Self-directed versus clinician-delivered cognitive behavioral therapy for chronic pain

Results from the COPES ExTRA pragmatic trial

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VA | U.S. Department of Veterans Affairs

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C • O • P • E • S
CO-OPERATIVE PAIN EDUCATION AND SELF MANAGEMENT

DISCLOSURES

No conflicts to disclose

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OVERVIEW



Cognitive behavioral therapy for chronic pain (CBT-CP) and rationale for COPES ExTRA



COPES ExTRA trial: Methods and Results



Overall findings and implications



Future considerations

BACKGROUND

Cognitive behavioral therapy for chronic pain (CBT-CP)

- First line treatment
- Improves pain and functional outcomes[1]
- Underutilized[2]



Patient Barriers

- Travel
- Schedule
- Health/mobility
- Burden



System Barriers

- Clinician scarcity
- High resource use
- Prevalence of pain

VHA CBT-CP



VHA has trained over 700 clinicians to deliver CBT-CP in the VA Evidence-Based Psychotherapy Program

Barriers to use remain

Self-directed CBT-CP (COPES)



Interactive voice response (IVR) with personalized feedback

Benefits



Treatment from home

No appointments

Low burden/low resource use

Includes clinician support

PRIOR FINDINGS



Research

JAMA Internal Medicine | Original Investigation

Interactive Voice Response–Based Self-management for Chronic Back Pain

The COPES Noninferiority Randomized Trial

Alicia A. Heapy, PhD; Diana M. Higgins, PhD; Joseph L. Goulet, PhD; Kathryn M. LaChappelle, MPH; Mary A. Driscoll, PhD; Rebecca A. Czlapinski, MA; Eugenia Buta, PhD; John D. Piette, PhD; Sarah L. Krein, PhD; Robert D. Kerns, PhD

Supplemental content

IMPORTANCE Recommendations for chronic pain treatment emphasize multimodal approaches, including nonpharmacologic interventions to enhance self-management. Cognitive behavioral therapy (CBT) is an evidence-based treatment that facilitates management of chronic pain and improves outcomes, but access barriers persist. Cognitive behavioral therapy delivery assisted by health technology can obviate the need for in-person visits, but the effectiveness of this alternative to standard therapy is unknown. The Cooperative Pain Education and Self-management (COPES) trial was a randomized, noninferiority trial comparing IVR-CBT to in-person CBT for patients with chronic back pain.

OBJECTIVE To assess the efficacy of interactive voice response–based CBT (IVR-CBT) relative to in-person CBT for chronic back pain.

DESIGN, SETTING, AND PARTICIPANTS We conducted a noninferiority randomized trial in 1 Department of Veterans Affairs (VA) health care system. A total of 125 patients with chronic back pain were equally allocated to IVR-CBT (n = 62) or in-person CBT (n = 63).

INTERVENTIONS Patients treated with IVR-CBT received a self-help manual and weekly prerecorded therapist feedback based on their IVR-reported activity, coping skill practice, and pain outcomes. In-person CBT included weekly, individual CBT sessions with a therapist. Participants in both conditions received IVR monitoring of pain, sleep, activity levels, and pain coping skill practice during treatment.

MAIN OUTCOMES AND MEASURES The primary outcome was change from baseline to 3 months in unblinded patient report of average pain intensity measured by the Numeric Rating Scale (NRS). Secondary outcomes included changes in pain-related interference, physical and emotional functioning, sleep quality, and quality of life at 3, 6, and 9 months. We also examined treatment retention.

RESULTS Of the 125 patients (97 men, 28 women; mean [SD] age, 57.9 [11.6] years), the adjusted average reduction in NRS with IVR-CBT (−0.77) was similar to in-person CBT (−0.84), with the 95% CI for the difference between groups (−0.67 to 0.80) falling below the prespecified noninferiority margin of 1 indicating IVR-CBT is noninferior. Fifty-four patients randomized to IVR-CBT and 50 randomized to in-person CBT were included in the analysis of the primary outcome. Statistically significant improvements in physical functioning, sleep quality, and physical quality of life at 3 months relative to baseline occurred in both treatments, with no advantage for either treatment. Treatment dropout was lower in IVR-CBT with patients completing on average 2.3 (95% CI, 1.0-3.6) more sessions.

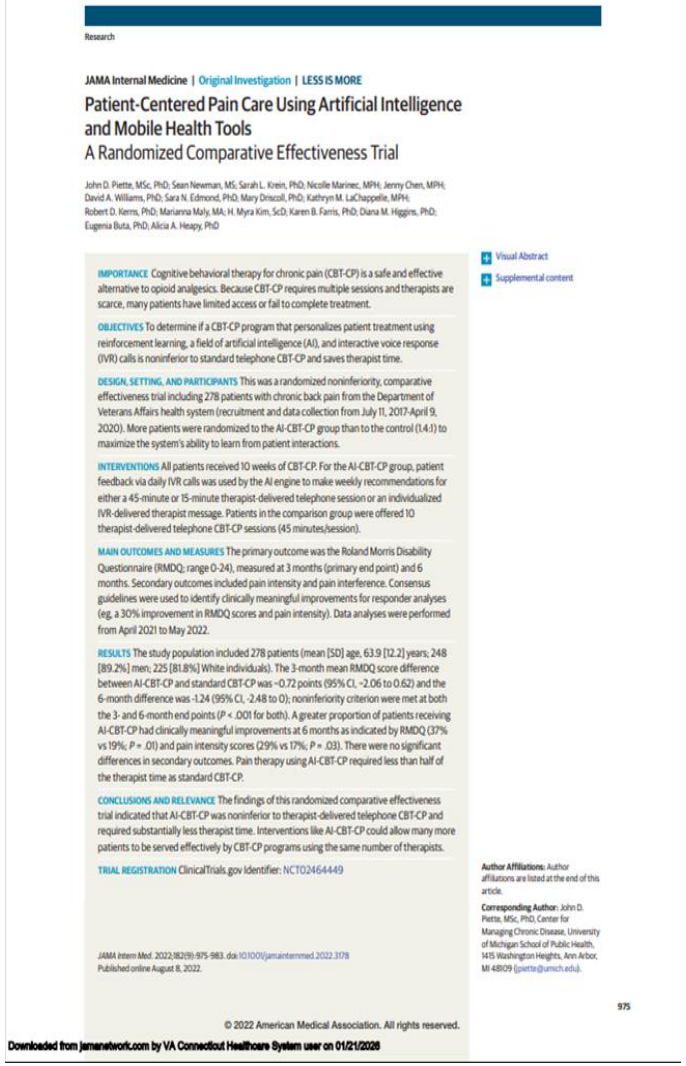
CONCLUSIONS AND RELEVANCE IVR-CBT is a low-burden alternative that can increase access to CBT for chronic pain and shows promise as a nonpharmacologic treatment option for chronic pain, with outcomes that are not inferior to in-person CBT.

TRIAL REGISTRATION clinicaltrials.gov Identifier: NCT01025752

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Research

JAMA Internal Medicine | Original Investigation | LESS IS MORE

Patient-Centered Pain Care Using Artificial Intelligence and Mobile Health Tools

A Randomized Comparative Effectiveness Trial

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Visual Abstract
Supplemental content

IMPORTANCE Cognitive behavioral therapy for chronic pain (CBT-CP) is a safe and effective alternative to opioid analgesics. Because CBT-CP requires multiple sessions and therapists are scarce, many patients have limited access or fail to complete treatment.

OBJECTIVES To determine if a CBT-CP program that personalizes patient treatment using reinforcement learning, a field of artificial intelligence (AI), and interactive voice response (IVR) calls is noninferior to standard telephone CBT-CP and saves therapist time.

DESIGN, SETTING, AND PARTICIPANTS This was a randomized noninferiority, comparative effectiveness trial including 278 patients with chronic back pain from the Department of Veterans Affairs health system (recruitment and data collection from July 11, 2017-April 9, 2020). More patients were randomized to the AI-CBT-CP group than to the control (1.4:1) to maximize the system's ability to learn from patient interactions.

INTERVENTIONS All patients received 10 weeks of CBT-CP. For the AI-CBT-CP group, patient feedback via daily IVR calls was used by the AI engine to make weekly recommendations for either a 45-minute or 15-minute therapist-delivered telephone session or an individualized IVR-delivered therapist message. Patients in the comparison group were offered 10 therapist-delivered telephone CBT-CP sessions (45 minutes/session).

MAIN OUTCOMES AND MEASURES The primary outcome was the Roland Morris Disability Questionnaire (RMDQ; range 0-24), measured at 3 months (primary end point) and 6 months. Secondary outcomes included pain intensity and pain interference. Consensus guidelines were used to identify clinically meaningful improvements for responder analyses (eg, a 30% improvement in RMDQ scores and pain intensity). Data analyses were performed from April 2021 to May 2022.

RESULTS The study population included 278 patients (mean [SD] age, 63.9 [12.2] years; 248 [89.2%] men; 225 [81.8%] White individuals). The 3-month mean RMDQ score difference between AI-CBT-CP and standard CBT-CP was −0.72 points (95% CI, −2.06 to 0.62) and the 6-month difference was -1.24 (95% CI, -2.48 to 0); noninferiority criterion were met at both the 3- and 6-month end points ($P < .001$ for both). A greater proportion of patients receiving AI-CBT-CP had clinically meaningful improvements at 6 months as indicated by RMDQ (37% vs 19%; $P = .01$) and pain intensity scores (29% vs 17%; $P = .03$). There were no significant differences in secondary outcomes. Pain therapy using AI-CBT-CP required less than half of the therapist time as standard CBT-CP.

CONCLUSIONS AND RELEVANCE The findings of this randomized comparative effectiveness trial indicated that AI-CBT-CP was noninferior to therapist-delivered telephone CBT-CP and required substantially less therapist time. Interventions like AI-CBT-CP could allow many more patients to be served effectively by CBT-CP programs using the same number of therapists.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT02464449

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Two non-inferiority trials (N =~ 400)

Self-directed CBT-CP was not inferior

- In-person CBT-CP[3]
- Telephone CBT-CP[4]

Significant improvement in pain intensity, pain-related disability, physical activity and sleep

Mean increase in steps of approximately 1 mile/day

Lower attrition and higher treatment dose

Treatment satisfaction comparable to standard CBT-CP

RATIONALE FOR PRAGMATIC TRIAL

1. Evaluate relative strengths and weaknesses of similar treatments

2. Inform future clinical use of CBT-CP in VHA

3. Hypothesized self-directed CBT-CP would produce superior outcomes relative to clinician-delivered CBT-CP

   - Convenience would result in a higher dose of treatment
   - Asynchronous delivery more consistent

COPES EXTRA AIMS

Objective: Assess the effectiveness of self-directed CBT-CP relative to clinician-delivered CBT-CP among adults with chronic musculoskeletal pain (N=764)



Aim 1: Determine whether self-directed CBT-CP+UC is superior to clinician-delivered CBT-CP+UC at 1, 4 (primary endpoint), 6, 12 months post-randomization on pain interference and related pain outcomes



Aim 2: Conduct cost and budget impact analyses



Aim 3: Conduct a process evaluation to observe and gather information on implementation of both forms of CBT-CP

METHODS

- **Design:** Randomized hybrid type 1 pragmatic superiority trial to compare 2 forms of CBT-CP[5]

- **Target population:** Veterans aged 18+ with chronic musculoskeletal pain
  - Chronic pain: 3 months or longer duration
  - Musculoskeletal pain: common conditions included low back pain, neck pain, joint pain, fibromyalgia, others
- **Target N=** 764 VHA patients (50% women) with chronic musculoskeletal pain
- **Sites:** 9 VHA healthcare systems in 8 states
- **Recruitment methods:**
  - Provider referral alert (automated electronic health record [EHR] clinical reminder) or clinician referral
  - Direct to patient outreach
- **Randomization**: Individual 1:1 randomization stratified by site and sex, in variable blocks of 4 and 6
- **Outcomes:** Obtained from EHR and automated IVR calls
- **NCCIH Pain Management Collaboratory:** One of 16 large scale pragmatic trials of nonpharmacologic pain approaches conducted in Veterans and military health systems

TREATMENTS

Self-Directed CBT-CP

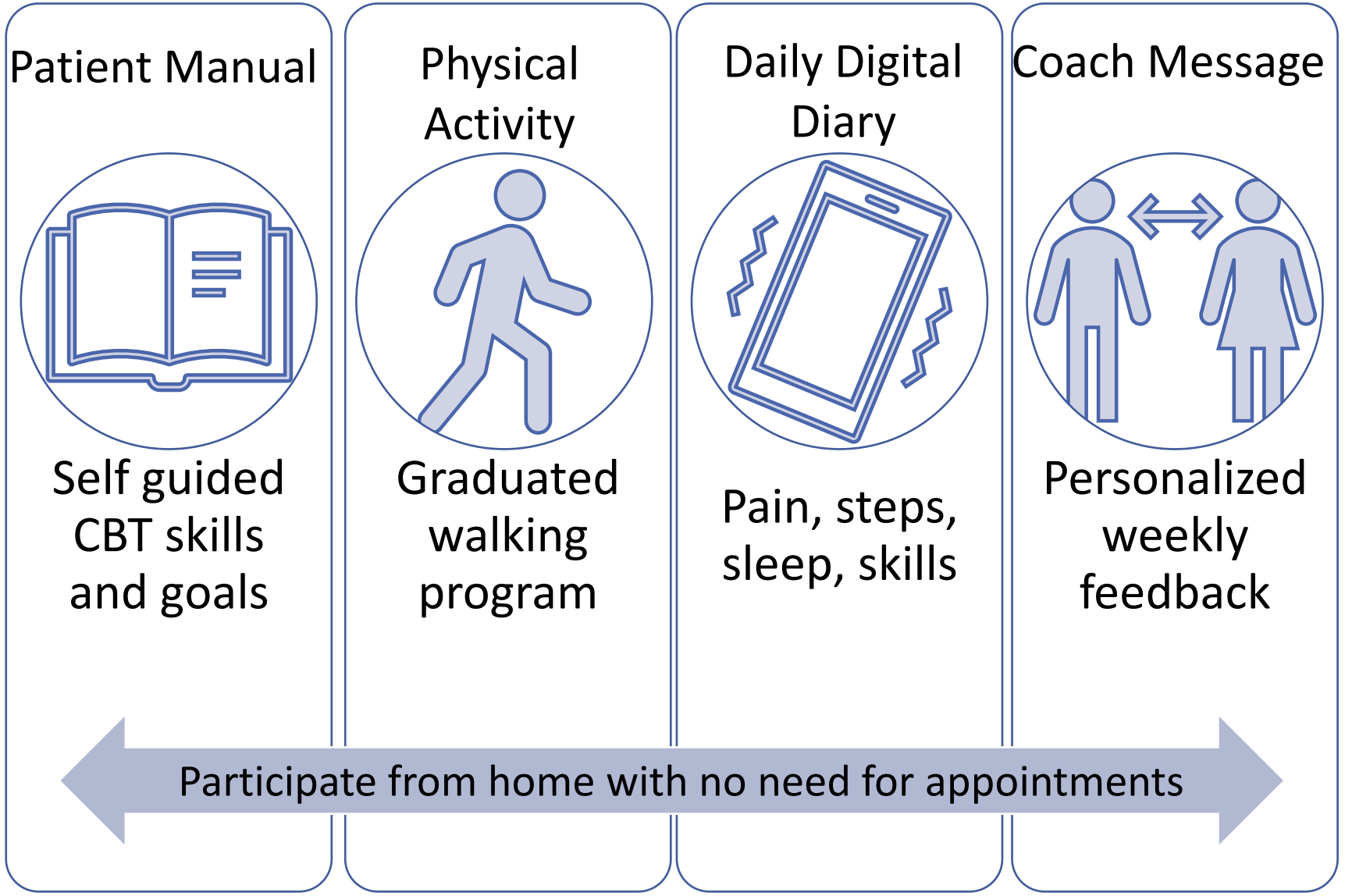
- Centrally delivered
- Trained coaches/weekly supervision
- 11 weeks of treatment
- Pain management skills and goal setting

Clinician Delivered CBT-CP

- Delivered by local VA clinician as part of job duties
- Usual clinical conditions
  - In person, video, and telephone
  - Individual and group
- Variability in number of planned treatment sessions
- Pain management skills and goal setting

SELF-DIRECTED CBT-CP (COPES)

What is COPES?



ELIGIBILITY CRITERIA

ICD-10 musculoskeletal and connective tissue condition or diagnoses of chronic pain syndrome or pain disorder with related psychological factors

Chronic pain of at least moderate severity (two or more pain intensity numeric rating scale (NRS) ratings of ≥ 4 in a 12-month period, with ≥ 30 days between occurrences)

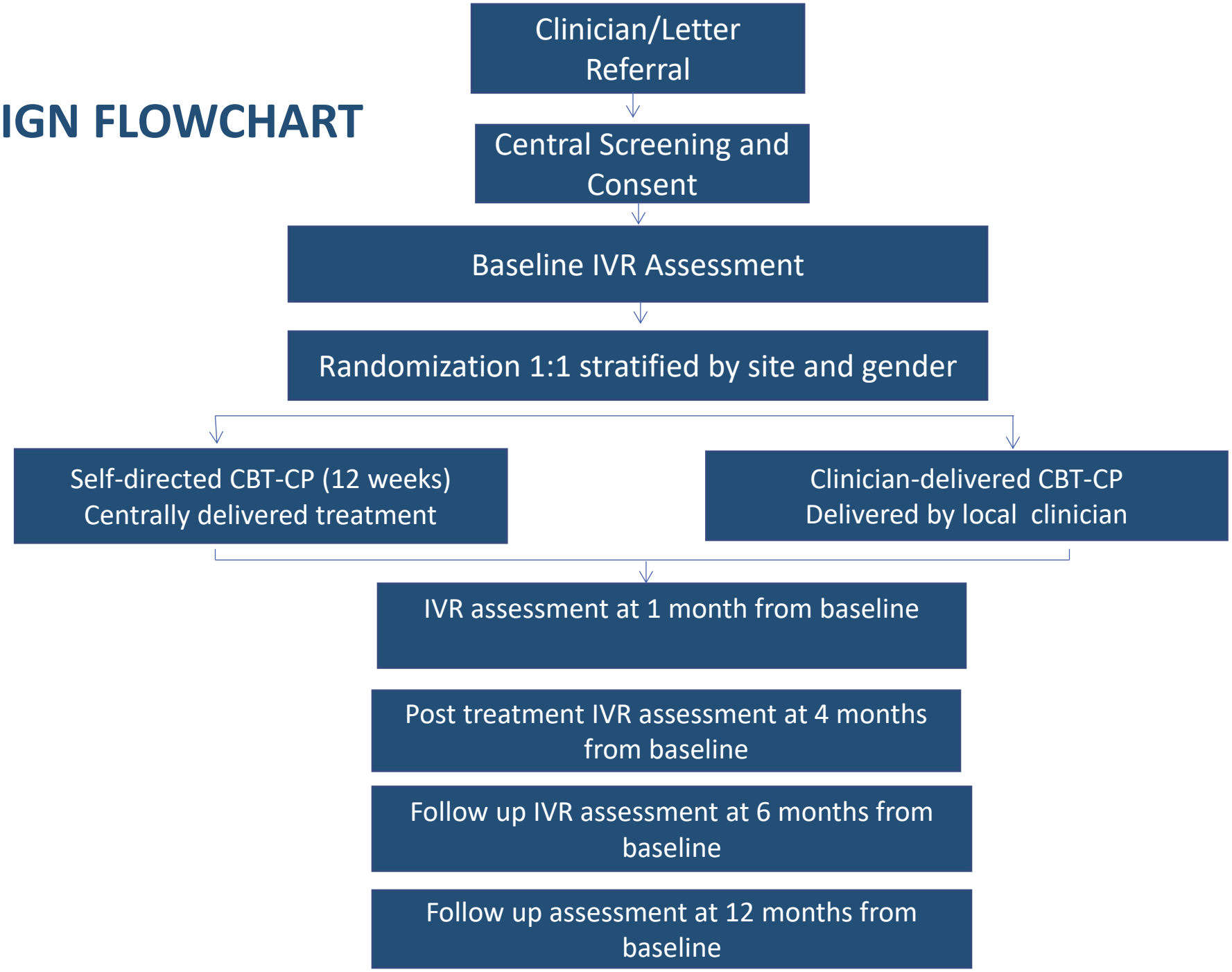
Absence of dementia diagnosis

Patient-reported ability to walk at least one block (and absence of foot ulcers and falls)

Availability of a touch-tone land-line or cellular telephone

Absence of current inpatient psychiatric hospitalization, hospice or end-of-life palliative care, vision or hearing deficits that would impede participation, current participation in CBT-CP, medical intervention causing meaningful increase in pain (e.g., surgery)

STUDY DESIGN FLOWCHART



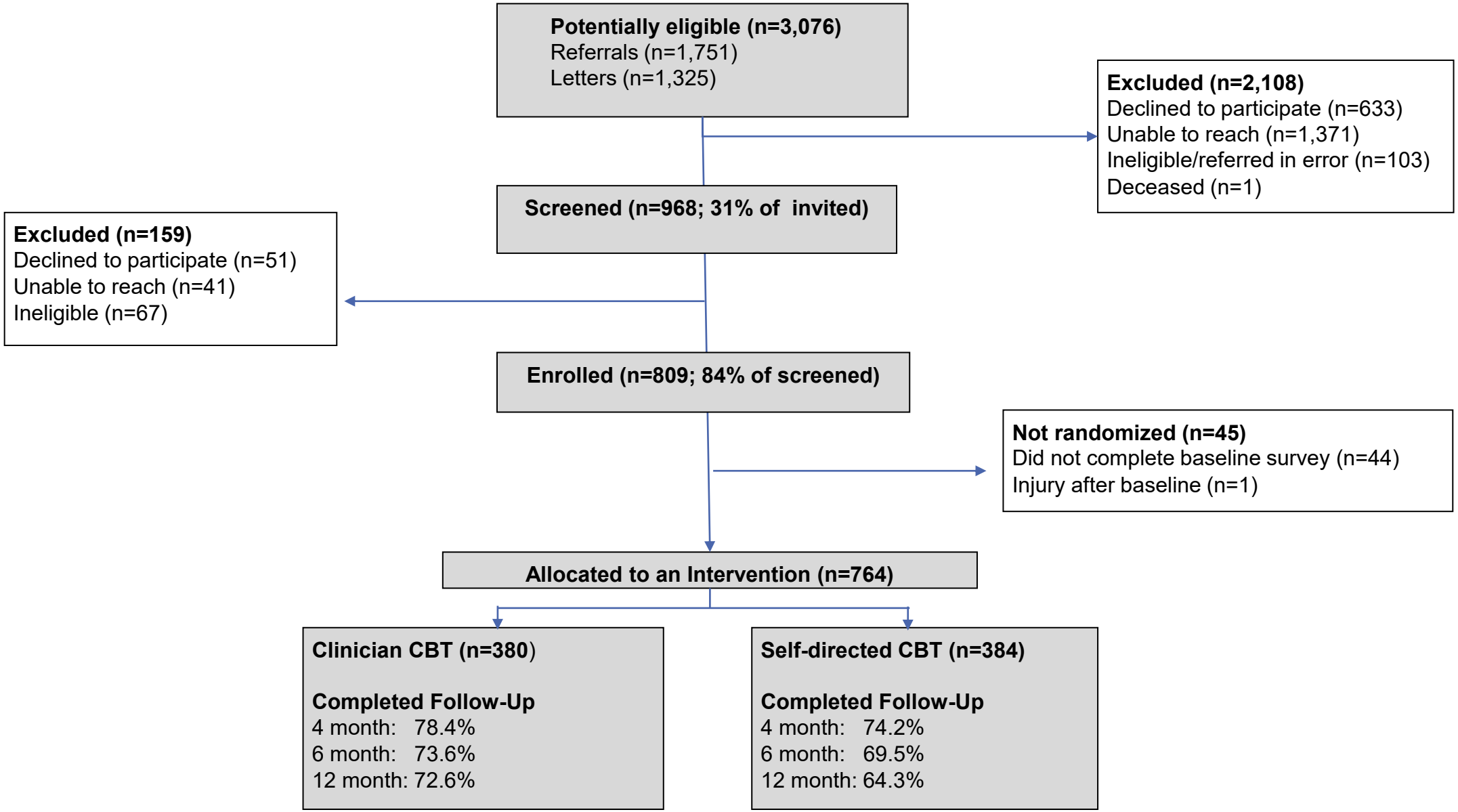
OUTCOME MEASURES[6]

Collected by automated IVR call at 0, 1, 4, 6 and 12 months

Primary Outcome
Pain Interference Brief Pain Inventory (BPI) Interference Subscale
Other outcomes
Total Pain Impact (PEG-3)
Pain Intensity (Numeric Rating Scale, 0-10)
Depressive Symptoms (PHQ-8)
Pain Catastrophizing Scale
Insomnia Severity Index
Pain Self-Efficacy Scale
Patient Global Impression of Change
Treatment Satisfaction (4 months)
Time from randomization to first treatment session
Number of treatment sessions

Collected by chart review or IVR

PARTICIPANT FLOW



RESULTS

Heapy AA, Driscoll MA, et al., Self-Directed vs Clinician-Delivered Cognitive Behavioral Therapy for Chronic Pain: A Randomized Clinical Trial. *JAMA.* Published online June 24, 2026. doi:10.1001/jama.2026.7861

SELECT BASELINE CHARACTERISTICS

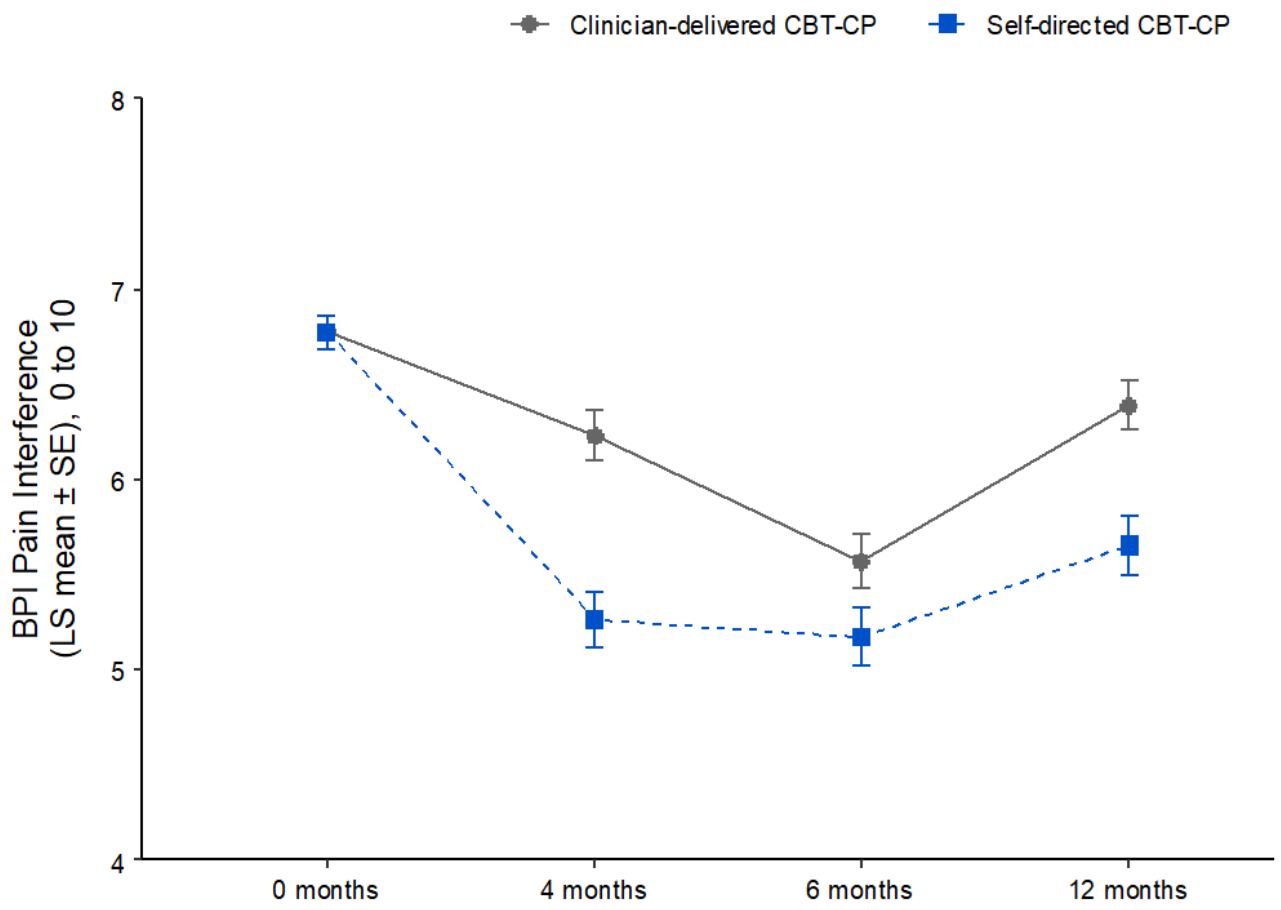
Characteristic	N	Self-directed CBT-CP (N=384)	Synchronous CBT-CP (N=380)	Total (N=764)
Demographic characteristics				
Age (years), *mean (SD)*	764	53.0 (12.3)	52.7 (12.2)	52.8 (12.3)
Sex, female, *n (%)*	764	149 (38.8)	150 (39.5)	299 (39.1)
Race, *n (%)*	739			
Black		139 (37.3)	150 (41)	289 (39.1)
White		209 (56)	190 (51.9)	399 (54)
Other		25 (6.7)	26 (7.1)	51 (6.9)
Declined		11	14	25
Ethnicity, Hispanic, *n (%)*	763	62 (16.2)	45 (11.8)	107 (14)
Relationship Status, single, *n (%)*	762	91 (23.8)	89 (23.4)	180 (23.6)
Rural and Highly Rural	764	94 (24.5)	92 (24.2)	186 (24.3)
Pain characteristics				
Pain Duration, years, *mean (SD)*	763	16.9 (11.9)	16.2 (10.9)	16.6 (11.4)
Pain at screening 0-10, *mean (SD)*	764	7.0 (1.4)	7.0 (1.5)	7.0 (1.5)
Long Term Opioid Therapy	764	52 (13.5)	54 (14.2)	106 (13.9)
Other Comorbidities				
PTSD diagnosis	764	122 (31.8)	130 (34.2)	252 (33)
Depressive Disorder diagnosis	764	147 (38.3)	156 (41.1)	303 (39.7)
Alcohol Use Disorder diagnosis	764	24 (6.3)	25 (6.6)	49 (6.4)
Substance Use Disorder diagnosis	764	28 (7.3)	21 (5.5)	49 (6.4)
High-Risk Alcohol Use (AUDIT-C), positive, *n%*	764	62 (16.1)	61 (16.1)	123 (16.1)

CLINICIAN-DELIVERED SESSIONS

Clinician-delivered CBT-CP (N=1621 sessions)	
Session Format	Video 74%
	In-person 17%
	Telephone 8%
	Unidentified 1%
Individual	84%

PRIMARY OUTCOME-PAIN INTERFERENCE

(BPI: 0-10, higher score indicates greater impact of pain on activities and enjoyment in the past week)



	0 months	4 months	6 months	12 months
Clinician-delivered	6.77 (0.09)	6.23 (0.13)	5.57 (0.14)	6.39 (0.13)
Self-directed	6.77 (0.09)	5.26 (0.15)	5.17 (0.15)	5.65 (0.16)
Difference (95% CI)		-0.98 (-1.31, -0.65)	-0.40 (-0.77, -0.04)	-0.75 (-1.10, -0.40)
P-value		<0.0001	0.03	<0.001

Results are from a longitudinal mixed model; negative values indicate lower interference in the self-directed group

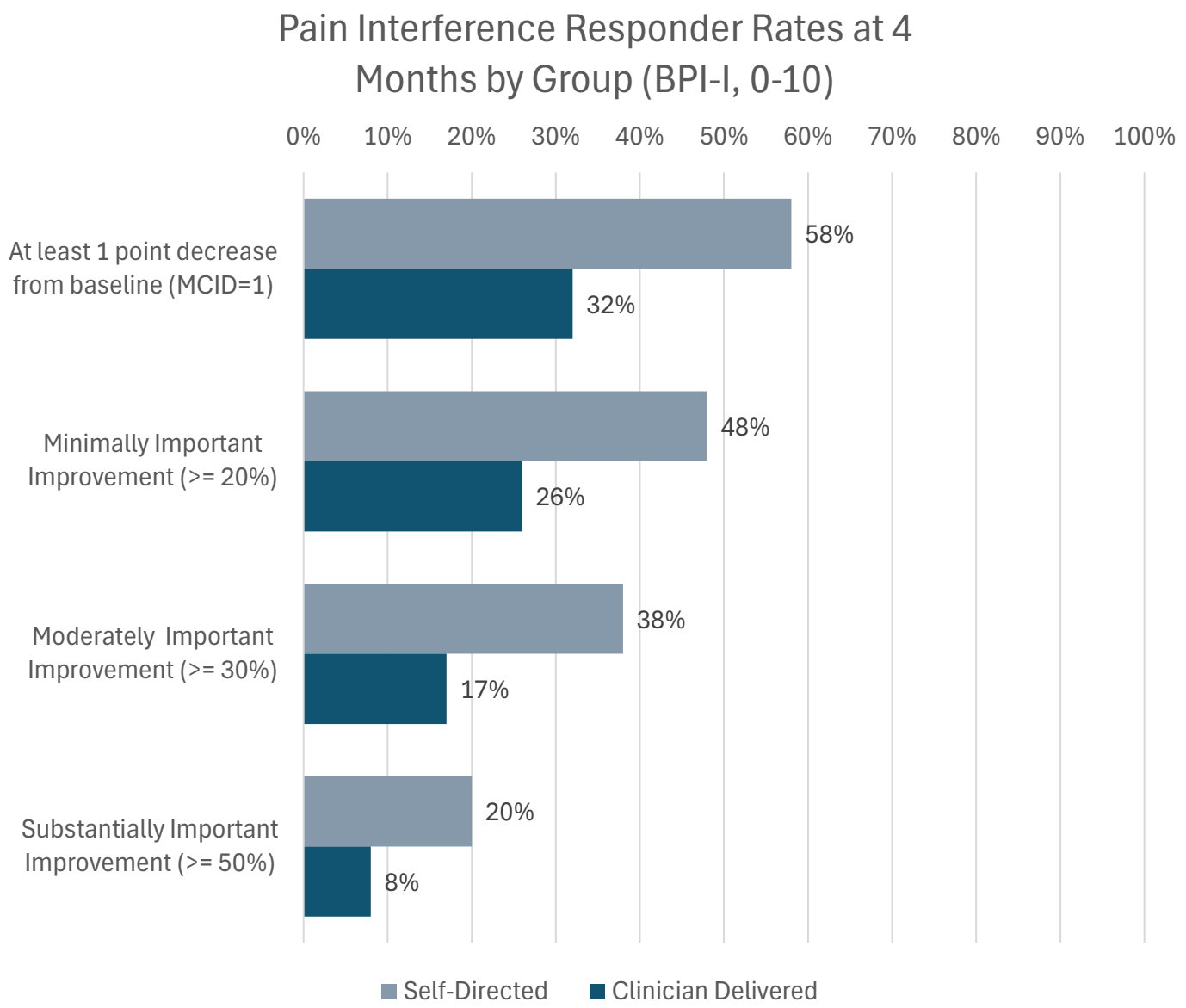
OTHER OUTCOMES[7]

Difference (self-directed vs clinician-delivered), LS Mean (95% CI; p value)

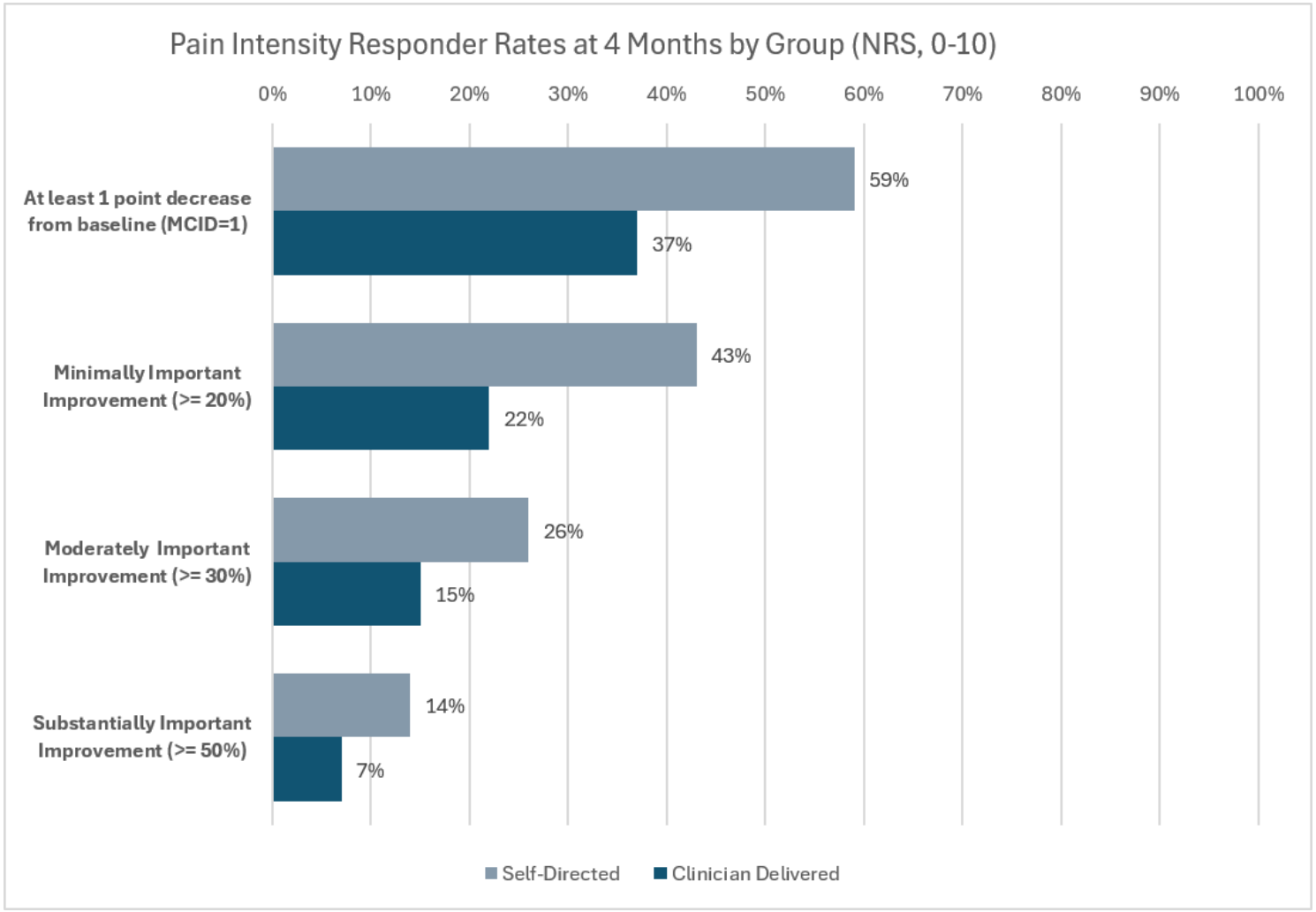
Outcome	4 months	6 months	12 months
PEG-3 (total pain impact)	**-1.02 (-1.37, -0.67) <.001**	**-0.51 (-0.88, -0.14) 0.01**	**-0.80 (-1.16, -0.43) <.001**
NRS Pain Intensity	**-0.71 (-1.02, -0.39) <.0001**	**-0.49 (-0.85, -0.14) 0.006**	**-0.57 (-0.92, -0.23) 0.001**
Insomnia Severity Index	**-2.23 (-3.17, -1.28) <.0001**	**-1.22 (-2.19, -0.26) 0.01**	**-1.38 (-2.43, -0.34) 0.01**
PHQ-8 (depressive symptom severity)	**-1.94 (-2.93, -0.95) 0.001**	-1.02 (-2.05, 0.01) 0.05	**-1.60 (-2.61, -0.60) 0.004**
Pain Catastrophizing	**-1.57 (-2.19, -0.95) <.001**	-0.60 (-1.24, 0.05) 0.07	**-0.96 (-1.60, -0.31) 0.005**
Pain Self-Efficacy	**1.25 (0.75, 1.76) <.001**	**0.91 (0.40, 1.41) 0.001**	0.22 (-0.30, 0.73) 0.39
Treatment Satisfaction	**0.50 (0.26, 0.74) 0.001**	N/A	N/A

Bolded values are statistically significant

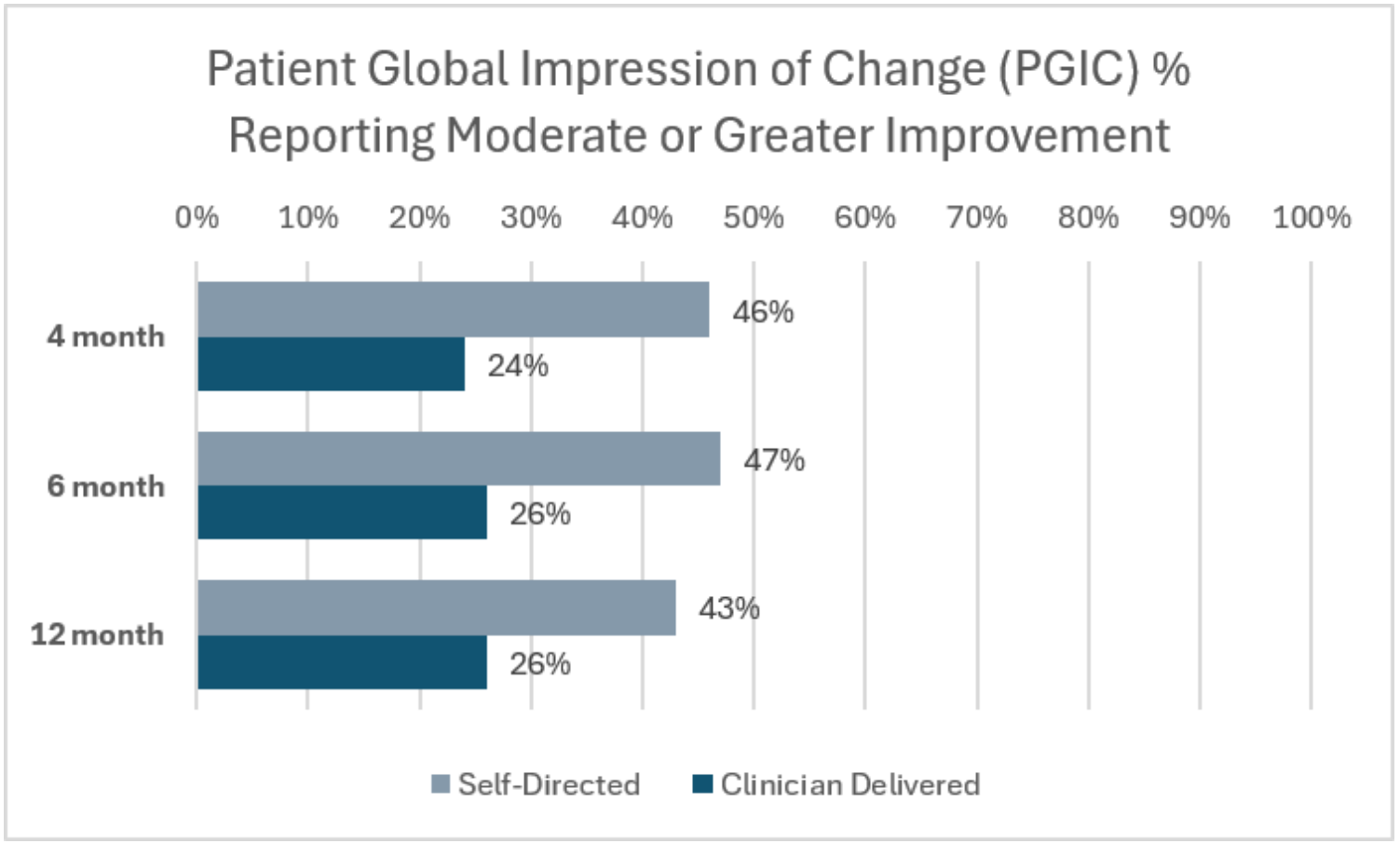
RESPONDER ANALYSIS



RESPONDER ANALYSIS



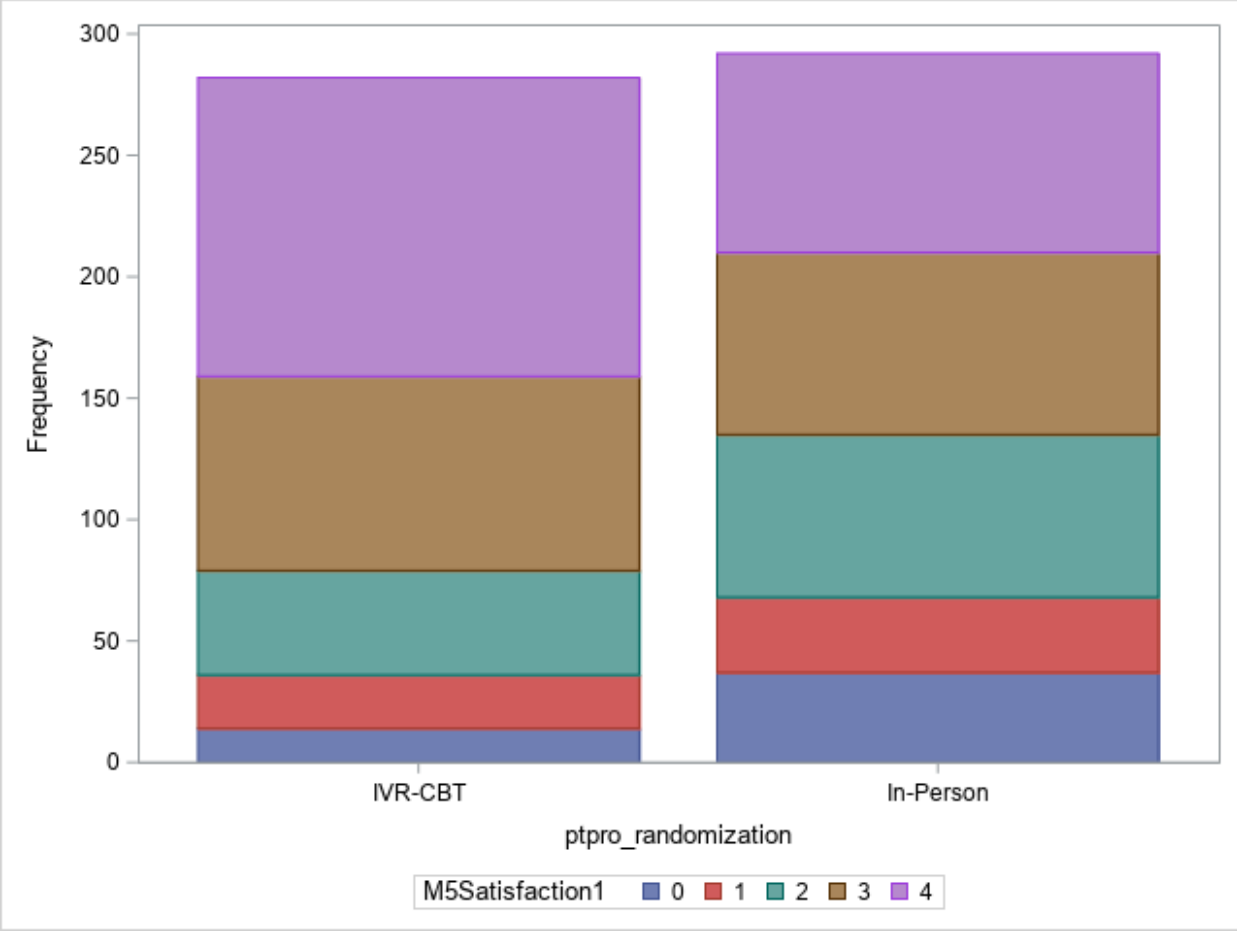
RESPONDER ANALYSIS



PARTICIPANT SATISFACTION

Overall, how satisfied are you with the treatment you received?

0 Dissatisfied 1 2 3 4 Very satisfied



p<0.0001

NUMBER OF TREATMENT SESSIONS

Treatment Group	Participants Assigned (N)	Mean Sessions Completed, M (SD)	Median Percent Sessions Completed of Expected, % [IQR]
Clinician-Delivered CBT-CP*	249		
4 Sessions	5	3.8 (0.5)	100% [100,100]
6 Sessions	56	4.6 (2.4)	83% [33,100]
8 Sessions	25	7.1 (2.9)	88% [75,100]
11 Sessions	163	7.2 (4.6)	73% [18, 100]
Self-Directed CBT-CP **	362		
11 Sessions	362	9.1 (3.4)	100% [73, 100]

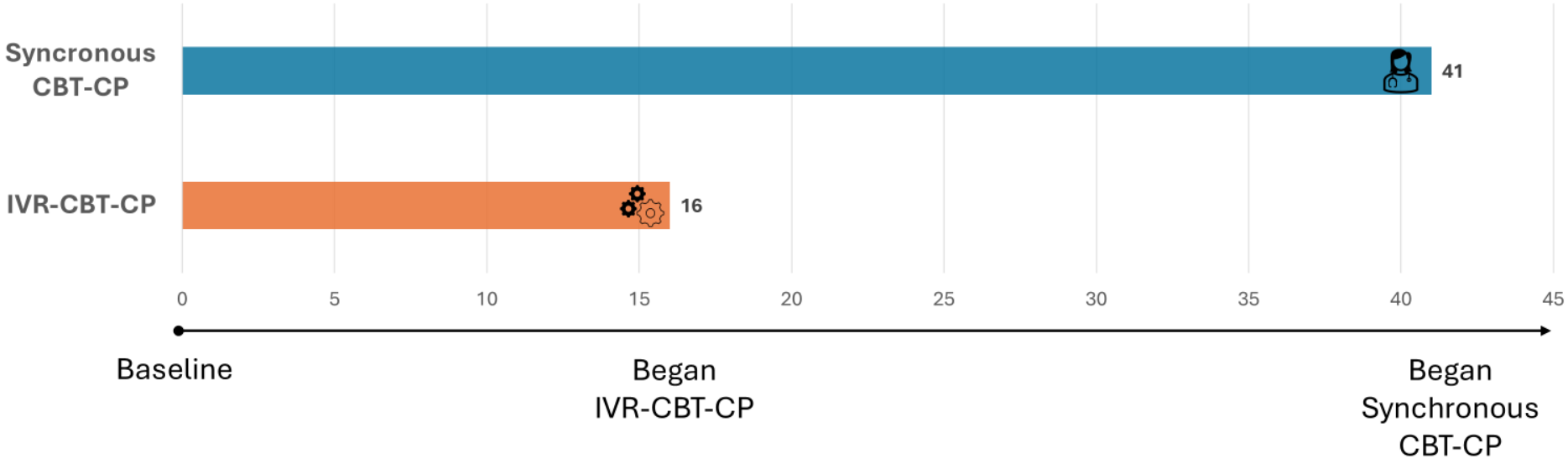
- Due to the pragmatic nature of this trial the number of sessions expected for the Clinician-Delivered CBT-CP varies depending on the treatment protocol each clinician used. This study placed no parameters on the length of treatment the local clinician used which varied from a 4-11 session protocol with individual adjustments based on clinical judgement and availability.

**Self-Directed CBT-CP was delivered via an asynchronous, centralized phone system and there was only one treatment plan offered, 11 sessions.

INITIATING TREATMENT

- Attended first session
  - Self-directed CBT-CP = 94%
  - Clinician-delivered CBT-CP = 66%

Median Number of Days to Treatment



OVERALL FINDINGS

- Self-directed CBT-CP showed superior improvements on pain interference, pain intensity, sleep, and depressive symptoms durable to 12 months
- Self-directed participants waited fewer days to start treatment and attended more treatment sessions
- Clinician delivered CBT-CP also produced clinically significant improvements
- Convenient, scalable self-directed CBT-CP may be an effective alternative to clinician-delivered CBT-CP
- Overall pattern of advantage in favor of self-directed treatment clinically important

STRENGTHS AND LIMITATIONS

- Pragmatic methods yielded sample representative of patients receiving care in VHA
- Evidence-based comparator treatment provided under usual care conditions
- Treatment fidelity was not evaluated in clinician-delivered CBT-CP
  - May not have been delivered as intended
  - Could have attenuated effects
- Self-directed CBT-CP group lower assessment completion rates
- Usual clinical practice for self-directed not established

WHAT DOES THIS TELL US ABOUT THE TREATMENTS?

FACTORS CONTRIBUTING TO SUCCESS OF SELF-DIRECTED CBT-CP

- Fidelity/consistency
- Therapeutic elements of daily diary/feedback
- Walking
- Faster time to treatment
- Prior studies informed refinement of the treatment and deployment of treatment
- Lower burden/resources use

FUTURE CONSIDERATIONS

- Potential benefits of offering both treatments across VHA:
  - Accommodates range of patient preferences and circumstances
  - Improves access and capacity systemwide
  - Reduces demand on local clinicians
    - Scarce resource
    - Experience burden/burnout
- Outside VHA
  - VHA can scale COPES widely, may be less feasible for smaller systems
  - Insurance reimbursement unclear

COPES CLINICAL

- Pain Management, Opioid Safety and PDMP (PMOP) supported

- COPES is now a VHA clinical program
  - Northeast Region
  - Plan for eventual national rollout

- Centralized Coaching Team at VHA Connecticut
  - No need for trained clinicians at every facility







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