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Title: Pilot Testing of a Multi-Component Cancer Pain-CBT mHealth App for Patients with Advanced Cancer

Running Title: mHealth Pain-CBT Pilot for Advanced Cancer

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Context summary:

Key Objective: Will patients with advanced cancer pain engage in pain CBT treatment delivered entirely digitally through a mobile health app?

Knowledge generated: This single arm pilot study found that over half of patients, a third of which lived in rural areas, found the pain-CBT app engaging and the majority reported high acceptability. Qualitatively, they described that pain-CBT treatment paired with opioid support that was delivered through an app helped to improve their pain self-management, opioid stigma, and overall quality of life.

Abstract (275 words max)

Purpose: Patients with advanced cancer often experience pain symptoms. Pain-CBT represents an effective psychological treatment for chronic pain, yet access remains limited. We conducted a pilot study to assess the feasibility and acceptability of a mobile health (mHealth) intervention that integrates pain-CBT with opioid education and tracking to improve chronic pain management in patients with advanced cancer.

Methods: Adults with advanced cancer and pain (≥4/10,Numeric Rating Scale) using opioids tested the smartphone-based intervention for 28 days, completed baseline, end-of-study, and 2-week post-intervention surveys, and participated in optional qualitative interviews. The intervention assessed pain, mood, catastrophizing, sleep, and opioid use, and provided tailored just-in-time adaptive interventions, and daily psychoeducation (articles, serious game). We assessed feasibility (≥50% app-use), acceptability (Acceptability E-Scale), pre-post intervention changes in pain, and conducted thematic analysis of perceived impact and usefulness.

Results: Among 64 eligible patients, 32 (mean age=55.41years, 55%female) were enrolled. Of those, 59%(n=19) used the app≥50% of days on study, and rated the intervention with good acceptability (mean=24.85,SD=3.72). Non-significant reductions in pain intensity, pain interference, and pain catastrophizing were observed from baseline to 4- and 6-week follow-ups. In debriefing interviews, patients described that the intervention contributed to pain self-management knowledge, promoted pain coping skills, and reduced opioid stigma.

Conclusion: Study results support feasibility and acceptability of a pain-CBT intervention for patients with advanced cancer pain. While exploratory analyses showed non-significant

improvements in pain outcomes, qualitative findings indicate meaningful engagement and skill development. Future testing is needed to determine intervention efficacy.

Précis: This pilot study tested the feasibility and acceptability of a multi-component mHealth Cancer Pain-CBT app for patients with advanced cancer pain. Over 28 days, 59% of participants used the app regularly, and 83% rated the app as highly acceptable. Exploratory analyses showed non-significant reductions in pain intensity, interference, and catastrophizing, with qualitative findings highlighting improved pain self-management, increased knowledge, and reduced opioid-related stigma, provides a rationale for future efficacy testing.

Data availability statement: The data that support the findings of this study are available from the corresponding author upon request.

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Ethics approval statement: The study was approved by the University of Oklahoma Health Sciences Center (OUHSC) and the Dana-Farber/Harvard Cancer Center (DF/HCC) Review Boards.

Patient consent statement: Participants provided informed consent to participate.

Permission to reproduce material from other sources: N/A

Clinical trial registration: NCT05774197

Conflicts of interest: None

Introduction

Up to 60% of patients with advanced cancer experience pain that significantly disrupts quality of life.(1, 2) Complementary treatments, including pain-Cognitive Behavioral Therapy (pain-CBT), are effective treatments for chronic non-cancer pain.(3-11) CBT has also been shown to improve pain coping and quality of life in adults with cancer,(12) although studies of pain-CBT specifically for cancer-related pain are few.(13, 14) Unfortunately, cancer patients' access to pain-CBT is limited due to a dearth of trained clinicians, lack of insurance reimbursement, and the burden of attending weekly, in-person sessions.(15) While pain-CBT telehealth interventions are feasible for cancer patients,(16-22) they are not sufficiently adapted to the advanced cancer context and may remain burdensome within complex cancer treatment schedules. Mobile health technology (mHealth) represents a promising strategy to expand reach, convenience, and personalization of pain-CBT and medication education to individuals with advanced cancer.

We utilized the ORBIT model,(23) to adapt pain-CBT for mHealth delivery for patients with advanced cancer.(24, 25) Phase I integrated relevant literature, current treatments, and theoretical frameworks,(16-20) mechanisms of change,(5, 26) and the biopsychosocial model of pain(27) to refine mHealth application content for inclusion in user-centered testing.(28, 29) Phase II "preliminary testing" included a proof-of-concept pre-pilot study at two NCI-designated cancer centers.(25) The current single-arm pilot study extends this Phase II piloting, assessing the feasibility, acceptability, and preliminary efficacy of the refined pain-CBT app among patients with advanced cancer and chronic pain.

Methods

Patients were recruited from the Stephenson Cancer Center (05/2023–02/2024), the sole

NCI-designated cancer center in the state of Oklahoma. Study procedures were approved by the SCC IRB (OUHSC#15482, 03/17/2023, Clinical Trials Number NCT05774197).

Participants

Study staff screened schedules within outpatient oncology and supportive care clinics for eligible participants. Patients were eligible if they were ≥18 years old, diagnosed with advanced cancer, had chronic pain related to cancer or treatment(≥4/10, Numeric Rating Scale), and had an active opioid prescription. Patients who were no longer on active treatment, had cognitive impairment, were hospitalized, had pain related to a recent surgery, or were unable to speak English were ineligible.

Procedures

Following physician approval, participants who provided written informed consent and completed a baseline survey were considered enrolled. A trained research technician (RT) met with participants in-person or remotely (Zoom/phone) to complete app onboarding on their personal or loaned study phone. During onboarding, the RT configured the app, including notification times, input participants' opioid medication(s), and helped them to input a SMART (sustainable, measurable, achievable, realistic, and time-based) goal related to pain self-management. The RT briefly described app features and prompted participants to practice using the app. Participants were instructed to use the app for 28 consecutive days. On day 28 of testing, participants were emailed an end-of-intervention survey and offered participation in a qualitative interview.

Cancer Pain-CBT App Intervention

The cancer pain-CBT intervention is a stand-alone app hosted on the Insight™ mHealth platform (mHealth Shared Resource at Stephenson Cancer Center(30)). The app prompts *daily* ecological momentary assessments (EMAs) of pain severity and interference, opioid use/opioid efficacy, mood, stress, pain catastrophizing, sleep, and goal achievement. The app delivers algorithm-based messages that are tailored to patients' reported severity of their pain, mood, catastrophizing, and sleep ratings, known as Just-In-Time Adaptive Interventions (JITAI).(31) Modified through iterative user-centered feedback, the app hosts extensive cancer pain and opioid education paired with pain-CBT content presented in brief, engaging formats (2D-animated videos, audio-recorded relaxation, texts with visuals and paired audio recordings, and behavioral serious mini-games: video games that focus on supporting health-based goals including restructuring maladaptive pain thoughts).(32) (Figure 1). A complete review of the app can be found elsewhere.(25, 28) The app sends two notifications at patients' preferred times to complete one daily EMA and review daily educational content, which are also accessible on the app home screen for 24 hours. If participants reported severe symptoms (Supplementary Table 1), the app instructed them to contact their medical team immediately, call 911, or go to the emergency room. Additionally, an email notification outlining patients' severe symptoms was shared with participants' medical teams and input in their medical record.

Assessments and Measures

Patients completed surveys to assess symptoms at baseline, end of intervention (4 weeks), and 6 weeks via REDCap.(33, 34) The baseline survey assessed standard socio-demographics and comfort with smartphone use. The end-of-intervention survey assessed app acceptability and usability. Clinical cancer characteristics were abstracted from the medical record.

App Use, Feasibility, and Acceptability Measures

App use statistics evaluated the proportion of daily EMAs completed and psychoeducational content reviewed by patients. *App feasibility* was pre-defined as ≥70% of individuals who completed app onboarding to perform at least one activity on the app (i.e. EMA completion or content review) for at least 50% of the study days. *Acceptability* was assessed with the 6-item Acceptability E-Scale, designed for technology-based interventions in oncology.(35) Acceptability benchmarks were pre-defined as mean total score on the Acceptability e-scale of ≥24/30 (80% benchmark). .Usability was assessed with the 10-item System Usability Scale (SUS) with total scores ranging from 0-100 following calculation.(36)

Patient Reported Outcomes

Baseline, 4-week and 6-week surveys included the Brief Pain Inventory (BPI) and evaluated pain severity (pain now, best-, worst-, average-pain, range 0-10) and pain interference (range 0-10).(37) *Quality of life* was assessed with the 27-item Functional Assessment of Cancer Therapy Scale-General (FACT-G).(38) *Pain catastrophizing* was measured using the 13-item pain catastrophizing scale (PCS, scores range 0-52),(39) *and depression, anxiety, sleep disturbance, and self-efficacy* were measured using the NIH-Patient-Reported Outcomes Measurement Information System (PROMIS) scales,(40, 41) with higher scores indicating worse symptomatology.

Qualitative Data Collection

A subset of participants were offered and opted to engage in an optional, semi-structured qualitative interview that evaluated the intervention's usability, the impact of the intervention on

pain self-management, and recommended intervention modifications. Interviews were conducted by SMD and supervised by DRA.

Data Analysis

Standard frequency analysis evaluated demographics with means and standard deviations for baseline clinical symptoms. App use was evaluated via completed EMA surveys and content review, with total usage summed per participant. Participants were grouped by app use: high utilizers ($\geq$50% of study days) and low utilizers (<50% of days). Demographic variables between high and low utilizers were compared using paired t-tests, Mann-Whitney U tests, or Chi-square/Fisher's Exact Test. Descriptive statistics were used to summarize acceptability data. Although not powered to assess efficacy, changes in symptoms from baseline to 4 weeks and baseline to 6 weeks were explored using paired t-tests. All statistical analyses were performed using SPSS and R, with significance set as $p \leq 0.05$.

Taking a thematic approach,(42, 43) SMD and KS used NVivo to code all interviews for semantic meaning, confirming code similarity and discussing any discrepancies with DRA. Using the coded extracts, we developed a focused codebook intended to explore intervention impact. The focused codebook was applied to interview data. Crosstabulations between qualitative codes and app utilization rates were compared to identify relationships. In keeping with a "small q"(44) or "codebook approach,"(42, 43, 45) participant frequencies for qualitative codes are presented to report on magnitude of clinical findings and compare incidence across high/low utilizers.

Results

A total of 120 participants were screened and 64 deemed eligible. Of those, 52 consented to participate (82% recruitment rate, See Figure 2) A few participants self-withdrew before onboarding due to feeling too ill (n=9), lack of interest/time (n=5), being lost to follow up (n=3), or other (n=3). From there, 32 were onboarded to the app and enrolled (62% enrollment rate). The enrolled sample had a mean age of 55.41 years (SD=12.22), and 55% identified as women. Most participants identified as White (77.4%, n=24), 12.9% identified as American Indian/Alaska Native (n=4), and 9.7% identified as Black (n=2), and 32% lived in a rural area. Educational background and annual household income varied, with 62% making ≤$60,000 per year. Notably, 62% (n=15) reported recently visiting an emergency department for uncontrolled pain (Table 1).

Cancer Pain-CBT App use, Feasibility, and Acceptability Ratings

Of the 32 participants who were onboarded to the app, 59% (n=19) used the app on ≥50% of days on study, below the predefined feasibility benchmark; 57% (n=16) were active on the app ≥70% of days, and 19% (n=6) were active ≤25% days on study. Participants completed a median of 17/28 (61%, IQR:9.5,23) daily EMAs and 11/28 (39%, IQR:2.5,18) daily educational content. They engaged with EMAs for an average of four minutes (SD=04:47), and educational content for a mean of five minutes (SD=8:16) per day, respectively. They spent an average of two hours and 40 minutes using the app across the 28 days (SD=3:02:08, range 0:21:00–13:06:00 hours, Figure 3a-c, Supplementary Table 3). Across the 32 patients, a total of 483 EMAs were completed out of a possible 728 (66.3%), resulting in 65 symptom alerts that led to care team follow-up. No demographic differences were found between high utilizers (n=19, 59% active >50% of days) and low utilizers (n=12, 38% active <50%) ([Supplementary Table 2]).

Participants reported working towards their self-identified SMART goal on an average of 66.1% (median=73.2%, ranging=17.6% to 100%) of EMAs.

Overall, app users reported high intervention acceptability with a mean total acceptability score of 24.9 (SD=3.72, validated cut off 24/30), and exceeded system usability ratings, mean score of 82 (SUS: 68/100 validated cut-off, Supplementary Table 3). Approximately one fifth of patients (n=7/32) reported technical issues, including major (e.g., app notifications not being sent [n=5]) and minor issues (e.g., glitches during game). Of 16 follow-up respondents, 93.7% (n=15) reported using strategies taught within the app (Figures 3a-c).

Exploratory Changes in Symptoms and Medication Use

No significant changes were observed in paired t-tests of clinical symptoms from baseline to 4 or 6 weeks. Numerical reductions were noted in pain intensity (BPI-SF, pain intensity $mean_{baseline}$=4.78 to $mean_{4weeks}$=4.23) and pain interference ($mean_{baseline}$=6.15 to $mean_{4weeks}$ =5.65, Table 2).

Qualitative Findings

While not all, over half of participants completed an optional qualitative interview (19/32) and the following themes were generated (Figure 4).

App use led to increased knowledge, insight, and greater healthcare engagement

Users reported that their app engagement led to increased insight into a) pain triggers, b) medication use, and c) the relationships between pain and other psychosocial factors, including stress and sleep. Notably, many explained that increased insight reduced their opioid hesitancy by encouraging open communication.

Knowledge and Insight. Over half of the interview participants (n=12) stated that the post-survey JITAI messages (algorithm-based support) helped them to develop insight because it felt "like y'all are listening to me," allowing them to gain new knowledge about pain management. One described, "But it did feel nice to kind of have that personalization after the survey. Tells me they're actually looking at [chuckle] what I'm saying, and it's not just random content thrown at me," (female, colorectal). Overall, users felt the app facilitated learning (n=11) because the information was relevant, focused, well-presented, and easy to navigate.

Psychological pain coping. Many (n=15) participants described improved pain coping: **"**It helped me to understand how to fight back and not let the pain take over my life," (male, rectal). Users (n=8) learned to restructure pain-specific catastrophic thoughts, typically through playing the cognitive restructuring serious game:

> *"I felt like it was kinda simple, but, it – made you take a look at how, you phrase things, and positive versus negative, and, I liked it… Uh, it definitely played into my ability to recognize my emotions and try and rephrase things."* (female, pancreatic)

Of the participants who endorsed learning how to restructure maladaptive pain thoughts, most were female (7/8) and used the app on ≥50% of study days (8/8).

While half described prior pain coping strategies (n=11), other users gained coping strategies through the app (n=8; e.g., breathing, distraction, cognitive restructuring). One said, "I thought they [app content] was interesting and gave me some different ideas of what I can do about my pain. Some of 'em I tried didn't really help too much and some of 'em made me feel better," (male, renal). Many described that the goal setting and tracking promoted engagement in valued activities.

Healthcare Engagement. Nearly half of participants' (n=12) daily survey reports triggered at least one severe symptom alert. Users stated they felt supported and comfortable contacting clinicians to clarify concerns about their pain/opioids. For example, one participant said the alerts

> *"Encouraged me to let the team know that –what I was going through, pain or feelings. before I was scared to speak up. But after learning from this app, that my care team is behind me, or part of me now. So, it helped a lot. So, I spoke up at my last doctor's appointment and I just told them everything. [Laughs]."* (female, endometrial)

One male with colorectal cancer stated, "Um, I'd've gone right to the ER," had the alert not been sent out.

Opioid Hesitance and Stigma. Nearly all (n=18) users expressed a need for opioids, yet many (n=12) voiced hesitance related to using opioid. Some shared hesitancy to take opioids due to fear of side effects (n=4) or addiction (n=5), discussing their own personal history of substance use (n=2), being a first responder to overdose (n=1), or familial misuse (n=1). Others shared concerns related to the opioid crisis (n=2) and worries about opioid surveillance (n=3). All participants who explicitly expressed fears of addiction (n=5) were high app utilizers. Many (n=8) appreciated learning about opioid dosing (e.g., short vs. long-acting). Opioid education, encouragement to contact clinicians, and the non-judgmental tone of the app was reported to support safer opioid dosing and openness to clinicians' recommendations.

App engagement preferences. A few participants (n=3) felt that the app would be more appropriate for younger audiences or those earlier in treatment when many have less self-management knowledge. Others were unmotivated because they were fatigued by notifications

or notifications were too easy to dismiss (n=2), were overwhelmed (n=1), preferred not to use a phone (n=1), or were uninterested in learning skills (n=1). Interestingly, two participants denied psychosocial concerns, stating the app did not pertain to them; however, both scored above the median on pain catastrophizing, depression, and anxiety at baseline.

Discussion

In this single arm pilot study, participants with advanced cancer and chronic pain tested a multi-component mHealth intervention that integrated pain-CBT with opioid education and tracking. Although app-use feasibility fell short of the pre-defined feasibility benchmark (59% instead of 70% of participants used the app on $\geq$50% of study days), participants rated the app to be highly acceptable and usable. Preliminary results demonstrate that a large subset of participants with advanced cancer and chronic pain engaged meaningfully with the interactive technology in this Cancer Pain-CBT app intervention and experienced improved pain self-management. High utilizers (59% of the sample) gained confidence in pain coping strategies and self-management skills, and experienced reductions in opioid hesitancy. While not designed or powered to test the app's efficacy, exploratory analysis revealed a non-significant trend towards reduction in pain intensity, pain interference, and pain catastrophizing.

Many participants reported that the app's regular symptom monitoring (EMAs), personalized, algorithm-based feedback (JITAI), and interactive behavioral serious games that were tailored to their cancer pain experiences helped them to feel validated and empowered in their pain self-management. Users described adopting skills such as cognitive restructuring through the mini-serious games and relaxation through audio-recorded breathing exercises. Participants reported the app was trustworthy because it was linked to their cancer care team.

While tailoring pain-CBT content to the cancer experience has previously been validated, stigma associated with pain psychology treatments remains a primary barrier to engagement.(15) Recommendations from patients recruited from palliative care in our pre-pilot trials highlight the importance of *integrating* psychological pain treatments within medical care and doing so *earlier* in the cancer treatment trajectory to improve usability and uptake.(24, 25) Findings from this trial, that recruited through outpatient oncology, reinforce this timing of delivery. While not all participants engaged, most were able to utilize and engage with the app intervention, and most reported benefitting from it.

To date, most mHealth cancer pain apps have focused on integrating electronic patient-reported outcomes to patients' care teams, but provide minimal symptom management support,(46, 47) or deliver static physical activity education or module-based pain-CBT with minimal interactive learning elements.(16-22, 48-51) While the effectiveness of JITAI technology has been demonstrated in various health contexts(31, 52) (e.g., smoking cessation), to our knowledge, no previous mHealth interventions exist that leverage technology-based algorithms to support in-the-moment pain-CBT management for patients with advanced cancer.

Our group and others have highlighted increasing rates of opioid hesitance and stigma among patients with advanced cancer.(14, 53, 54) Participants described negative opioid histories that drove their hesitance. We recruited from the sole NCI-designated cancer center in Oklahoma, a state that experienced a 15-fold increase in fentanyl-related deaths (2019-2023)(55) and has limited access to specialty pain/palliative care services.(56) While opioids are indicated for managing moderate-severe cancer pain, fears and misuse are prevalent and highly context dependent. Non-judgmental, patient-centered messaging can reduce stigma and promote open

opioid communication(57, 58) and safe and effective opioid use is more likely when paired with comprehensive pain education, as delivered in this intervention. This may be especially critical for patients living in regions with limited specialty pain care, as in Oklahoma, or individuals undergoing cancer treatment with inadequate time or access to behavioral pain management.(15)

Despite the promising results, this study has limitations. First, the single-arm design limits the ability to draw definitive efficacy conclusions. We are conducting a randomized trial to further evaluate the intervention's feasibility and preliminary efficacy. Second, the sample size was relatively small, which limits generalizability. As a strength, few mHealth interventions are tested among users reporting low income, living in rural areas, and identifying as Native American, such as in this trial. Additionally, about a quarter of participants who enrolled were low app users, which may be due to being too ill or a lack of interest/comfort with technology. Even still, attrition and engagement rates were similar to other pain trials in advanced cancer.(59-61)

Conclusion

Cancer-related pain can be complex and few patients with cancer have access to pain psychology treatments. Findings from this feasibility study suggest that mHealth interventions can destigmatize and integrate pain psychology treatment with opioid tracking and education to address cancer pain-related treatment gaps. Further research is needed to determine efficacy, optimal timing, and greater personalization and individual factors that may influence app use. Results suggest that earlier intervention delivery during outpatient oncology care may be more relevant than during late-stage palliative care to improve pain self-management. This Cancer Pain-CBT mHealth intervention holds promising potential to deliver accessible and scalable

cancer pain psychology treatment and become a standard component of comprehensive cancer pain care.

Table 1. Baseline demographic and study specific clinical characteristics

Baseline	M(SD) [range]	n(%)
Age	55.41 (12.22) [21.99-77.05]	
Gender		
Male		14(45.16)
Female		17(54.83)
Hispanic		
Yes		3(9.68)
Race		
White		24(77.4)
American Indian or Alaskan Native		4(12.9)
Black or African American		3(9.68)
Education level		
Some High School		3(9.7)
High School Diploma		11(35.5)
Some College		8(25.8)
College Degree		4(12.9)
Higher level Degree		5(16.1)
Household Income (n=21)		
≤$60k		19(61.29)
>$60k		7(22.58)
Missing		5(16.13)
Insurance type		
Private		16(51.60)
Medicare		7(22.60)
Medicaid		5(16.10)
No insurance		2(6.45)
Other		1(3.23)
Rural dwelling		
Yes		10 (32.26)
Marital status		
Single		8(25.8)
Married		12(38.7)
Separated		2(6.45)
Divorced		9(29.0)
Confidence filling out medical forms (0-5 Likert scale)		
Low ≤3		8(25.8)
High >4		23(74.2)
Cancer types		
Colon/Rectal Cancer		9 (29.0)
Others		6 (19.4)
Pancreatic Cancer		3 (9.68)
Ovarian Cancer		3 (9.68)
Renal Cancer		2 (6.45)
Uterine Cancer		2 (6.45)
Prostate Cancer		1 (3.23)
Lung Cancer		1 (3.23)
Esophageal or Gastric Cancer		3 (9.68)
Head and Neck Cancer		1 (3.23)
Cancer stage (n=26)		
I*		1(3.23)
II		0(0)
III		12(38.71)

IV	16(51.61)
Unstaged*	2(6.45)
Medication use	
Long-acting opioids	
Yes	14(45.16)
Short-acting	
Yes	25(80.65)
Anxiolytic medication	
Yes	10(32.3)
Mood medications (n=25)	
Yes	7(22.58)
Other methods I use to relieve my pain	
Relaxation	19(61.3)
Warm Compress	15(48.4)
Cold Compress	7(22.6)
Distraction	13(41.9)
Other	5(16.1)
Biofeedback	2(6.45)
Hypnosis	1(3.23)
Media and Technology Usage and Attitudes Scale	
Read emails on mobile phone (≥several times a week or more)	
Yes	23(74.2)
Browse web on mobile phone (≥several times a week or more)	
Yes	25(80.6)
Use apps on mobile phone (≥several times a week or more)	
Yes	28(90.3)
End of app use abstraction (n=31):	
Deceased 6-months after intervention use	7(22.58)

Note: *Cellphone use* was assessed with the Media and Technology Usage and Attitudes Scale which prompts patients to state how frequently they have used cell phone features from 1 (never) to 10 (all the time) (62) *While all participants were diagnosed with an advanced cancer, some had not been staged or re-staged since initial diagnosis.

Table 2. Changes in symptoms reported from baseline to 4 weeks and baseline to 6 weeks

	Baseline	End of app use (4 weeks)	2-week-follow up (6 weeks)	Baseline to 4 weeks[b]	Baseline to 6 weeks[b]
	M(sd)	M(sd)	M(sd)	*p*	*p*
Pain intensity[a] (0-10)	4.78 (1.69)	4.23 (1.75)	4.27 (2.34)	0.925	0.156
Pain interference (0-10)	6.15 (2.22)	5.65 (2.19)	5.61 (2.27)	0.531	0.721
How much relief have pain treatment or meds provided? (0-10)	6.23 (2.10)	6.40 (2.06)	6.44 (2.37)	0.554	0.495
Pain catastrophizing (0-52)	15.62 (13.32)	13.76 (15.10)	13.73 (12.56)	0.599	0.938
Self-efficacy, t-score (0-100)	42.78 (5.71)	46.97 (7.92)	44.68 (5.49)	0.530	0.457
Sleep Disturbance, t-score (0-100)	56.58 (9.42)	54.93 (9.17)	55.08 (4.86)	0.844	0.774
Depression, t-score (0-100)	50.42 (8.87)	52.86 (13.13)	53.68 (10.29)	0.656	0.307
Anxiety, t-score (0-100)	53.28 (9.48)	52.92 (11.02)	55.17 (10.52)	0.461	0.447
Medication management, t-score (0-100)	47.68 (8.71)	48.13 (6.59)	48.94 (6.68)	0.895	0.710
Wellbeing - Total score (0-108)	65.28 (14.28)	63.69 (18.15)	65.90 (13.14)	0.696	0.097
Physical wellbeing (0-28)	14.46 (5.73)	13.48 (6.87)	13.81 (6.26)	0.426	0.049*
Social/family wellbeing (0-28)	21.44 (4.76)	20.35 (6.25)	21.83 (5.35)	0.949	0.245
Emotional wellbeing (0-24)	17.08 (4.35)	16.9 (6.53)	16.76 (5.02)	0.836	0.706
Functional wellbeing (0-28)	12.31 (5.26)	12.96 (5.00)	13.49 (4.04)	0.899	0.869

Note: [a] The BPI-SF pain intensity score is calculated as the mean of the scores from four individual items(average pain, best pain, worst pain, current pain) within the BPI, with higher scores indicating greater pain intensity. BPI-SF pain interference: higher scores represent more interference of pain with daily activities; PROMIS t-scores (used for pain self-efficacy, sleep quality-4, depression-4, anxiety-4, and medication management): with higher t-scores indicating better outcomes for pain self-efficacy and medication management, and worse outcomes for sleep disturbance, depression, and anxiety; Pain Catastrophizing Scale: with higher scores indicating higher levels of catastrophizing; FACT-G, Well-being: higher scores represent better quality of life, higher scores on the FACT-G subscales for physical, social/family, emotional, and functional well-being reflect better well-being in these respective domains. [b] indicates paired sample t-tests to compare changes in mean scores across participants between the noted time points. *$p<0.05$.

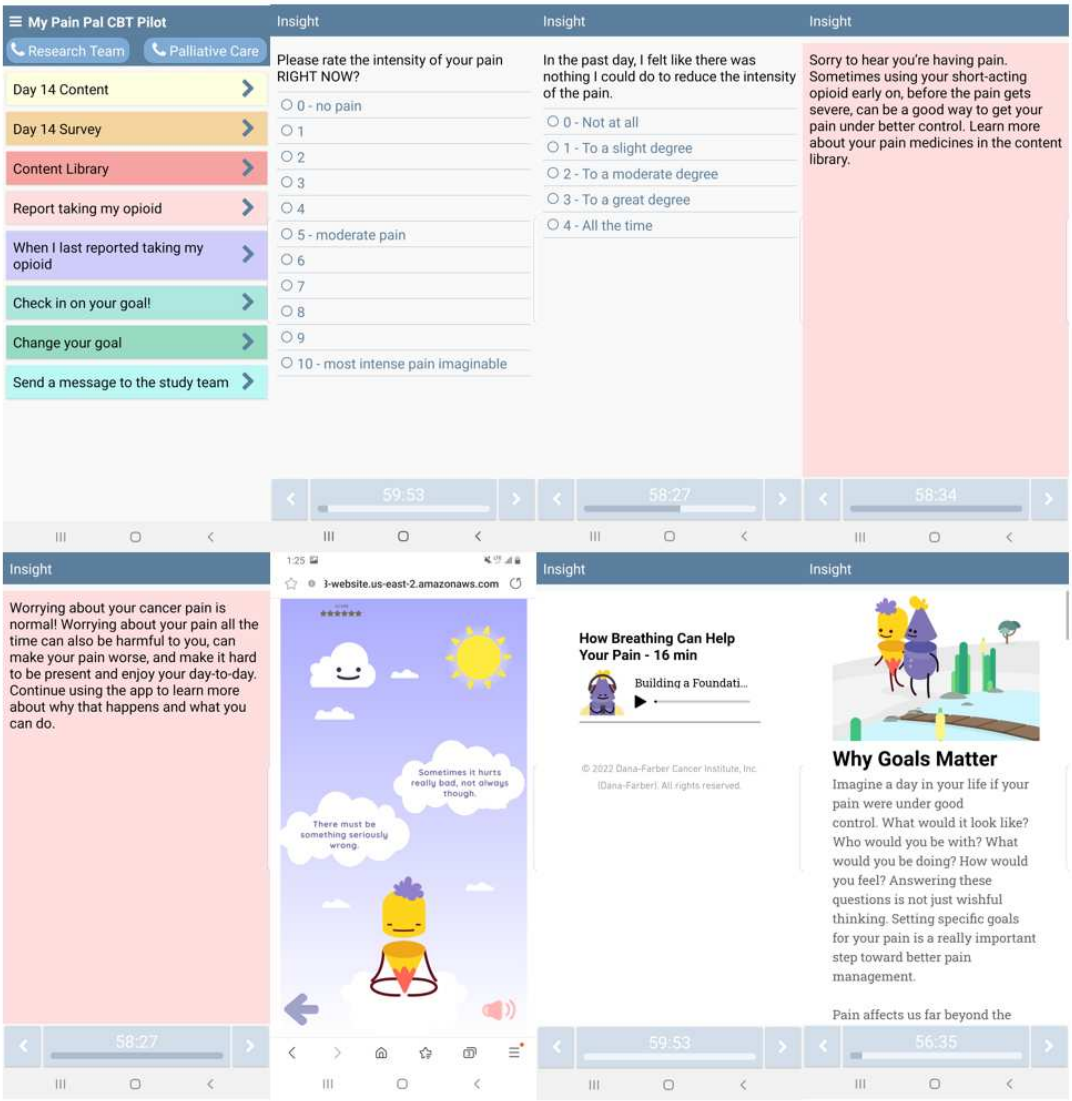


Figure 1. Representative images of the Cancer Pain-CBT app intervention including home page, example items of pain intensity and pain catastrophizing, example JITAI message for high pain and high catastrophizing, example behavioral game, audio-recorded relaxation exercise, and goal-setting written content (from left to right). If participants report severe symptoms (Supplementary Table 1), the app instructs them to contact their medical team immediately, call 911, or go to the emergency room. Additionally, an email notification outlining symptoms is shared with participants' medical teams.

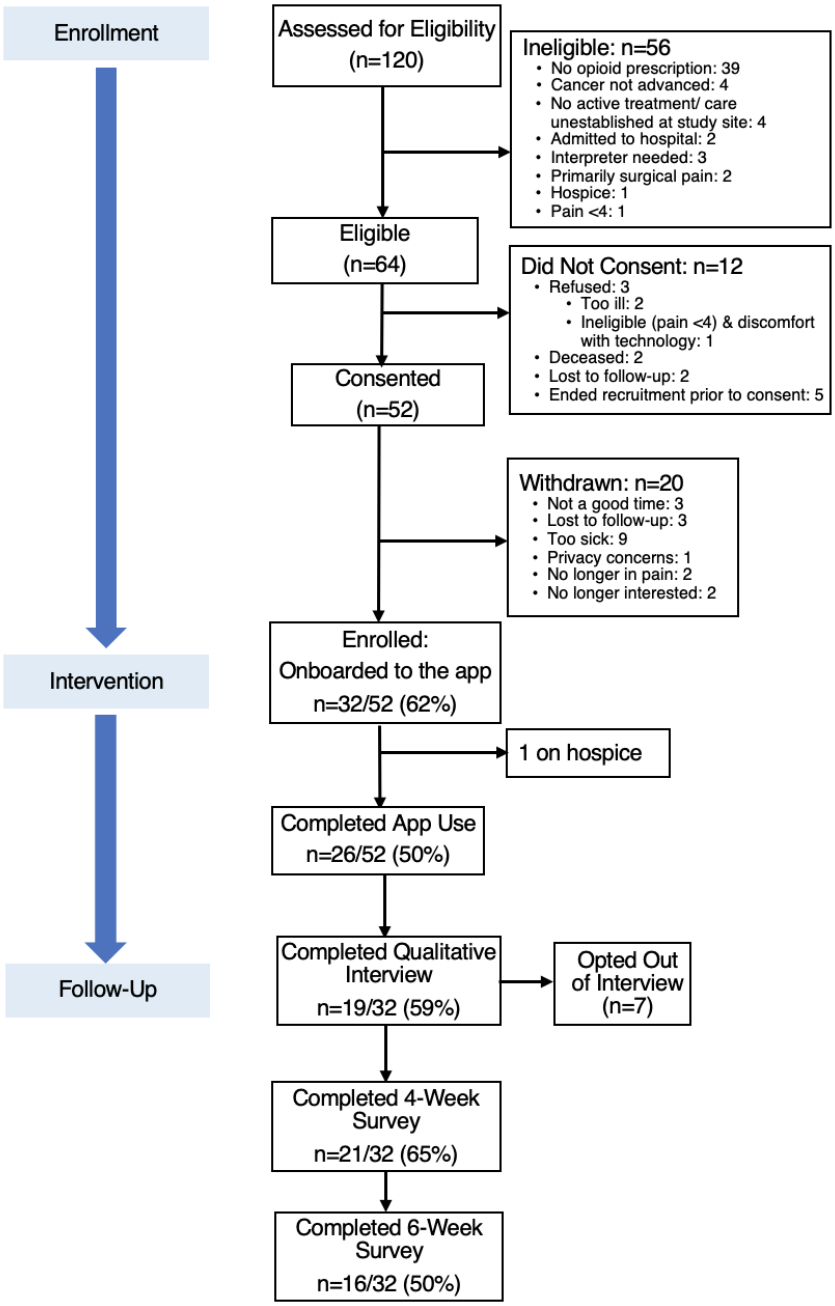
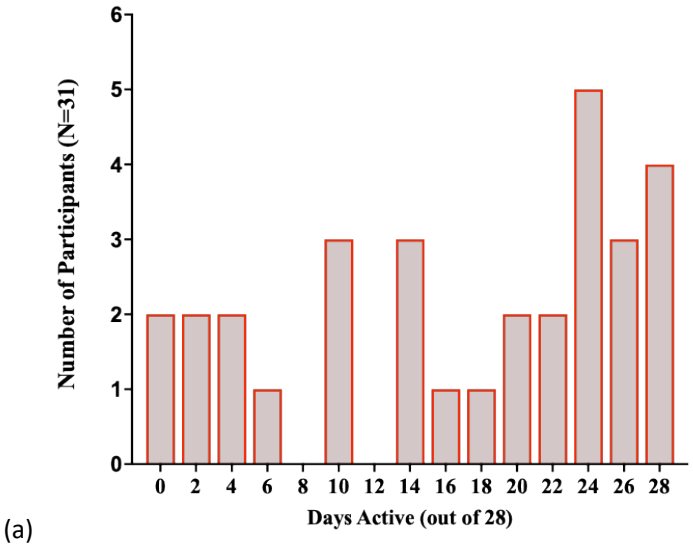
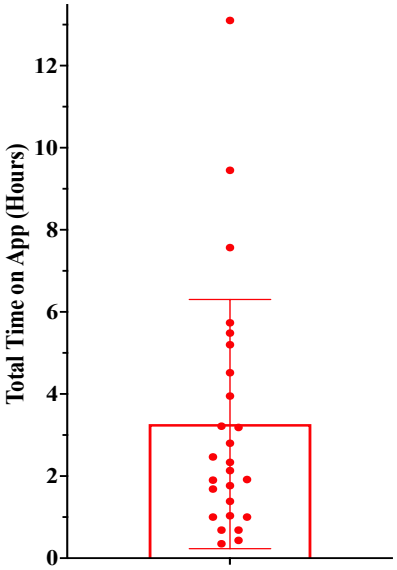


Figure 2. CONSORT Diagram of Cancer Pain-CBT mHealth Application that integrates pain-CBT with pharmacologic education

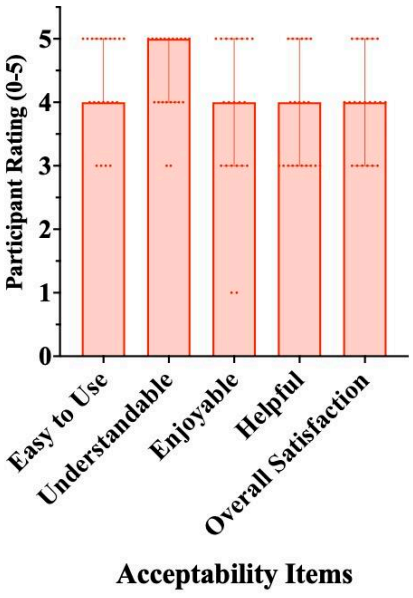
Figure 3. (a) Days active on the Cancer Pain-CBT app for all 32 participants. (b) Total time using the Cancer Pain-CBT app over the 28-day study period for 32 participants (c) Acceptability ratings of the Cancer Pain-CBT app following pilot testing



(a)



(b)



(c)

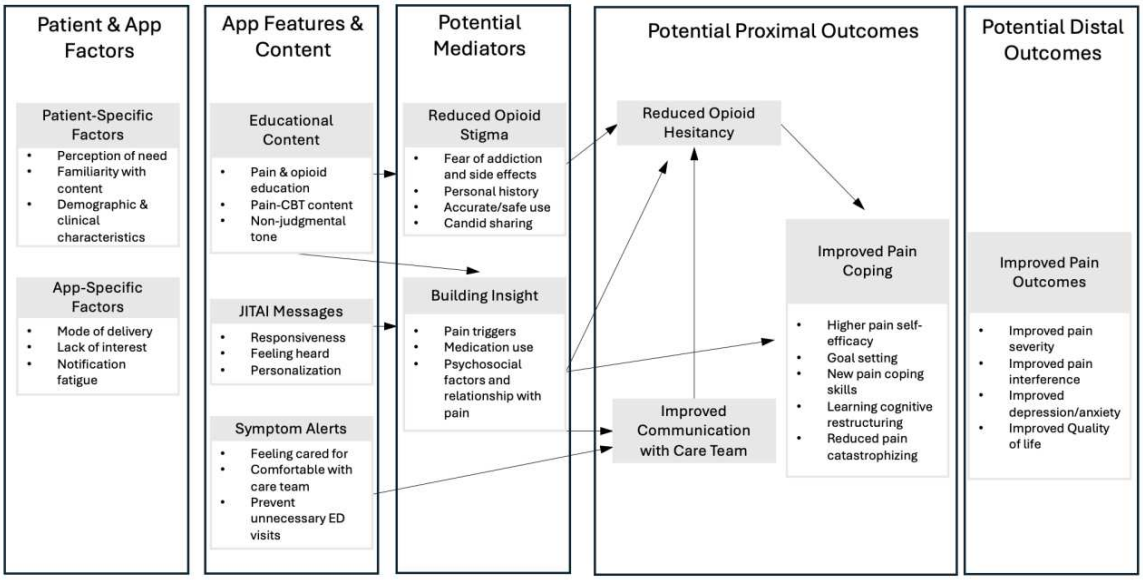


Figure 4. Introductory model outlining themes and constructs identified from qualitative debriefing interviews with participants who pilot tested the Cancer Pain-CBT mHealth app intervention. Many reported that different components of the app allowed them to build insight and pain coping strategies. Notably, the app resulted in improved understanding of pain triggers, medication use and psychosocial factors and promoted open communication with clinicians that reduced opioid hesitancy.

Supplementary Table 1. Severe Symptoms that trigger an email alert to the study team

Pain
• Worst pain = 9-10 • Worst pain = 7-10 and new pain
Red Flag Symptoms
• Severe weakness or fatigue • Lightheadedness or feeling like I was going to pass out • No gas or stool from my bottom (or ostomy) in the last 2 days • Vomiting 2 or more times in the last 24 hours • Fever of 100.5 or greater • New or worsening chest pain • New or worsening shortness of breath • New or worsening back pain • New numbness and weakness in one or both of your legs • Severe difficulty eating or drinking • Hallucinations/nightmares
Opioid Side Effects
• Hallucinations

Supplementary Table 2.

Category	Subcategory	High Utilizer (N=19)	Low Utilizer (N=12)	P Value
Age		56.33	53.95	0.5803
Hispanic/Latino	Yes	1 (5.26%)	2 (16.67%)	1.000
	No	18 (94.74%)	10 (83.33%)	
Race	American Indian or Alaskan Native	3 (15.79%)	1 (8.33%)	0.6665
	Black or African American	1 (5.26%)	2 (16.67%)	
	White	15 (78.95%)	9 (75%)	
	I don't know	0 (0%)	0 (0%)	
Highest Level of Education	Some high school	1 (5.26%)	2 (16.67%)	0.4135
	High school diploma	8 (42.11%)	3 (25%)	
	Some college (AA other)	3 (15.79%)	5 (41.67%)	
	College degree (BA BS other)	3 (15.79%)	1 (8.33%)	
	Higher level degree	4 (21.05%)	1 (8.33%)	
Household Income	$0-15K	5 (31.25%)	2 (18.18%)	1.000
	$16-25K	1 (6.25%)	2 (18.18%)	
	$26-40K	2 (12.5%)	2 (18.18%)	
	$41-60K	3 (18.75%)	2 (18.18%)	
	$61-75K	0 (0%)	1 (9.09%)	
	$76-100K	2 (12.5%)	2 (18.18%)	
	$>100K	2 (12.5%)	0 (0%)	
	Missing or prefer not to answer	4 (21.05%)	1 (8.33%)	
Marital Status	Single	4 (21.05%)	4 (33.33%)	0.2325
	Married	9 (47.37%)	3 (25%)	
	Separated	0 (0%)	2 (16.67%)	
	Divorced	6 (31.58%)	3 (25%)	
Have Primary Caregiver	No	9 (47.37%)	6 (50%)	1.000
	Yes	10 (52.63%)	6 (50%)	
Number of Times to ED Past 12 Months for Pain	0 times	7 (36.84%)	7 (58.33%)	0.1702
	1 time	1 (5.26%)	3 (25%)	
	2 times	6 (31.58%)	1 (8.33%)	
	3 times	1 (5.26%)	0 (0%)	
	4-6 times	3 (15.79%)	0 (0%)	
	7-10 times	1(5.26%)	1(8.33%)	
Confidence Filling Out Medical Forms	Extremely	7 (36.84%)	5 (41.67%)	0.164
	Quite a bit	9 (47.37%)	2 (16.67%)	
	Somewhat	2 (10.53%)	4 (33.33%)	
	A little bit	0(0%)	1(8.33%)	
	Not at all	1 (5.26%)	0 (0%)	
Long-Acting Opioids	Yes	11 (57.89%)	3 (25%)	0.155
	No	8 (42.11%)	9 (75%)	
Short-Acting Opioids	Yes	16 (84.21%)	9 (75%)	0.6526
	No	3 (15.79%)	3 (25%)	
Anxiolytic Medication	Yes	8 (42.11%)	2 (16.67%)	0.2396
	No	11 (57.89%)	10 (83.33%)	
Mood Medications	Yes	5 (26.32%)	2 (18.18%)	1.000
	No	14 (73.68%)	9 (81.82%)	

	Blank	0 (0%)	1 (8.33%)	
Read Emails on Mobile Phone	>=Several Times a Week	15 (78.95%)	8 (66.67%)	0.6757
	<Several Times a Week	4 (21.05%)	4 (33.33%)	
Use Apps on Mobile Phone	>=Several Times a Week	17 (89.47%)	8 (66.67%)	0.1735
	<Several Times a Week	2 (10.53%)	4 (33.33%)	
Browse Web on Mobile Phone	>=Several Times a Week	18 (94.74%)	10 (83.33%)	0.5435
	<Several Times a Week	1 (5.26%)	2 (16.67%)	
Need More Pain Medication	Yes	3 (15.79%)	6 (50%)	0.1719
	No	10 (52.63%)	3 (25%)	
	Uncertain	6(31.58)	3 (25%)	
Concerned Overuse Pain Meds	Yes	3 (15.79%)	2 (16.67%)	0.4149
	No	15 (5.26%)	9 (75%)	
	Uncertain	1 (5.26%)	1 (8.33%)	
Need Further Info on Pain Meds	Yes	2 (11.11%)	3 (25%)	0.2157
	No	16 (88.89%)	9 (25%)	
	Missing	1 (5.26%)		
Insurance Type	Private	11 (57.89%)	5 (41.67%)	0.771
	Medicare	3 (15.79%)	4 (33.33%)	
	Medicaid	3 (15.79%)	2 (16.67%)	
	No Insurance	1 (5.26%)	1 (8.33%)	
	Other	1 (5.26%)	0 (0%)	
Cancer Stage	Stage I	1 (5.56%)	0 (0%)	0.653
	Stage II	0 (0%)	0 (0%)	
	Stage III	6 (33.33%)	6 (54.55%)	
	Stage IV	11 (61.11%)	5 (45.45%)	
	Unknown	1 (5.26%)	1 (8.33%)	
Number of Admissions for Pain	0	15 (78.95%)	9 (75%)	1.000
	1	1 (25%)	1 (33.33%)	
	2+	3 (75%)	2 (66.67%)	
Has Patient Received Chemo	Yes	18 (94.74%)	11 (91.67%)	1.000
	No	1 (5.26%)	1 (8.33%)	
Has Patient Received Immunotherapy	Yes	6 (31.58%)	3 (25%)	1.000
	No	13 (68.42%)	9 (75%)	
Has Patient Received Radiation	Yes	12 (63.16%)	6 (50%)	1.000
	No	7 (36.84%)	6 (50%)	
Has Patient Received Surgery	Yes	10 (52.63%)	4(33.33%)	1.000
	No	9 (47.37%)	8 (66.67%)	
Baseline pain severity		4.44(SD=1.46)	5.61 (SD=2.03)	0.201
Pain catastrophizing		14.74(SD=14.04)	15.42 (SD=9.76)	0.875
Pain interference		4.83(SD=1.93)	4.90 (SD=2.79)	0.451
Depression (t-score)		49.69(SD=9.26)	50.08 (SD=8.68)	0.481
Anxiety (t-score)		52.02(SD=9.78)	52.91 (SD=9.48)	0.803
Sleep disturbance (t-score)		55.81(SD=8.77)	57.16 (SD=8.74)	0.679

End of Study Chart Abstraction (N=26 unless otherwise noted)

	Subcategory	High Utilizer (N=19)	Low Utilizer (N=6)	P Value
Deceased (N=31)	Yes	4 (21.05%)	3 (25%)	0.760
	No	15 (78.95%)	9 (75%)	

Admitted for Pain	1 Admission	1 (11.8%)	1 (0%)	0.538
During Intervention	≥ Admissions	3 (88.2%)	2 (100%)	
	No admissions	15	9	
Calls to Care Team	0	14 (73.7%)	6 (100%)	0.199
During Intervention	1	4(21.1%)	0 (0%)	
	3	1(5.3%)	0(0%)	
Opioids Modified	Yes	9 (50%)	2(33.3%)	0.410
During Intervention	No	9 (50%)	4 (66.7%)	
	Total	18	6	
Pain Interventions	Yes	1 (5.3%)	0 (0%)	0.760
During Study	No	18 (94.7%)	6 (100%)	
2 Week Follow Up Survey (N=16 unless otherwise noted)				
	Subcategory	High Utilizer (N=12)	Low Utilizer (N=4)	P Value
Continued Use of My	Never	0 (0%)	1 (25%)	0.180
Pain Pal App	Sometimes	4 (33.3%)	2(50%)	
	Fairly often	5(41.7%)	0	
	Very often	3(25.0%)	1(50%)	

Supplementary Table 3. Cancer Pain-CBT App use, health care utilization during 28-day testing period, acceptability, and usability

(n=26)	Mean(SD)	Median(%4-5/5)	Total(%) [Range]
Total Daily EMA surveys and content / total possible for all participants across 28-day study period			483 (66.3%)/ 728
Daily survey completion per participant (28 days)	15.58(9.19)	17	
Daily content completion per participant (28 days)	11.87(9.26)	11	
Severe symptom alerts (n=17 patients)	2.50(3.31)	1	65 [0-13 per patient]
Duration of daily survey completion (mins)	4.47(4.24)	3.42	[0.02– 49.82]
Duration of daily content completion (mins)	4.16(13.71)	3.09	[0.05-111.22]
Total time spent on survey and content(mins)	168.67(181.13)	121.21	[0-819.35]
Participants who used study phone to test the app			17 (54.8%)
Visits to the emergency department during 28-day study period (pain)			5 visits, 2 participants
Visits to the emergency department during 28-day study period (non-pain)			2 visits, 2 participants
Acceptability E-Scale			
How easy was the app for you to use?	4.29 (0.78)	(81)	
How understandable was the content in the app?	4.43 (0.77)	(90.5)	
How much did you enjoy the using the app?	3.81 (1.25)	(61.9)	
How helpful was the app as you managed your pain?	3.81 (0.87)	(52.4)	
How acceptable was the amount of time it took you to use the app?	4.52 (0.81)	(81)	
How would you rate your overall satisfaction with the app?	4.00 (0.77)	(80)	
Total Acceptability E-scale score*	24.85 (3.72)		
Study-specific acceptability items			
How much did you enjoy the content/education available in the app?	3.90 (1.22)	(71.4)	
How much did you learn from the app about pain management?	3.71 (1.15)	(57.1)	
How likely would you be to recommend the app to another patient?	4.29 (0.84)	(85.7)	
The app helped me build confidence in managing my pain	3.57 (1.03)	(52.3)	
The combination of behavioral and medication support in the app helped me to manage my pain better	3.81 (0.98)	(61.9)	
The concepts in the app content/education were easy to understand	4.33 (0.73)	(85.7)	
The content/education reviewed in included topics that were new to me	3.67 (0.97)	(61.9)	
The app was overwhelming to use	1.43 (0.81)	(4.8)	

System Usability Scale	82.02 (15.12)
2-week follow-up survey (n=16):	
Have you continued to use what you learned in the app? (n=16)	
Never	1(6.3)
Sometimes	6(37.5)
Fairly often/Very Often	9(56.2)

Note: Acceptability E-scale, Range 0-30, higher scores indicate higher acceptability (35). System Usability Scale, Range 0-100, higher scores indicate higher usability

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