INTERNET-BASED PAIN SELF-MANAGEMENT FOR VETERANS: FEASIBILITY AND PRELIMINARY EFFICACY OF THE PAIN EASE PROGRAM

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Overview

- Pain self-management in VHA
- Challenges with accessing pain self-management
- Using the internet to deliver treatment
- Pain EASE program
  - Phase I-Development
  - Phase II-Feasibility and preliminary efficacy trial
- Considerations and limitations
- Future directions

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Using Pain Self-Management to address chronic pain in VHA

- Chronic pain affects approximately 20.4% of the US population and 26% of veterans[1]

- VHA has promoted CBT-based pain self-management for chronic pain (CBT-CP)[2,3]
  - Evidence-based
  - Non-pharmacological

- CBT-CP (including progressive physical activity)
  - Goals: reducing pain, improving functioning and quality of life
  - Usually 6-12 outpatient visits
    - Cognitive skills (e.g., attention diversion, development of coping self-statements)
    - Behavioral skills (e.g., activity pacing, relaxation)
    - Progressive physical activity

Challenges accessing pain self-management[4,5]

- Patient level barriers
  - Transportation
  - Caregiver responsibilities
  - Health and mobility
  - Scheduling and time-commitment

- System level barriers
  - Adoption and promotion of a biopsychosocial model
  - Stigma
  - Limited number of trained providers/clinic availability

Using technology to deliver pain care

- Development of technology-assisted delivery systems (e.g., telehealth, smartphone applications, interactive voice response, and internet) may enhance access to care[6]

- Systematic review (N=29 studies)
  - Patients with chronic pain demonstrate significant improvements following engagement in internet-based self-management pain programs (e.g., CBT or ACT)[7]
    - May not generalize to veterans as data quality were variable and samples homogeneous (i.e., predominantly White, female)

Using technology to deliver pain care

- Self-guided (i.e., no clinician involvement) internet-based programs for chronic pain are promising and may have additional benefits
  - Reduce operating costs
  - Greater access (no need to rely on trained clinicians to facilitate participants' program progress)

- Self-guided, CBT-based pain self-management programs delivered via the internet have not focused on veteran samples

Self-guided internet-based pain self-management programs for chronic pain

- *Living Well with Fibromyalgia (now called FibroGuide)[4]*
  - Participants (95% female) with fibromyalgia provided with education and CBT skills for pain management
  - Program did not involve clinician contact between randomization and 6 months following study enrollment
  - Participants reported improvements in pain, physical functioning, global improvement

- *painTRAINER (formerly Pain COACH)* for hip and knee osteoarthritis[8]
  - Used a self-directed (i.e., non-clinician guided), CBT format
  - Participants (predominantly female) demonstrated improvements in self-efficacy, pain-related functional interference, anxiety, positive and negative affect
  - Reported high satisfaction with the program
  - The trial experienced low attrition

Self-guided internet-based pain self-management programs for chronic pain

- *Health eRide* for veterans with chronic pain[9]
  - Pilot study of a self-guided mobile health intervention used the transtheoretical model of behavior change to tailor pain self-management to patients
  - Included CBT skills
  - Found statistically significant reductions in pain and pain impact but included only a 30-day follow-up

The Pain EASE (e-health for Activity, Skills, and Education) Program[10]

- Internet-based, interactive CBT-CP intervention developed specifically for veterans with cLBP
  - VA RR&D Merit Award: PIs: D. Higgins & R. Kerns

- Self-guided pain self-management program delivered via internet
  - No clinician involvement

- Feasibility and preliminary efficacy trial

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Aims and Hypotheses

- **Aim 1:** Develop and refine an internet-based behavioral pain self-management intervention (Pain EASE)

- **Aim 2:** Test feasibility and preliminary efficacy of the Pain EASE program in veterans with cLBP

  - Hypothesis 2a: Participants would report high levels of credibility, use, and satisfaction with Pain EASE

  - Hypothesis 2b: Participants would report a clinically meaningful reduction in pain-related functional interference at 10 weeks post-baseline, and improvement on other important problems commonly associated with cLBP

Phase I: Prototype Development

- Patient materials based on those used in the COPES trial[11]
  - (PI: A. Heapy)

- Informatics expert and usability engineer/graphic designer

- Expert Panel of clinicians and researchers with expertise in pain management, rehabilitation and health services pain research, conduct of clinical trials of behavioral interventions, and adaptation of therapy materials for technology-based delivery

- Phase I results used to modify prototype for Phase II trial

Phase I: Post-Intervention Questionnaire Results (N=15)

PIQ Item*	Median [IQR] responses
1. I liked the layout of the website (for example, the general look of the website).	7 [5; 8]
2. I found it easy to navigate through the various parts of the website (for example, moving from one topic to the next, completing the modules on the website).	7 [7; 9]
3. I found the topics that were presented in the internet program to be relevant to my situation.	8 [7; 10]
4. I found the self-test at the beginning of the program helpful.	7 [5; 7]
5. I found the self-test at the beginning of the program easy to use.	7 [7; 10]
6. I found it easy understand the material presented in the program.	8 [7;10]
7. I found the amount of material presented in the program to be just the right amount (not too much and not too little).	5 [3; 9]
8. I liked the graphics or images in the program.	7 [3; 7]
9. I would prefer to complete this program via the internet rather than in-person with a counselor.	5 [3; 7]
10. Did you have any difficulty accessing the internet?**	All 15 participants indicated "no"
11. I would recommend this program to others with low back pain.	10 [5; 10]
12. Did you encounter any problems with using the program?**	3/15 respondents answered "yes"

*0 10 likert scale (0=strongly disagree, 10=strongly agree)

** Items 10 and 12 on the PIQ were Yes/No response questions. Results are presented as frequencies rather than median [interquartile range (IQR)].

Phase I: Qualitative Methods and Results

- ◉ Think Aloud method
  - Two 2.5-hour visits verbal feedback of experiences with website usability, design, and navigation

- ◉ Results
  - Participants (N=15): 47% female, 60% White, age 50.9 (range 36-60 years), pain duration 12.3 years, pain intensity 6.9 (range 4-10)

  - Qualitative feedback:
    - ○ Minor style changes (e.g., color changes, images)
    - ○ Reduction of content for some modules
    - ○ Addition of "Test Your Knowledge" quiz for all modules
    - ○ Minor functional changes (e.g., addition of links for forms, links to the dashboard)
    - ○ Restyling the tracking forms for enhanced usability

Pain EASE program description

- Self-guided, internet-delivered (device-agnostic), CBT-based self-management intervention

- Ability to **log in** and be recognized by the program
  - Required to access features of the program and save patient-entered data (e.g., step counts, sleep tracking, relaxation practice)

- Brief **Self-assessment** based on the Chronic Pain Coping Inventory (CPCI)[12]
  - "Personalized Plan" is generated
    - Suggested coping skills modules based upon low item scores on CPCI (i.e., infrequently used adaptive coping skills)
    - Access to all modules regardless of Personalized Plan suggestions

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Pain EASE program description: Skill Modules

Module structure:

1. Brief content presented with graphics and/or audio

2. Self-assessment regarding module content followed by automated feedback (i.e., Test Your Knowledge quiz)

3. Tools for identifying and overcoming barriers to change and supporting resource materials specific to each module (e.g., self-monitoring forms)

Pain EASE Skill Modules

	Skill name	Skill content
1.	Pain Education	Information about chronic pain, biopsychosocial model, chronic pain self-management
2.	Setting personal goals	SMART goals
3.	Planning meaningful activities	Choosing and adding productive, social, or fun activities to daily life
4.	Physical Activity	Pedometer-based walking program, stretching, body mechanics
5.	Relaxation	Diaphragmatic breathing, visual imagery, progressive muscle relaxation
6.	Developing Healthy Thinking Patterns	Identifying and changing unhealthy thoughts
7.	Pacing and Problem-solving	Time-based pacing, problem solving strategies
8.	Improving Sleep	Sleep hygiene
9.	Effective communication	Anger management and communicating effectively with healthcare providers
10.	Preparing for the Future	Skills consolidation and plan for addressing future pain flares

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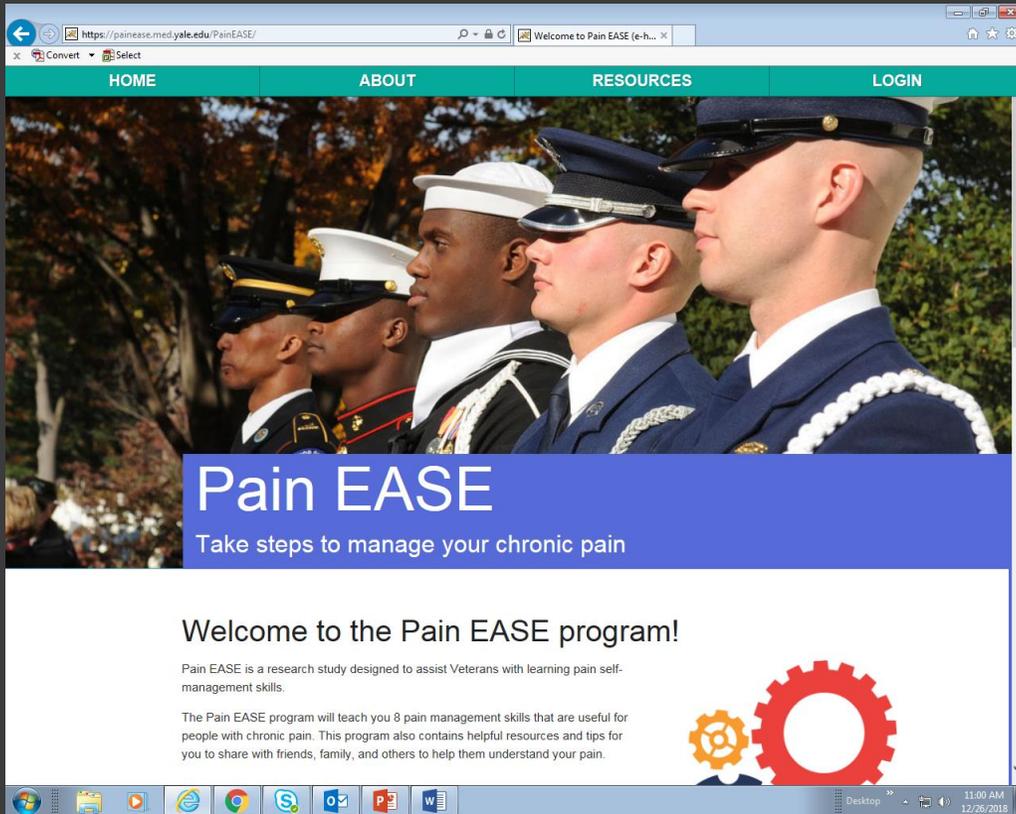*e* health for activity, skills, and education

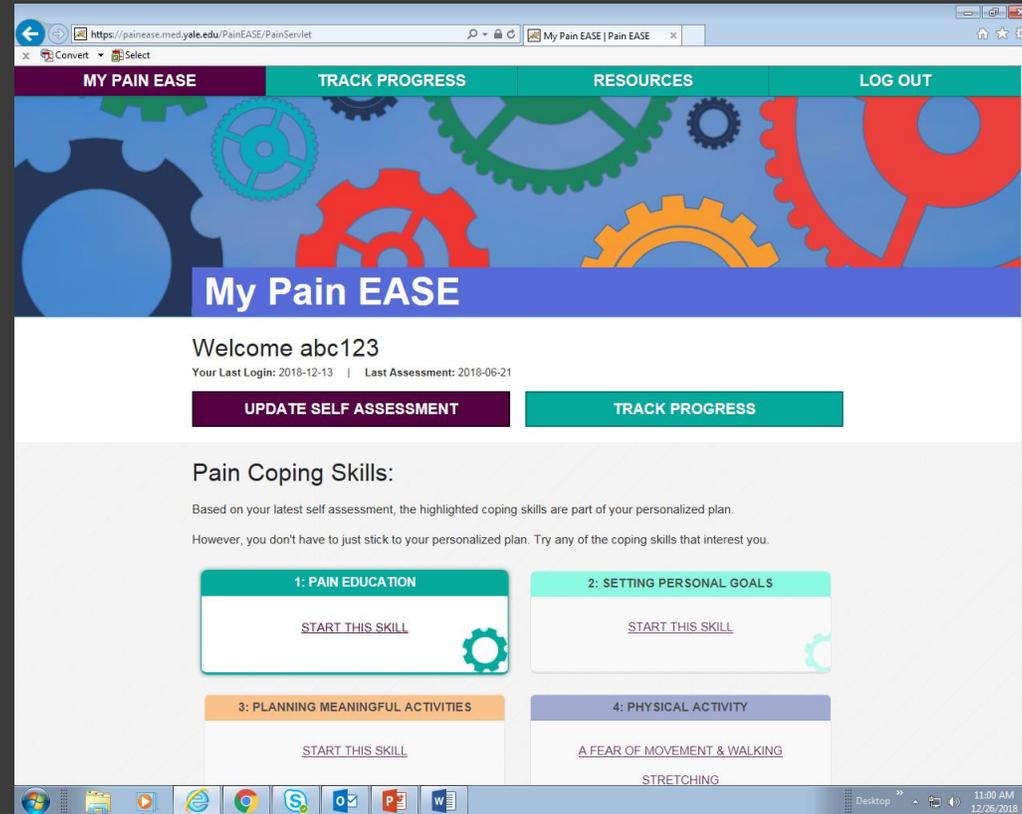# Pain EASE program description: Additional Features

- ◉ Self-monitoring feature to enter data (numerically/graphically displayed)
  - Pain intensity
  - Sleep quality
  - Number of steps walked

- ◉ Tracking forms commonly used in CBT to guide participants in use of the pain coping skills
  - Creating SMART goals
  - Balancing unhealthy thinking
  - Tracking relaxation practice

- ◉ Access to the Test Your Knowledge quizzes

- ◉ Resources section with web links to education about chronic pain and comorbid problems as well as links for free smartphone applications for veterans

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Pain EASE: homepage and personalized plan

Pain EASE: Time-based pacing example

Phase II: Feasibility Outcome Measures

- Module Completion
- Usability
- Treatment Credibility
- Patient Satisfaction
- Additional program feedback (PIQ responses)

Phase II: Preliminary Efficacy Outcome Measures

- Primary Outcome:
  - Pain interference (WHYMPI-Int)

- Secondary:
  - Pain intensity (pain intensity NRS)
  - Emotional functioning (BDI, POMS)
  - Fatigue (Multidimensional Fatigue Inventory)
  - Sleep problems (MOS Sleep scale)

Phase II: Analysis Plan

- Descriptive statistics
  - Demographics and clinical characteristics, Usability, Engagement, Treatment Credibility, Patient Satisfaction

- Mixed models regression (n=58) examined within-subject change from baseline to 10 weeks post-baseline in pain interference, pain intensity, mood, depression symptoms, fatigue, sleep

Phase II: Demographics and Clinical Characteristics

- Enrolled (N=59), N=58 completed baseline, N=41 completed post-treatment
  - 29% attrition at 10 week post-baseline assessment

- Demographics (N=59)
  - Male: 93%
  - 59.3% White, 32.2% Black, 8.5% other
  - Average Age: 55 years (29-77 years)
  - Pain Intensity: 5.9/10
  - Pain duration: 12.7 years (range 0.67-47.0 years)
  - Medication use: NSAID 29.3%, opioid 15.5% 41.4% were not prescribed a medication for pain

Phase II Feasibility Results: Engagement

Engagement Variables	% (N)	Untransformed Mean (SD)	Untransformed Median [IQR]	Untransformed Range	%N	Square Root Transformation Mean	Square Root Transformation Median [IQR]	Square Root Transformation Range
Logins (N=57)								
Total Number of Logins		5.3 (5.8)	3 [1,6.5]	1 - 29		2.04 (1.1)	1.73 [1, 2.5]	1 –5.39
Module Access (N=57)								
Total Number of Modules Accessed		3.3 (3.3)	2 [1,4.5]	0 -10		1.59 (.87)	1.41 [1, 2.1]	0-3.16
Total Number of Days of Module Access		3.35 (3.5)	2 [1,4]	0 -16		1.61 (.87)	1.41 [1, 2]	0-4
Weekly Check in Calls (N=55)								
Completed Weekly Check-In Calls		5.82 (3.17)	6 [3, 8]	0 -10		5.82 (3.17)	6 [3, 8]	0-10
Module Quizzes (N=57)								
Total Number of Completed Module Quizzes		2.07 (3.1)	1 [0, 3]	0 - 10		.95 (1.1)	1 [0, 1.7]	0-3.16
Self-Monitoring								
% of Participants with ≥ 1 self-monitoring entry	36.8 (21)				36.8 (21)			
Practice Forms								
% of Participants with ≥ 1 practice form completed	15.8 (9)				15.8 (9)			

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Preliminary Analyses: Demographic Predictors of Engagement

- **Non-white participants:**
  - Logged in fewer days ($Mdn = 1$ vs $Mdn = 3$, $p = 0.01$)
  - Accessed fewer modules ($Mdn = 1$ vs $Mdn = 2$, $p < 0.01$)
  - Less likely to self-monitor ($Mdn = 0$ vs $Mdn = 1$, $p < 0.01$)
  - No significant differences on # of phone check-ins ($M = 5.11$ vs. $M = 5.81$, $p = 0.46$)

- **Older Age: Positively associated # Days logged in and # Modules accessed**
  - Linear regression: significant positive relationships between
    - Age and number of days logged in ($F_{(1 ,55)} = 7.12$, $p = 0.01$, $R^2 = 0.12$)
    - Age and number of modules accessed ($F_{(1,55)} = 4.80$, $p = 0.03$, $R^2 = 0.08$).

- **Gender: Not significantly related to engagement variables**

Phase II Feasibility Results: Treatment Credibility

Treatment Credibility (0-10 scale)	Mean (SD)
1. How logical did this type of treatment seem to you?	7.9 (SD=2.4)
2. How confident are you that this treatment successfully helped you with your pain?	7.3 (SD=2.4)
3. How confident are you about recommending this treatment to a friend who has a pain problem?	7.9 (SD=2.5)
4. How willing were you to participate in the pain treatment program described?	8.8 (SD=1.9)
5. How successful do you think that this program was in helping you with your pain?	7.1 (SD=2.5)

Likert Scale 1-10 (1=Strongly Negative, 10=Strongly Positive)

Phase II Feasibility Results: Treatment Satisfaction

- ◉ Overall treatment satisfaction
  - • 80% moderately to very satisfied

- ◉ Amount of treatment received
  - • 80% moderately to very satisfied

- ◉ Pain EASE program
  - • 85% (34/40) moderately to very satisfied

- ◉ Return to program in future
  - • 35% Definitely
  - • 42.5% Probably
  - • 7.5% Maybe
  - • 15% Probably Not

- ◉ Extent that program met needs
  - • 5% Almost all needs met
  - • 35% Most of needs met
  - • 47.5% Some of needs met
  - • 7.5% Only a few needs
  - • 5% None of needs met

Phase II Feasibility Results: Post-Intervention Questionnaire

Post-Intervention Questionnaire (PIQ) Item (0-10 scale)	Mean (SD)
1. I liked the layout of the website (for example, the general look of the website).	8.2 (1.7)
2. I found it easy to navigate through the various parts of the website (for example, moving from one topic to the next, completing the modules on the website).	8.3 (2.2)
3. I found the topics that were presented in the internet program to be relevant to my situation.	8.1 (2.4)
4. I found the self-test at the beginning of the program helpful.	7.8 (2.4)
5. I found the self-test at the beginning of the program easy to use.	8.2 (2.3)
6. I found it easy understand the material presented in the program.	8.6 (2.1)
7. I found the amount of material presented in the program to be just the right amount (not too much and not too little).	7.4 (2.4)
8. I liked the graphics or images in the program.	7.7 (2.1)
9. I would prefer to complete this program via the internet rather than in-person with a counselor.	5.8 (3.2)
10. Did you have any difficulty accessing the internet?*	10/40 (25.0%) answered Yes
11. I would recommend this program to others with low back pain.	8.3 (1.9)
12. Did you encounter any problems with using the program?*	8/40 (20.0%) answered Yes

*Items 10 and 12 on the PIQ were Yes/No response questions. Results are presented as frequency of "yes" responses, rather than mean (SD).

Phase II: Preliminary Efficacy Results

Outcome	Scale range	Baseline (N=58*)	10-week post-baseline (N=41**)	Within-subject change 10-week vs. baseline		
		Mean (SE)	Mean (SE)	Mean (95% CI)	p-value	Cohen's d
Primary outcome:						
WHYMPI interference	0 to 6	3.8 (0.2)	3.3 (0.2)	-0.5 (-0.9, -0.1)	0.008***	-0.4
Secondary outcomes:						
POMS						
Tension	0 to 36	13.5 (1.0)	10.9 (1.0)	-2.6 (-4.3, -1.0)	0.002***	-0.5
Depression	0 to 60	16.7 (1.8)	13.6 (1.9)	-3.0 (-5.6, -0.5)	0.02***	-0.4
Total mood disturbance	-32 to 200	49.5 (5.6)	40.0 (5.9)	-9.6 (-17.7, -1.4)	0.02***	-0.4
Beck Depression Inventory (BDI-I)	0 to 63	15.5 (1.4)	13.2 (1.6)	-2.3 (-4.4, -0.2)	0.03***	-0.4
MOS Sleep Scale						
Snoring	0 to 100	51.0 (5.0)	39.2 (5.8)	-11.8 (-22.0, -1.7)	0.02***	-0.4

*All estimates were obtained from mixed models fit on N=58 subjects. Cohen's d effect sizes were estimated as mean within subject change at 10 weeks vs. baseline divided by the standard deviation of the change.

Phase II: Preliminary Efficacy Results

- Change from baseline to 10 weeks post-baseline: Non-significant results
  - Pain intensity NRS
  - Multidimensional Fatigue Scale
  - Additional POMS subscales
  - Additional MOS sleep scale subscales

- Clinical Improvement calculations (≥ 30% and ≥ 50%)
  - Pain interference
    - 26.8% (11/41) improved by at least 30% from baseline
    - 4.6% (6/41) improved by at least 50% from baseline
  - Pain intensity
    - 19.5% (8/41) improved by at least 30% from baseline
    - 4.9% (2/41) improved by at least 50% from baseline

Phase II: Overall Results

- Statistically significant reductions in:
  - Pain interference
  - Mood symptoms
  - Depression symptoms
  - Tension

- Veterans with chronic low back pain may benefit from technology-delivered interventions and these interventions may reduce symptoms of comorbid depression
  - A reduction in both pain and depression is not reported universally among internet-based self-management programs

- Internet-based self-management is a feasible and satisfactory method of receiving pain self-management for veterans

Study Limitations

- Pilot designed primarily to test feasibilty/preliminary efficacy

- 29% attrition

- Login data was variable among participants

- No comparison condition

- Small sample
  - Generalizability of feasibility data

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Implementation Considerations

- Veteran engagement with the program
  - How to better engage younger, non-White veterans with cLBP in this program
    - No race/ethnicity differences in check-in phone calls
    - The role of clinical support for internet-delivered pain care
  - Creating device-agnostic programs
  - Patients almost evenly divided on preference for in-person pain management treatment compared with technology-delivered treatment

- Veteran access
  - Internet access
  - Use of smartphones

- Data Safety and technical considerations

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Future Directions

- Leverage benefits of technology-assisted interventions
  - Promote maintenance of treatment effects
  - Facilitate treatment fidelity
  - Potentially effective as a first line or adjunctive treatment for chronic pain and comorbidities

- Participant engagement with Pain EASE and similar programs

- VA CSP study, "Sequential and Comparative Evaluation of Pain Treatment Effectiveness Response: The SCEPTER Trial" (CSP#2009; PIs Clark & Bair).
  - A pragmatic, 2-step comparative effectiveness study aimed to identify the optimal approach to treating chronic pain with non-pharmacological interventions
  - Pain EASE will be offered in the 1st step of the study, compared to Pain EASE+ a tailored exercise program prescribed by PT; study contains a TAU condition
  - Participants failing to achieve clinically significant reductions in pain interference at the end of the step 1 period will be randomized to one of 3 other non-pharmacological interventions

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