observed for the primary outcome, with significantly better scores for both the painTRAINER and health coach groups compared with usual care plus at 3 months, persisting over 12-month follow-up with modest attenuation (Table 2 and **Table 3**). Standardized effect sizes (SMDs) of change in pain severity were modest for both the painTRAINER (3-month SMD, −0.26) and health coach (3-month SMD, −0.36) groups compared with usual care plus (Table 3).

Adverse Events

Hospitalizations occurred among 7.9% of participants (n = 183 with 247 events), and n = 17 (0.7%) deaths occurred. Rates were similar across study groups in hospitalizations (8.1% for usual

Figure 2. Adjusted Percentage With 30% or Greater Reduction in Pain Severity (Primary Outcome)



Observed No.			
Usual care plus	621	622	639
painTRAINER	542	547	583
Health coach	635	621	639

The primary outcome occurred at 3 months. Whiskers indicate 95% CIs. Adjustment of outcomes is explained in footnote b of Table 2.

care plus [n = 63 with 82 events], 7.1% for painTRAINER [n = 55 with 81 events], and 8.4% for health coach [n = 65 with 84 events]) and deaths (0.9% for usual care plus [n = 7], 0.4% for painTRAINER [n = 3], and 0.9% for health coach [n = 7]). No hospitalizations or deaths were identified as related or possibly related to study participation. Nonserious adverse events were not systematically collected and only ascertained via patient-initiated report, biasing collection to the intervention groups with more staff contact. Sixteen adverse events were reported by participants in the health coach group (2.0%); the majority were mild and unrelated to the intervention. One adverse event was reported in the painTRAINER group (0.1%), and no adverse events were reported by the usual care plus group.

Discussion

Among adults with high-impact chronic musculoskeletal pain, CBT-CP delivered by both remote formats resulted in greater improvement in pain severity after treatment (at 3 months) compared with usual care plus a resource guide and a larger effect for those in the health coach group than among those in the painTRAINER group. The modest benefit of active CBT-based interventions over usual care was sustained during longer-term follow-up (6 and 12 months), with no relative benefit observed for the health coach group compared with the painTRAINER group at these later points. Patterns of findings for secondary, broader pain outcomes as well as for patient-valued outcomes beyond pain-specific domains (ie, physical and social functioning, patient global impression of change) showed similar patterns of improvement sustained over the year of the study.

Systematic reviews and meta-analyses examining the effect of CBT for chronic pain have reported reliable, sustained, and statistically significant but modest effects.[60-62] As such, the modest sustained benefits observed here are consistent with findings from other RCTs. Trials assessing other nonpharmacologic (eg, acupuncture, mindfulness programs, exercise, and spinal manipulation)[5] and pharmacologic approaches for management of chronic pain[63,64] have reported benefits of similar magnitude. Collectively, these reviews and meta-analyses assessing chronic pain treatments suggest that CBT has reliable beneficial effects consistent with the findings reported in this trial. Because this pragmatic-oriented effectiveness trial has several features that might attenuate benefits, the findings are an important contribution. Specifically, there have been recent calls by the Centers for Disease Control and Prevention and others to focus treatment on individuals experiencing the most disabling effects of chronic pain[2,65,66]—yet, to our knowledge, this is the first trial to screen for and exclusively enroll individuals meeting criteria for high-impact chronic pain. This is a population for whom attenuation in the effect of remote CBT-based interventions might be expected, particularly when delivered in a manner congruent with everyday clinical practice (ie, limited outreach for treatment nonadherence). The active study interventions demonstrated the benefits observed in pain-related and other secondary outcomes despite lower adherence, informing understanding of the effect of offering such remote CBT programs as they would likely be delivered in clinical care.

Outcomes between the 2 remote CBT-CP programs at 6- and 12-month follow-up did not differ, suggesting that centralized delivery of either modality can be offered to patients in areas lacking clinicians with expertise in CBT-CP. Further, this suggests that painTRAINER may provide effective pain management for many patients with high-impact chronic pain. An important caveat, however, is that the intervention adherence for the online painTRAINER intervention was substantively lower than that observed in the health coach group. As a pragmatically oriented effectiveness trial, the goal was to provide onboarding and light outreach support for painTRAINER group participants that mirrors the kind of support that could reasonably be offered by a medical assistant or ancillary health care staff in a primary care setting. As such, an important aspect of the study was to provide estimates of adherence and treatment effects that could be achieved in real-world clinical settings. While other means of support could have increased adherence to the online program (eg, video visit onboarding or a guided self-help approach in which a therapist routinely checks in with the patient's progress), such approaches do not represent the most common and feasible means of providing online CBT-based programs in integrated health care systems.

This study addresses existing gaps in the CBT-CP literature. The focus on patients with high-impact chronic pain is important because it characterizes individuals for whom pain-related functional limitations are marked and who have often tried several pain-related treatments without success. Additional strengths include the size and geographic diversity of the sample. Roughly 40% of participants were from

Table 2. Adjusted Percentage of Participants Attaining or Exceeding Minimal Clinically Important Difference (30% Improvement) in Pain Score by Treatment Group and Adjusted Relative Risk Between-Group Comparisons for the Primary and Secondary Pain Outcomes[a]

	Adjusted % with ≥30% improvement in pain score (95% CI)[b]			Adjusted RR (95% CI)[b]				Adjusted No. needed to treat (95% CI)[d,e]		
	painTRAINER (n = 643)	Health coach (n = 690)	Usual care plus (UC) (n = 703)	painTRAINER vs usual care plus	Health coach vs usual care plus	Health coach vs painTRAINER	Omnibus *P* value[c]	painTRAINER vs usual care plus	Health coach vs usual care plus	Health coach vs painTRAINER
Primary outcome										
Pain severity[f]										
3 mo[g]	26.6 (23.4-30.2)	32.0 (29.3-35.0)	20.8 (18.0-24.0)	1.28 (1.06-1.55)	1.54 (1.30-1.82)	1.20 (1.03-1.40)	<.001	18 (10-71)	9 (7-14)	19 (11-102)
Secondary outcomes										
Pain severity[f]										
6 mo	32.9 (29.5-36.7)	37.1 (34.1-40.5)	22.9 (20.0-26.1)	1.44 (1.21-1.70)	1.62 (1.39-1.90)	1.13 (0.98-1.30)	<.001	10 (7-19)	8 (6-11)	24 (12-186)
12 mo	35.9 (32.4-39.7)	38.3 (36.8-39.9)	27.1 (24.1-30.5)	1.32 (1.13-1.54)	1.41 (1.25-1.59)	1.07 (0.96-1.19)	<.001	12 (8-26)	9 (7-13)	41 (17-76)
Pain intensity[h]										
3 mo[g]	24.3 (21.2-27.8)	27.0 (24.0-30.5)	17.7 (15.1-20.7)	1.37 (1.12-1.69)	1.53 (1.26-1.86)	1.11 (0.93-1.33)	<.001	16 (10-43)	11 (8-20)	37 (14-57)
6 mo	26.9 (23.7-30.5)	31.8 (28.3-35.7)	21.1 (18.3-24.3)	1.27 (1.06-1.54)	1.51 (1.26-1.80)	1.18 (1.00-1.40)	<.001	18 (10-76)	10 (7-17)	21 (11-5524)
12 mo	32.1 (28.7-35.8)	33.7 (31.2-36.3)	26.4 (23.4-29.8)	1.21 (1.03-1.43)	1.28 (1.11-1.47)	1.05 (0.92-1.20)	.003	18 (10-106)	14 (9-31)	63 (18-38)
Pain-related interference[i]										
3 mo[g]	30.6 (27.3-34.4)	35.6 (33.7-37.6)	23.4 (20.5-26.8)	1.31 (1.10-1.55)	1.52 (1.32-1.75)	1.16 (1.02-1.32)	<.001	14 (9-40)	9 (7-12)	21 (12-100)
6 mo	37.0 (33.5-40.9)	40.9 (37.0-45.1)	24.3 (21.3-27.6)	1.52 (1.30-1.79)	1.68 (1.43-1.98)	1.10 (0.96-1.27)	<.001	8 (6-13)	7 (5-9)	26 (11-67)
12 mo	39.6 (36.1-43.5)	42.3 (40.6-44.0)	30.6 (27.4-34.2)	1.29 (1.12-1.49)	1.38 (1.23-1.55)	1.07 (0.97-1.18)	<.001	12 (8-25)	9 (7-13)	39 (16-79)

Abbreviation: RR, relative risk.

[a] Unadjusted results are presented in eTable 9 in Supplement 4.

[b] Adjusted mean percentage and adjusted RR were calculated from a modified Poisson regression model fit using generalized estimating equations for each binary outcome. Adjusted mean percentage assumes the mean of the covariate distribution to calculate randomized population average effects.

[c] Omnibus *P* value is the Wald Test to assess if there is any difference between the 3 groups. To control for multiple comparisons, between-group comparisons should only be compared if omnibus $P < .05$ following the least significant difference approach.

[d] Number needed to treat (NNT) to gain 1 additional 30% improvement, ie, 1 over the difference in the adjusted percent with an 30% improvement or greater.

[e] If CIs for the absolute risk difference contain zero the NNT confidence limits appear nonsensical and include infinity due to division by zero. In these cases, the estimate is interpreted as being consistent with an NNT from the lower limit (positive number) to infinity, and a number needed to harm from the upper limit (negative number) to negative infinity.

[f] Attaining or exceeding a 30% improvement in Pain Severity score from baseline (score is based on modified 11-item version of the BPI-SF; score is the calculated mean of all 11 items; range, 0-10).

[g] Primary time point.

[h] Attaining or exceeding a 30% improvement in Pain Intensity score from baseline (score is based on 4-item subscale of the BPI-SF; score is the calculated mean of all 4 items; range, 0-10).

[i] Attaining or exceeding a 30% improvement in Pain-related Interference score from baseline (score is based on 7-item subscale of the BPI-SF; score is the calculated mean of 7 items; range, 0-10).

Table 3. Adjusted Mean Change From Baseline of Continuous Secondary Outcomes by Treatment Group and Adjusted Mean Differences in Change Between-Group Comparisons[a]

	Adjusted mean change from baseline (95% CI)[b]			Adjusted between-group mean difference (95% CI)[b]				Standardized mean difference (95% CI)[d]		
	painTRAINER	Health coach	Usual care plus	painTRAINER vs usual care plus	Health coach vs usual care plus	Health coach vs painTRAINER	Omnibus *P* value[c]	painTRAINER vs usual care plus	Health coach vs usual care plus	Health coach vs painTRAINER
Pain severity										
No.	643	690	703							
3 mo[e]	−1.2 (−1.3 to −1.0)	−1.2 (−1.3 to −1.1)	−0.8 (−0.9 to −0.6)	−0.4 (−0.6 to −0.2)	−0.4 (−0.6 to −0.3)	−0.0 (−0.2 to 0.1)	<.001	−0.25 (−0.28 to −0.02)	−0.34 (−0.36 to −0.13)	−0.13 (−0.15 to 0.08)
6 mo	−1.3 (−1.4 to −1.1)	−1.4 (−1.5 to −1.3)	−0.9 (−1.0 to −0.8)	−0.4 (−0.6 to −0.2)	−0.5 (−0.7 to −0.4)	−0.1 (−0.3 to 0.1)	<.001	−0.26 (−0.34 to −0.08)	−0.36 (−0.43 to −0.19)	−0.12 (−0.19 to 0.04)
12 mo	−1.5 (−1.6 to −1.3)	−1.4 (−1.6 to −1.3)	−1.1 (−1.2 to −0.9)	−0.4 (−0.6 to −0.2)	−0.4 (−0.6 to −0.2)	0.0 (−0.2 to 0.2)	<.001	−0.25 (−0.24 to 0.01)	−0.36 (−0.35 to −0.12)	−0.11 (−0.11 to 0.12)
Pain intensity										
No.	643	690	703							
3 mo[e]	−0.9 (−1.0 to −0.8)	−0.9 (−1.0 to −0.8)	−0.6 (−0.7 to −0.5)	−0.3 (−0.5 to −0.1)	−0.3 (−0.5 to −0.2)	−0.0 (−0.2 to 0.2)	<.001	−0.21 (−0.21 to −0.01)	−0.29 (−0.30 to −0.11)	−0.08 (−0.09 to 0.09)
6 mo	−1.0 (−1.1 to −0.9)	−1.1 (−1.2 to −1.0)	−0.7 (−0.9 to −0.6)	−0.2 (−0.4 to −0.1)	−0.3 (−0.5 to −0.2)	−0.1 (−0.3 to 0.1)	<.001	−0.17 (−0.23 to −0.06)	−0.27 (−0.32 to −0.17)	−0.04 (−0.10 to 0.05)
12 mo	−1.1 (−1.3 to −1.0)	−1.1 (−1.3 to −1.0)	−0.9 (−1.0 to −0.8)	−0.2 (−0.4 to −0.1)	−0.2 (−0.4 to −0.1)	0.0 (−0.2 to 0.2)	.01	−0.16 (−0.16 to 0.00)	−0.27 (−0.26 to −0.12)	−0.03 (−0.03 to 0.11)
Pain-related interference										
No.	643	690	703							
3 mo[e]	−1.3 (−1.4 to −1.1)	−1.4 (−1.5 to −1.2)	−0.8 (−1.0 to −0.7)	−0.5 (−0.7 to −0.3)	−0.5 (−0.7 to −0.3)	−0.1 (−0.3 to 0.2)	<.001	−0.25 (−0.28 to −0.03)	−0.34 (−0.37 to −0.13)	−0.13 (−0.15 to 0.07)
6 mo	−1.5 (−1.6 to −1.3)	−1.6 (−1.8 to −1.4)	−1.0 (−1.1 to −0.8)	−0.5 (−0.7 to −0.3)	−0.6 (−0.8 to −0.4)	−0.1 (−0.4 to 0.1)	<.001	−0.27 (−0.34 to −0.08)	−0.37 (−0.44 to −0.19)	−0.14 (−0.21 to 0.04)
12 mo	−1.6 (−1.8 to −1.5)	−1.6 (−1.8 to −1.5)	−1.2 (−1.3 to −1.0)	−0.5 (−0.7 to −0.3)	−0.5 (−0.7 to −0.3)	0.0 (−0.2 to 0.2)	<.001	−0.26 (−0.25 to 0.01)	−0.37 (−0.36 to −0.11)	−0.12 (−0.12 to 0.12)
Social role functioning[f]										
No.	636	683	696							
3 mo[e]	1.5 (1.0 to 2.1)	2.2 (1.7 to 2.7)	0.7 (0.3 to 1.2)	0.8 (0.0 to 1.5)	1.5 (0.8 to 2.2)	0.7 (−0.0 to 1.4)	<.001	0.12 (0.23 to 0.11)	0.0 1 (0.12 to −0.00)	0.20 (0.29 to 0.19)
6 mo	2.2 (1.6 to 2.8)	2.5 (2.0 to 3.1)	1.0 (0.5 to 1.5)	1.2 (0.4 to 1.9)	1.5 (0.8 to 2.2)	0.3 (−0.4 to 1.1)	<.001	0.18 (0.23 to 0.05)	0.06 (0.11 to −0.06)	0.26 (0.30 to 0.15)
12 mo	2.6 (2.0 to 3.2)	2.7 (2.2 to 3.3)	1.4 (0.8 to 1.9)	1.3 (0.5 to 2.1)	1.4 (0.6 to 2.1)	0.1 (−0.7 to 0.9)	.001	0.19 (0.21 to 0.01)	0.07 (0.09 to −0.10)	0.27 (0.28 to 0.12)
Physical functioning[g]										
No.	639	684	699							
3 mo[e]	1.4 (1.1 to 1.8)	1.7 (1.4 to 2.1)	1.0 (0.7 to 1.4)	0.4 (−0.1 to 0.9)	0.7 (0.2 to 1.2)	0.3 (−0.2 to 0.8)	.02	0.09 (0.16 to 0.07)	−0.02 (0.05 to −0.04)	0.16 (0.22 to 0.15)
6 mo	2.0 (1.6 to 2.4)	1.8 (1.4 to 2.1)	1.4 (1.0 to 1.7)	0.6 (0.1 to 1.2)	0.4 (−0.1 to 0.9)	−0.3 (−0.8 to 0.3)	.05	0.15 (0.09 to −0.06)	0.02 (−0.03 to −0.18)	0.22 (0.16 to 0.05)
12 mo	2.2 (1.8 to 2.7)	2.1 (1.7 to 2.5)	1.3 (0.9 to 1.7)	0.9 (0.3 to 1.5)	0.8 (0.2 to 1.4)	−0.1 (−0.7 to 0.5)	.004	0.20 (0.18 to −0.03)	0.07 (0.04 to −0.16)	0.27 (0.25 to 0.09)

(continued)

Table 3. Adjusted Mean Change From Baseline of Continuous Secondary Outcomes by Treatment Group and Adjusted Mean Differences in Change Between-Group Comparisons[a] (continued)

	Adjusted mean change from baseline (95% CI)[b]			Adjusted between-group mean difference (95% CI)[b]				Standardized mean difference (95% CI)[d]		
	painTRAINER	Health coach	Usual care plus	painTRAINER vs usual care plus	Health coach vs usual care plus	Health coach vs painTRAINER	Omnibus *P* value[c]	painTRAINER vs usual care plus	Health coach vs usual care plus	Health coach vs painTRAINER
Patient Global Impression of Change–Pain[h]										
No.	640	687	702							
3 mo[e]	2.2 (2.1 to 2.3)	2.0 (1.9 to 2.1)	2.9 (2.8 to 3.0)	−0.7 (−0.8 to −0.6)	−0.9 (−1.0 to −0.8)	−0.2 (−0.3 to −0.1)	<.001	−0.62 (−0.81 to −0.19)	−0.62 (−0.76 to −0.25)	−0.37 (−0.51 to −0.05)
6 mo	2.2 (2.1 to 2.3)	2.1 (2.0 to 2.2)	2.8 (2.7 to 2.9)	−0.6 (−0.8 to −0.5)	−0.7 (−0.8 to −0.5)	−0.1 (−0.2 to 0.1)	<.001	−0.54 (−0.59 to −0.05)	−0.55 (−0.60 to −0.16)	−0.29 (−0.33 to 0.06)
12 mo	2.2 (2.1 to 2.3)	2.2 (2.1 to 2.4)	2.8 (2.7 to 2.9)	−0.6 (−0.8 to −0.5)	−0.6 (−0.7 to −0.4)	0.1 (−0.1 to 0.2)	<.001	−0.55 (−0.50 to 0.05)	−0.57 (−0.54 to −0.08)	−0.29 (−0.25 to 0.14)
Patient Global Impression of Change–General[i]										
No.	640	687	702							
3 mo[e]	2.0 (1.9 to 2.1)	1.6 (1.5 to 1.7)	2.7 (2.6 to 2.8)	−0.7 (−0.8 to −0.6)	−1.1 (−1.2 to −1.0)	−0.4 (−0.5 to −0.3)	<.001	−0.66 (−1.04 to −0.38)	−0.66 (−0.98 to −0.42)	−0.40 (−0.67 to −0.18)
6 mo	2.1 (2.0 to 2.2)	1.8 (1.7 to 1.9)	2.5 (2.5 to 2.6)	−0.5 (−0.6 to −0.3)	−0.7 (−0.9 to −0.6)	−0.2 (−0.4 to −0.1)	<.001	−0.46 (−0.69 to −0.24)	−0.50 (−0.70 to −0.32)	−0.24 (−0.41 to −0.07)
12 mo	2.0 (1.9 to 2.1)	1.9 (1.8 to 2.0)	2.6 (2.5 to 2.7)	−0.6 (−0.7 to −0.4)	−0.7 (−0.8 to −0.5)	−0.1 (−0.3 to 0.0)	<.001	−0.53 (−0.64 to −0.11)	−0.58 (−0.67 to −0.22)	−0.28 (−0.36 to 0.03)

[a] Unadjusted results are presented in eTables 10 and 11 in Supplement 4.

[b] Adjusted mean change from baseline and adjusted between group mean differences were calculated using linear regression model fit using generalized estimating equations for each continuous outcome. Adjusted means assume the mean of the covariate distribution to calculate randomized population average effects.

[c] Omnibus *P* value is the Wald Test to assess if there is any difference between the 3 groups. To control for multiple comparisons, between-group comparisons should only be compared if omnibus *P* < .05 following the least significant difference approach.

[d] The adjusted between-group mean difference divided by the standard deviation in the change in outcome at the given time point among the usual care plus group.

[e] Primary time point.

[f] Patient-Reported Outcomes Measurement Information System (PROMIS) Ability to Participate in Social Roles and Activities–Short Form 4a. Score by summing the 4 items (each item response 1-5) and then converting raw score to standardized T score, using the HealthMeasures Scoring Service, with mean of 50 and standard deviation of 10. Higher T score indicates better ability to participate in social roles and activities. Score 40 or less indicates moderate (40-30) to severe (<30) limitations in ability to participate.

[g] PROMIS Physical Function–Short Form 6b. Score by summing the 6 items (each item response 1-5) and then converting raw score to standardized T score, using the HealthMeasures Scoring Service, with mean of 50 and standard deviation of 10. Higher T score indicates better physical functioning. Score 40 or less indicates moderate (40-30) to severe (<30) limitations in physical functioning.

[h] Patient Global Impression of Change–Pain: One item assessing participant's perception of change in pain since start of study; range 1-7 (1 = much better, 2 = moderately better, 3 = a little better, 4 = No change, 5 = a little worse, 6 = moderately worse, 7 = much worse). Higher score = worsening of pain.

[i] Patient Global Impression of Change–General: One item assessing participant's perception of change in overall status since start of study; range 1-7 (1 = much better, 2 = moderately better, 3 = a little better, 4 = No change, 5 = a little worse, 6 = moderately worse, 7 = much worse). Higher score = worsening of overall status.

rural and/or medically underserved areas, and many had limited financial resources and higher social determinants of health needs. Generalizability of the findings is increased by broad inclusion and limited exclusion criteria. The trial included individuals with diverse types of musculoskeletal chronic pain, rather than limiting participation to those with chronic pain at a single anatomical location, and also included those with substantial self-reported concomitant mood disorders (depression and anxiety) and sleep-related problems. Additionally, although this study was funded prior to the emergence of COVID-19, the pandemic brought a shift toward online and telehealth-based clinical services for conditions like chronic pain. This shift renders the RESOLVE study questions particularly timely and salient, namely, the comparative effectiveness of 2 widely accepted, remote forms of CBT-CP treatments with delivery facilitated by frontline staff without previous expertise in management of chronic pain.[67,68]

Limitations

Limitations of this study must be acknowledged. First, because this was a pragmatic comparative effectiveness trial, it used a usual care comparator because it was most pertinent to evaluate the added benefit of these CBT-based interventions in real world settings,[23,69,70] and the study purposely focused on patient self-reported pain and pain-related interference as these are commonly used metrics in clinical care.[71,72] Yet such an approach does not permit teasing out the effect of attention or the subjectivity of patient self-report on the overall findings. Second, the online painTRAINER program could not be offered in Spanish, and consequently the study had low enrollment of patients identifying as Hispanic. Third, while efforts were made to correct for potential missing-outcome bias with imputation and nonresponse weighting, potential bias may remain, especially given the differential assessment follow-up response rates by group (substantively lower in the painTRAINER group).

Conclusions

Among adults with high-impact chronic musculoskeletal pain, remote CBT-CP–based skills training programs (telehealth and self-completed online) resulted in greater reduction in pain severity after treatment, sustained through 12 months, when compared with usual care. Findings suggest that centralizing delivery of the CBT-CP based programs via telephone/videoconferencing and online interventions is effective, with potential for widespread dissemination into clinical care and health care organizations nationwide.

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