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Efficacy of an online self-management program for chronic burn pain: A randomized controlled trial of the Take Charge of Burn Pain program

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ABSTRACT

This randomized controlled trial investigated the effectiveness of an online self-management program, "Take Charge of Burn Pain (TCBP)," for 96 individuals living with chronic burn pain. Participants were randomly assigned to either the 7-week TCBP program integrating cognitive-behavioral therapy techniques, pain education, and self-management strategies or an attention control group focused on general burn recovery information. Assessments conducted at baseline, post-treatment, and 2- and 5-month follow-ups included measures of pain severity, pain interference, pain self-efficacy, posttraumatic stress disorder symptoms, and depression. Compared to the control group, participants in the TCBP program demonstrated greater reductions in pain severity (mean difference: −1.24, 95 % CI: −1.93 to −0.55, p = 0.0007) and pain catastrophizing (mean difference: −5.41, 95 % CI: −10.33 to −0.49, p = 0.0318) post-treatment when adjusting for key variables. At the two-month follow-up, the TCBP group showed significant improvements in pain interference (P = 0.0123), self-efficacy (P = 0.0269), functional abilities (P = 0.0014), and social role participation (P = 0.0498) compared to the control group. Treatment effects were not sustained at 5-month follow-up. Participants in both groups reported high levels of satisfaction with the online intervention, with the majority finding the program helpful and easy to use, and being willing to recommend it to others with pain. Findings suggest preliminary support for short-term benefits of TCBP for managing certain facets of chronic burn pain. This underscores the need to refine digital approaches to maintain and promote long-term improvements. The potential of self-guided online psychological interventions to enhance pain coping strategies for burn survivors persists.

1. Introduction

Burn injuries are a major source of trauma worldwide, with 9 million new cases reported per year [1]. Upon discharge, patients frequently experience pain and psychological distress. For a significant portion of survivors, this pain and psychological distress persist beyond the immediate aftermath of the injury. Research indicates that in the year following a burn incident, nearly 40 % of patients experience chronic burn pain [2] — pain that persists beyond six months or after complete healing of burn wounds and skin graft donor sites [3]. A decade after a severe burn injury, the prevalence of chronic burn pain remains high, ranging between 35 % to 50 % [4]. Moreover, long-term psychological effects are profound: up to 55 % of burn survivors exhibit symptoms of depression, [5] and nearly 45 % fulfill the criteria for PTSD [6]. over two

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years post injury. Notably, heightened pain-related distress correlates with diminished long-term quality of life [7]. Hence, identifying and addressing chronic burn pain becomes essential for the rehabilitation and societal reintegration of burn survivors.

Clinical guidelines consistently champion psychological treatments for chronic pain as a cornerstone for addressing chronic pain. [8–10] Although these treatments can be effective in alleviating pain and associated distress [11], burn survivors in the United States (US) often encounter barriers when seeking post-discharge psychological service care. Many survivors point to geographical challenges, especially for those in rural locales far from specialized burn centers. A visible lack of expert providers in such areas, coupled with daunting costs, exacerbates the issue [12]. A professional survey in burn care highlights these concerns, revealing that the majority of attention is given during hospitalization with a marked drop-off in post-discharge psychotherapy offerings beyond the six-month post injury mark [13]. Financial hindrances particularly stand out in the US, often putting vital post-discharge mental health services out of survivors' reach. Furthermore, the long-term use of opioids for managing chronic burn pain raises concerns about adverse effects and the potential for misuse, underscoring the need for non-pharmacological interventions. Faced with these systemic shortcomings, there is an urgent need for practical solutions to address current obstacles, ensuring that burn survivors dealing with chronic pain have access to psychological treatments for chronic pain.

In the face of glaring gaps in access to care, the past few decades have seen a rise in the development and adoption of digital behavioral health interventions. Digital psychological and behavioral health interventions refer to therapeutic techniques delivered through online platforms or digital devices, aimed at improving mental health and behavior patterns, which include web-based programs, mobile applications, and other digital tools designed to provide psychological support and behavior modification strategies. Introduced as a contemporary solution to the access barriers of traditional face-to-face mental health approaches, digital psychological and behavioral health interventions improve accessibility for many users. Clinical studies demonstrate that digital psychological and behavioral health interventions yield substantial therapeutic benefits in treatment outcomes compared to control groups [14], including among adults with chronic pain [15]. An expanding body of research suggests that digital psychological and behavioral health interventions may be beneficial for pain management and reducing concomitant distress [16,17]. For example, a randomized controlled trial by Ruehlman et al. [17] found that an online chronic pain self-management program showed promise in reducing pain severity, interference, and emotional burden compared to a waitlist control group. Similarly, several studies have demonstrated the potential effectiveness of digital interventions for improving pain-related outcomes among individuals with conditions such as osteoarthritis [18] and Lupus [19]. However, it is important to note that the effectiveness of these interventions may vary depending on factors such as intervention design, participant engagement, and the specific chronic pain population targeted. Moreover, while digital psychological and behavioral health interventions offer the advantages of accessibility and scalability, these interventions also face challenges, particularly in terms of participant retention and engagement [20,21].

Despite the recognized potential of digital interventions for pain [18, 19,22,23], there remains a significant gap in their application and evaluation for addressing chronic burn pain specifically, highlighting the urgent need for research in this area. The current study focused on evaluating the effect of a digital psychological and behavioral health intervention designed specifically for chronic burn pain entitled "Take Charge of Burn Pain (TCBP)" against a time and attention-equivalent control group. Our first aim was to evaluate whether participants assigned to the TCBP program exhibited greater improvements in pain and pain-related outcomes compared to those in the attention control group, by examining differences between groups at post-treatment and follow-up time points. We also conducted a secondary clustering analysis to account for potential correlations among participants recruited from the same source, as this could influence their response to the intervention. This analysis aimed to provide a more accurate estimation of treatment effects by considering the potential impact of recruitment type on outcomes. Given the beneficial impacts of prior digital psychological and behavioral health interventions for those living with chronic pain [15], we hypothesized that TCBP participants would report greater reductions in pain severity and interference, as well as greater improvements in pain-related self-efficacy, compared to their counterparts in the attention control group. Our second aim was to evaluate the impact of the TCBP program on participants' psychological well-being and engagement in daily activities. We hypothesized that individuals in the TCBP program would demonstrate improvements in depressive and post-traumatic stress symptoms and show increased engagement in life activities compared to those in the attention control group. Finally, we assessed the acceptability and usability of the TCBP program and the online intervention platform. We anticipated that participants in both groups would find the online intervention helpful, easy to use, and would be willing to recommend it to others with chronic pain.

2. Methods

A randomized controlled trial (RCT) was conducted between April 2016 and February 2019. Assessments were at baseline, post-treatment, 2 months follow-up and 5 months follow-up. All participant assessments were conducted using a secure website. Intervention was provided via the online program without interaction with the intervention team. The trial was prospectively registered on clinicaltrials.gov (NCT02661724; Take Charge of Burn Pain). The institutional review board of the Johns Hopkins University reviewed and approved this study.

2.1. Participants

2.1.1. Recruitment

Participants were recruited from several sources. Our primary partner in recruitment was The Phoenix Society, the national organization of burn survivors. Their programs and reach, which extends to approximately 45,000 individuals within the burn community annually, supports the goal of nationwide recruitment. Participants were also recruited from several burn centers including Johns Hopkins, the University of Washington, and the Spaulding Rehabilitation Hospital. Finally, we utilized national burn conferences as a platform to attract further participants from the burn population.

2.1.2. Eligibility criteria

Inclusion criteria for the study were: between 18 and 70 years of age; having a history of a burn injury that required hospitalization at least 6 months prior to enrollment; experiencing moderate to severe pain, as characterized by a score of 4 or above on the Brief Pain Inventory (BPI); persistent pain for a duration of at least 3 months; and demonstrating proficient written and spoken English. Exclusion criteria included any significant pre-existing neurological or psychiatric conditions that could potentially hinder the capacity to provide informed consent, and the absence of consistent access to a computer with an internet connection.

2.2. Randomization

A research coordinator conducted the screening of participants via telephone. If deemed eligible, participants were then asked to complete a baseline assessment using a secure assessment website. Post treatment and follow-up assessments were completed using the same secure website. Once baseline assessment was completed, participants were randomized using a prearranged 1:1 randomization scheme devised by a biostatistician (RC). The study did not employ blinding of participants due to the nature of the intervention. However, the allocation of

participants to the TCBP or control group was concealed from the research team. Furthermore, all participant assessments were conducted using a secure website, reducing the influence of researcher bias.

2.3. Study interventions

2.3.1. Take charge of burn pain

Participants allocated to the Take Charge of Burn Pain (TCBP) program were encouraged to complete seven self-paced on-line lessons, with each lesson completed weekly. TCBP is grounded in cognitive-behavioral therapy (CBT) principles, which posit that a person's thoughts (cognitions), behaviors, and emotions are intricately connected and that changes in any one of these areas can influence the others [24]. TCBP seeks to facilitate changes in participants' behaviors, cognitions, and emotional responses to better manage pain and reduce negative pain beliefs and improve self-efficacy (Fig. 1 for Intervention Outline). The online content included psychoeducational presentations, patient and expert testimonials demonstrating pain management strategies, and questions focusing on burn pain self-management. For instance, lessons involve teaching strategies to challenge negative pain-related thoughts (cognitive restructuring) or to manage stress and relaxation techniques (behavioral strategies). The program is available at https://www.TakeChargeofBurnPain.org/. Participants constructed a pain self-management plan and were encouraged to practice the imparted skills between lessons. The program was adapted and refined from a pre-existing web-based self-management program, utilizing a participatory action research strategy to tailor it to the needs of individuals with burn-related pain [25]. As with the control program, this adaptation process involved patients, burn experts (JF, LAP, The Phoenix Society), and pain experts (JH, SW).

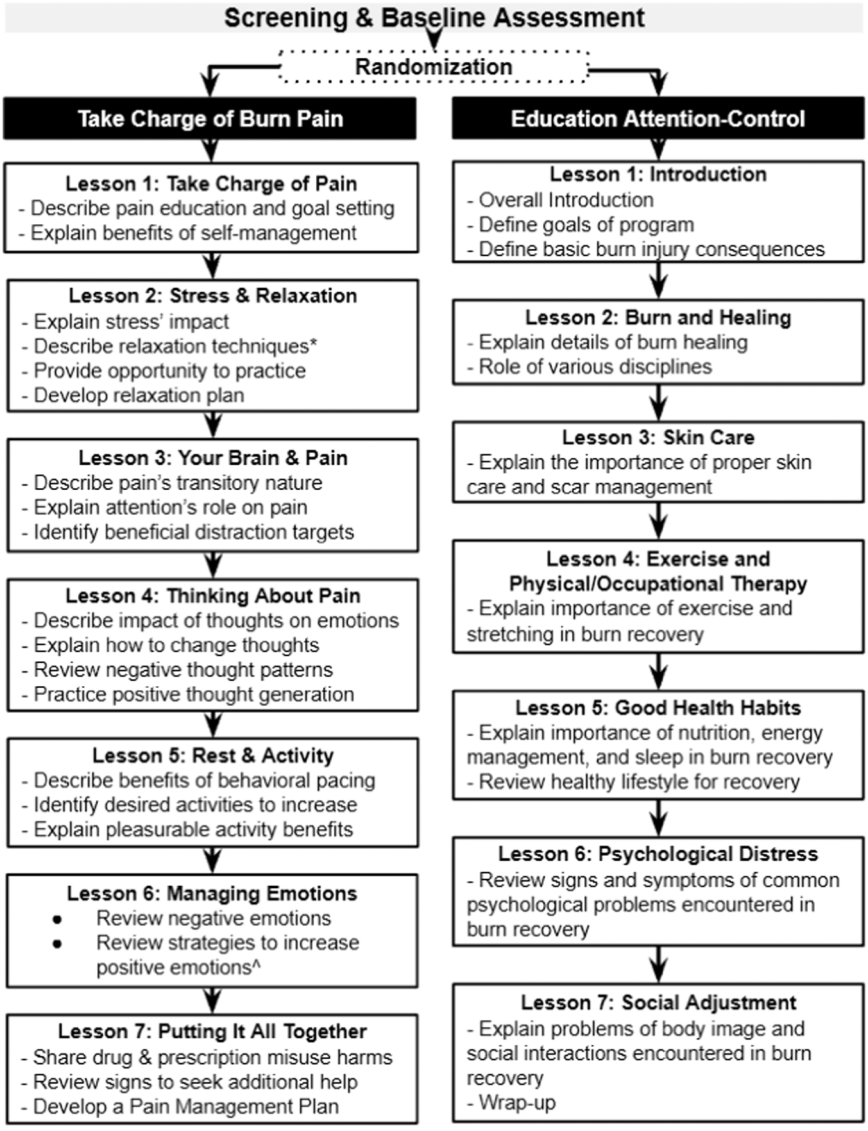

Fig. 1. : Overview of the intervention structure for the "Take Charge of Burn Pain" (TCBP) program compared to the Education Attention-Control group. The TCBP arm includes seven lessons focusing on self-management techniques for chronic burn pain, incorporating education on pain, stress and relaxation strategies, the relationship between brain and pain, cognitive reframing regarding pain, behavioral pacing, emotional management, and the development of a comprehensive pain management plan. The Education Attention-Control arm also comprises seven lessons, but instead offers general information on burn injury, healing, skin care, exercise and therapy, health habits, psychological distress related to burn injury, and social adjustment issues. Each arm is designed to match for time and attention, ensuring comparability in the time participants engage with the material. *Indicates sessions in TCBP that incorporate deep breathing, progressive muscle relaxation, countdown, imagery, and touch. ^ Indicates sessions in TCBP that incorporate social support, addressing thoughts, activity, and relaxation. This structured approach allows for a controlled comparison of the specific impact of cognitive-behavioral strategies on pain management against standard educational content.

2.3.2. Attention control

Participants assigned to the attention control group were asked to complete seven self-paced on-line educational lessons over an eight-week period. The focus of the online content was on providing patient education burn recovery information widely applicable to burn survivors (Fig. 1 for Intervention Outline). Designed as an attention education control, the patient education material was developed using a participatory action research strategy. This approach incorporated contributions from patients, burn experts from our partner organization (The Phoenix Society), and burn specialists (TK, LW).

Module completion was tracked electronically through the online platform, allowing us to see which participants completed each learning module.

2.4. Outcome measures

All outcome measures were completed on the study secure website. Participants who did not complete follow-up assessments as scheduled were sent reminders via automated electronic messages. Those who did not complete follow-up assessments after receiving electronic reminders received a telephone call to encourage follow-up assessment completion. Demographic characteristics such as age, educational level, working status, burn injury treatment, and information about symptoms, and injury events were obtained at baseline.

The **primary outcome** measures included the mean score for the pain severity derived from the worst, least, average, and current pain severity over the last 24 h measured with 0 (no pain) and 10 (worst possible pain) on the Numeric Rating Scale of the Brief Pain Inventory (BPI) [26]. Pain interference was assessed via the Patient Reported Outcomes Information System (PROMIS®) using a computerized adaptive test (CAT) approach based on item response theory [27]. Developed as part of the larger PROMIS initiative, the pain interference CAT is designed to adapt to each respondent's pattern of answers, allowing for a more precise measurement of pain interference with fewer questions compared to traditional fixed-length questionnaires. PROMIS-Pain interference assesses the extent to which pain interferes with physical, cognitive, emotional, and recreational functioning. The responses are captured on a 5-point Likert scale that may range from 1 ("Not at all") to 5 ("Very much"), over the past seven days. Scores from the Pain Interference CAT are converted to a T-score, a standardized score with a mean of 50 and a standard deviation of 10. A higher T-score is indicative of a greater degree of pain interference in daily activities, while a lower score suggests less interference. In addition, the Self-Efficacy for Coping with Symptoms subscale of the Chronic Pain Self-Efficacy Scale was used to assess patients' confidence regarding their ability to cope with pain symptoms [28]. This scale typically comprises 8 items; however, in our study, we removed the item assessing fatigue and only used 7 items focused on pain. This modification was made to maintain a specific focus on pain-related self-efficacy, as fatigue, while often correlated with pain, is a distinct symptom that may not be directly relevant to all participants with burn pain. Despite the missing item, scoring was conducted in line with established guidelines: the scale score is calculated as the mean of the completed items. The responses for the self-efficacy scale are transformed into a 0 to 100 scale, where higher scores denote higher self-efficacy.

Secondary outcomes focused on PTSD and depression symptoms. The PTSD Checklist - DSM-IV six item [29] measures the frequency of specific symptoms related to PTSD, such as intrusive thoughts or hypervigilance. Responses typically range from 1 ("Not at all") to 5 ("Extremely"), capturing how much a respondent has been bothered by each symptom in the past month. Sum scores can range from 6 to 30, with higher scores suggesting a greater likelihood or severity of PTSD symptoms. The PROMIS Depression CAT asks questions that pertain to emotional states such as feeling hopeless, worthless, or disinterested in activities. The frequency of these feelings or states is rated on a 5-point Likert scale ranging from 1 ("Never") to 5 ("Always"). Scores are converted into a T score with a higher T score corresponding to higher levels of depressive symptoms [30].

Tertiary outcomes of interest beyond aims 1 and 2 were also assessed. The Burn Specific Health Scale-Brief (BSHS) - Functional Abilities subscale includes 9-items that measure physical functioning in burn patients. Responses range from 0 (extreme) to 4 (none), sum scores range from 0 to 36 [31]. The 21-item Generic subscale measures psychological and social issues in burn patients. Responses range from 0 (extreme) to 4 (none), sum scores range from 0 to 84 [31]. We assessed participant self-reported health status for anxiety [30], anger [30], quality of life, and social role participation [32] using the PROMIS CAT.

2.4.1. Protocol deviations

Protocol deviations were made from the registered protocol (NCT02661724). Specifically, the registered protocol specified that the Brief Pain Inventory (BPI), Patient Health Questionnaire-9, World Health Organization Disability Assessment Scales, and PTSD Checklist-Civilian Version were to be used as measures of pain interference, depression, participation in life activities, and PTSD symptoms, respectively. However, we elected to use the PROMIS Pain Impact, PROMIS Depression, Burn Specific Health Scale-Brief (BSHS), and PTSD Checklist - DSM-IV Short-form to promote generalization of findings as the PROMIS measures were being widely adopted.

2.5. Acceptability and usability measures

To assess the acceptability and usability of the online intervention, participants in both the TCBP and control groups completed a series of questions at post-treatment, 2-month follow-up, and 5-month follow-up. These questions included ratings of the program's helpfulness in their recovery on a scale from 0 (not at all helpful) to 10 (extremely helpful), willingness to recommend the program to others with pain (yes/no), and ease of use on a scale from 0 (not at all easy to use) to 10 (very easy to use). In addition to the self-reported measures of acceptability and usability, we also examined the completion rates for the intervention modules as an objective measure of usability.

Participants had the opportunity to report serious adverse events (defined as an event that is life-threatening, requires inpatient hospitalization, or will result in persistent or significant disability or incapacity) through online submission to the study team. No participant adverse events were reported.

2.6. Statistical analyses

We conducted linear regression analyses to determine whether enrollment in TCBP significantly improved primary, secondary, and tertiary outcomes. Results are presented as unadjusted linear models, and adjusted models to account for module adherence and data missingness. Module adherence to the intervention was assessed based on the number of lesson modules completed by participants in each group. Adherence was defined as a dichotomous variable, with participants who completed at least 5 lesson modules considered adherent and those who completed fewer considered non-adherent. This dichotomous adherence variable was used as a control in the adjusted regression analyses. Missingness was also used as a control variable in the adjusted regression analyses. A logistic regression model was developed to predict missingness. The variables that were identified as important predictors of missingness in this model were used as adjusters in the main regression analyses. In two separate models with adherence and missingness as the dependent variables, age and education level were found to be the most important predictors, and both variables were used in the adjusted models.

In addition to the primary analysis, we conducted a secondary analysis to account for potential clustering effects based on the recruitment type (e.g., Other Burn Center, Conference, Phoenix Society website, Johns Hopkins Burn Center, University of Washington Burn

Center, Email, Other). Participants recruited from the same source may share similar characteristics or experiences that could influence their response to the intervention. To address this potential issue, we performed a clustering analysis using linear regression models with cluster-robust standard errors. This approach allows for the estimation of treatment effects while accounting for the potential correlation of outcomes within recruitment clusters. The clustering analysis was performed for both unadjusted and adjusted models, with the adjusted models accounting for baseline scores, module adherence, and missingness, in addition to the clustering effect. The results of the clustering analysis are presented in the Appendix (Tables S1 and S2). All analyses were conducted using R version 4.1.1.

3. Results

3.1. Participants and assessment completion

A total of 96 participants were enrolled in the study and randomly assigned to either the TCBP intervention (n = 47) or the control group (n = 49). Participant demographics, injury characteristics, and computer literacy are described in Table 1. Baseline characteristics of the participants were similar between the two groups (Table 1). The mean age of participants was 43 ± 14 years, and the majority were female (61 %), white (70 %), and non-Hispanic (87 %). Most participants had experienced their burn injury within the last 9 years (54 %) and reported high levels of computer literacy, with 50 % spending between 10 and 29 h on the computer in the week prior to enrollment.

Retention rates varied between the two groups, with the control group having higher completion rates at all time points (Fig. 2). In the TCBP group, 26 (55 %), 23 (49 %), and 19 (40 %) participants completed the primary outcome measures at post-treatment, 2-month, and 5-month follow-ups, respectively. In the control group, 37 (76 %), 29 (59 %), and 26 (53 %) participants completed the primary outcome measures at the same time points.

3.2. Module adherence and module completion

In the TCBP group, 53 % of participants (25 out of 47) completed all 7 modules, and 64 % (30 out of 47) completed greater than 4 modules. In contrast, 90 % of participants (44 out of 49) in the control group completed all 7 modules, and 90 % (44 out of 49) completed greater than 4 modules. The difference in module completion ($\chi^2 = 15.90$, $p < .001$) and module adherence rates ($\chi^2 = 9.16$, $p = .002$) between the two groups was statistically significant. These findings suggest that participants in the control group had higher module adherence to the intervention compared to those in the TCBP group.

3.3. Primary outcomes

The primary outcomes of the study were pain severity, pain interference, and pain self-efficacy (Table 2). Table 3 shows different effects between treatment arms for each outcome measure. The linear regression models show unadjusted treatment effects, where a negative coefficient indicates a lower value for the intervention group than the control group. At baseline, there were no significant differences between the TCBP and control groups for any of the primary outcomes (Table 3). The unadjusted analysis (Table 3) showed no significant differences between the TCBP and control groups for pain severity, pain interference, or pain self-efficacy at any time point. However, after adjusting for baseline scores, module adherence, and missingness (Table 4), the TCBP group demonstrated significantly lower pain severity scores compared to the control group at post-treatment (estimated treatment difference = −1.24, 95 % CI = −1.93, −0.55, P = 0.0007). This difference was not maintained at the 2-month and 5-month follow-ups.

The adjusted analysis also revealed that the TCBP group had significantly lower pain interference scores (estimated treatment difference =

Table 1
Characteristics of Take Charge of Burn Pain Participants, Overall and by Arm.

Characteristic	Overall, N = 96	Control, N = 49	Intervention, N = 47
Gender			
Female	58 (61 %)	30 (61 %)	28 (61 %)
Male	37 (39 %)	19 (39 %)	18 (39 %)
Race			
White	67 (70 %)	35 (71 %)	32 (68 %)
African American	13 (14 %)	7 (14 %)	6 (13 %)
Native Hawaiian or other	1 (1.0 %)	0 (0 %)	1 (2.1 %)
Pacific Islander	2 (2.1 %)	0 (0 %)	2 (4.3 %)
American Indian or Alaskan	3 (3.1 %)	2 (4.1 %)	1 (2.1 %)
Native	2 (2.1 %)	0 (0 %)	2 (4.3 %)
Asian	7 (7.3 %)	5 (10 %)	2 (4.3 %)
More than one			
Other			
Latino or Hispanic			
No	83 (87 %)	42 (86 %)	41 (89 %)
Yes	12 (13 %)	7 (14 %)	5 (11 %)
Age Range			
20 to 29	20 (21 %)	12 (24 %)	8 (17 %)
30 to 39	18 (19 %)	11 (22 %)	7 (15 %)
40 to 49	20 (21 %)	11 (22 %)	9 (19 %)
50 to 59	23 (24 %)	13 (27 %)	10 (21 %)
60 to 69	15 (16 %)	2 (4.1 %)	13 (28 %)
Highest education level			
9th to 12th grade, no diploma	4 (4.2 %)	2 (4.1 %)	2 (4.3 %)
GED or high school graduate	16 (17 %)	11 (22 %)	5 (11 %)
Some college, no degree	22 (23 %)	12 (24 %)	10 (21 %)
Associates degree (2-year	7 (7.3 %)	2 (4.1 %)	5 (11 %)
degree)	21 (22 %)	8 (16 %)	13 (28 %)
Bachelor's degree/college	6 (6.2 %)	5 (10 %)	1 (2.1 %)
degree	19 (20 %)	9 (18 %)	10 (21 %)
Some graduate work, no			
degree			
Graduate degree			
How did you hear about the			
study?			
(Recruitment Type)	9 (9.4 %)	4 (8.2 %)	5 (11 %)
Other Burn Center	15 (16 %)	8 (16 %)	7 (15 %)
Conference	42 (44 %)	21 (43 %)	21 (45 %)
Phoenix Society website	5 (5.2 %)	3 (6.1 %)	2 (4.3 %)
Johns Hopkins Burn Center	4 (4.2 %)	1 (2.0 %)	3 (6.4 %)
University of Washington	4 (4.2 %)	2 (4.1 %)	2 (4.3 %)
Burn Center	17 (18 %)	10 (20 %)	7 (15 %)
Email			
Other			
When did your burn injury			
occur?			
Greater or equal to 6 months	94 (98 %)	48 (98 %)	46 (98 %)
Less than 6 months	2 (2.1 %)	1 (2.0 %)	1 (2.1 %)
How many years ago was your			
burn injury?			
0 to 9	51 (54 %)	25 (51 %)	26 (57 %)
10 to 19	15 (16 %)	9 (18 %)	6 (13 %)
20 to 29	15 (16 %)	8 (16 %)	7 (15 %)
30 to 39	5 (5.3 %)	3 (6.1 %)	2 (4.3 %)
40 to 49	3 (3.2 %)	2 (4.1 %)	1 (2.2 %)
50 to 59	5 (5.3 %)	2 (4.1 %)	3 (6.5 %)
60 to 69	1 (1.1 %)	0 (0 %)	1 (2.2 %)
Do you use the computer to look			
up something on the internet?			
No	0 (0 %)	0 (0 %)	0 (0 %)
Yes	96 (100 %)	49 (100 %)	47 (100 %)
Do you use the computer to send			
or receive email?			
No	7 (7.3 %)	3 (6.1 %)	4 (8.5 %)
Yes	88 (92 %)	46 (94 %)	42 (89 %)
Do you use the computer to			
order something online?			
No	6 (6.2 %)	2 (4.1 %)	4 (8.5 %)
Yes	89 (93 %)	47 (96 %)	42 (89 %)
Do you use the computer to			
make a reservation?			
No	17 (18 %)	9 (18 %)	8 (17 %)
Yes	78 (81 %)	40 (82 %)	38 (81 %)

(continued on next page)

Table 1 (*continued*)

Characteristic	Overall, N = 96	Control, N = 49	Intervention, N = 47
Do you use the computer to look up something on the internet?			
No	3 (3.1 %)	0 (0 %)	3 (6.4 %)
Yes	92 (96 %)	49 (100 %)	43 (91 %)
In the last week, how many hours have you spent on the computer?			
0 to 9	6 (6.4 %)	2 (4.1 %)	4 (8.9 %)
10 to 19	22 (23 %)	12 (24 %)	10 (22 %)
20 to 29	25 (27 %)	17 (35 %)	8 (18 %)
30 to 39	10 (11 %)	4 (8.2 %)	6 (13 %)
40 to 49	14 (15 %)	6 (12 %)	8 (18 %)

−2.81, 95 % CI = −5.01, −0.61, P = 0.0123) and significantly higher self-efficacy scores (estimated treatment difference = 8.97, 95 % CI = 1.03, 16.92, P = 0.0269) compared to the control group at the 2-month follow-up (Table S2). These differences were not observed at post-treatment or the 5-month follow-up.

The clustering analysis, which accounted for potential correlations among participants recruited from the same source, yielded similar results (Tables S1 and S2). In the adjusted clustering analysis, the TCBP group had significantly lower pain severity scores at post-treatment, as well as significantly lower pain interference and significantly higher self-efficacy scores at the 2-month follow-up, compared to the control group.

These findings suggest that while the unadjusted analysis did not reveal significant differences between the groups, the adjusted analysis indicated that the TCBP intervention had a short-term beneficial effect on pain severity immediately after treatment, as well as on pain interference and self-efficacy at the 2-month follow-up. However, these effects were not sustained at the 5-month follow-up.

3.4. Secondary outcomes

The secondary outcomes of the study were PTSD symptoms (PTSD Checklist - DSM-IV), depression (PROMIS Depression CAT), and pain catastrophizing (Table 2). At baseline, there were no significant differences between the TCBP and control groups for any of the secondary outcomes (Table 3). The unadjusted analysis (Table 3) showed no significant differences between the TCBP and control groups for PTSD symptoms, depression, or pain catastrophizing at any time point. However, after adjusting for baseline scores, module adherence, and

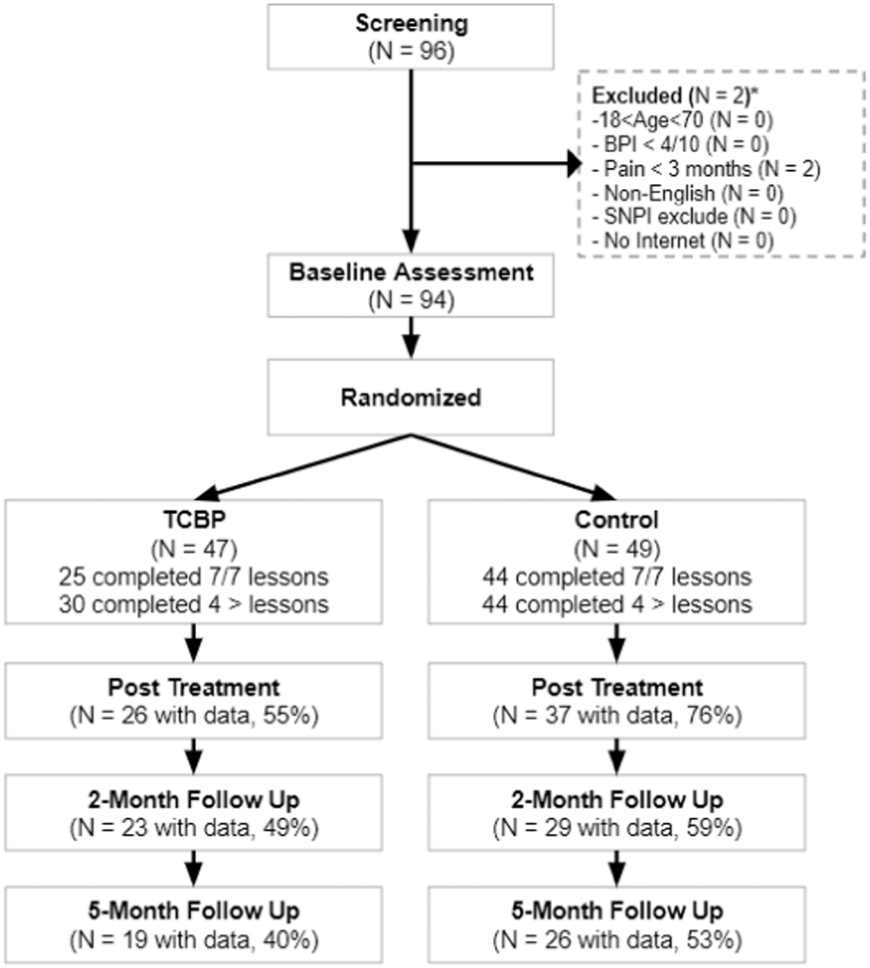

Fig. 2. : CONSORT Flow Diagram of Participant Progress Through the Randomized Controlled Trial of the Take Charge of Burn Pain Program. The flow diagram illustrates participant progression through the trial, from initial screening through final follow-up. Of 96 individuals screened, 2 were excluded (*Note: sum may not match total due to possible overlap in exclusion criteria), with 94 completing baseline assessment and randomization. The TCBP intervention group (N = 47) had 25 participants complete all 7 lessons and 30 complete more than 4 lessons. Retention rates for the TCBP group were 55 % (26/47) at post-treatment, 49 % (23/47) at 2-month follow-up, and 40 % (19/47) at 5-month follow-up. The control group (N = 49) showed higher completion rates, with 44 participants completing both all 7 lessons and more than 4 lessons. Control group retention rates were 76 % (37/49) at post-treatment, 59 % (29/49) at 2-month follow-up, and 53 % (26/49) at 5-month follow-up. Exclusion criteria included: age outside 18–70 years, BPI < 4/10, pain duration < 3 months, non-English speaking, significant neurological or psychiatric conditions precluding informed consent (SNPI), and lack of internet access.

Table 2
Primary and Secondary Outcome Characteristics.

	Outcomes	Total Sample mean ± SD, N	Control mean ± SD, n	Intervention mean ± SD, n
Primary Outcomes	Pain Severity			
	Baseline	4.5 ± 1.8, 91	4.7 ± 1.7, 47	4.3 ± 1.9, 44
	Post-Assessment	3.8 ± 1.9, 60	4.1 ± 1.9, 37	3.2 ± 1.8, 23
	2-Month Follow Up	4.1 ± 2.2, 54	4.3 ± 2.3, 31	4.0 ± 2.1, 23
	5-Month Follow Up	4.0 ± 2.0, 45	4.1 ± 1.9, 26	3.9 ± 2.2, 19
	Self-Efficacy			
	Baseline	55.7 ± 18.7, 91	58.1 ± 17.2, 47	53.1 ± 20.1, 44
	Post-Assessment	66.0 ± 18.7, 60	65.3 ± 20.0, 37	67.3 ± 16.8, 23
	2-Month Follow Up	66.3 ± 16.6, 53	67.0 ± 17.3, 30	65.4 ± 16.1, 23
	5-Month Follow Up	66.2 ± 20.5, 45	65.3 ± 20.0, 26	67.4 ± 21.6, 19
	Pain Interference (PROMIS Impact)			
	Baseline	62.8 ± 5.7, 91	62.0 ± 6.1, 47	63.7 ± 5.2, 44
	Post-Assessment	59.1 ± 5.8, 60	59.0 ± 5.6, 37	59.3 ± 6.2, 23
	2-Month Follow Up	58.4 ± 5.7, 53	59.1 ± 5.0, 30	57.4 ± 6.5, 23
	5-Month Follow Up	58.1 ± 6.9, 45	57.3 ± 5.6, 26	59.3 ± 8.5, 19
Secondary Outcomes	PTSD Checklist - DSM-IV			
	Baseline	16.7 ± 5.5, 90	17.2 ± 5.4, 47	16.2 ± 5.5, 43
	Post-Assessment	15.3 ± 6.3, 60	16.0 ± 6.1, 37	14.0 ± 6.5, 23
	2-Month Follow Up	14.3 ± 5.5, 53	14.7 ± 5.4, 30	13.7 ± 5.7, 23
	5-Month Follow Up	15.8 ± 5.5, 45	15.8 ± 5.4, 26	15.7 ± 5.8, 19
	PROMIS Depression CAT			
	Baseline	58.7 ± 8.2, 90	58.6 ± 8.1, 47	58.7 ± 8.4, 43
	Post-Assessment	55.8 ± 8.8, 60	56.2 ± 7.7, 37	55.1 ± 10.5, 23
	2-Month Follow Up	56.5 ± 8.5, 53	56.5 ± 8.0, 30	56.6 ± 9.4, 23
	5-Month Follow Up	58.6 ± 9.0, 45	59.3 ± 10.0, 26	57.5 ± 7.6, 19
	Pain Catastrophizing			
	Baseline	20.8 ± 11.3, 90	21.5 ± 10.6, 47	20.0 ± 12.0, 43
	Post-Assessment	16.2 ± 11.3, 60	17.6 ± 11.8, 37	14.0 ± 10.3, 23
	2-Month Follow Up	16.2 ± 11.3, 53	17.7 ± 12.5, 30	14.3 ± 9.4, 23
	5-Month Follow Up	17.2 ± 13.4, 45	17.6 ± 12.5, 26	16.7 ± 15.0, 19

missingness (Table 4), the TCBP group demonstrated significantly lower pain catastrophizing scores compared to the control group at post-treatment (estimated treatment difference = −5.41, 95 % CI = −10.33, −0.49, P = 0.0318). This difference was not maintained at the 2-month and 5-month follow-ups.

The adjusted analysis did not reveal any significant differences between the TCBP and control groups for PTSD symptoms or depression at any time point (Table 4).

The clustering analysis, which accounted for potential correlations among participants recruited from the same source, yielded similar results (Tables S1 and S2). In the adjusted clustering analysis, the TCBP group had significantly lower pain catastrophizing scores at post-treatment compared to the control group. However, no significant differences were observed for PTSD symptoms or depression at any time point.

These findings suggest that while the unadjusted analysis did not reveal significant differences between the groups, the adjusted and clustering analyses indicated that the TCBP intervention had a short-term beneficial effect on pain catastrophizing immediately after treatment. However, this effect was not sustained at the 2-month and 5-month follow-ups. The intervention did not demonstrate significant effects on PTSD symptoms or depression at any time point.

3.5. Tertiary outcomes

The tertiary outcomes of the study included the Burn Specific Health Scale-Brief (BSHS) - Functional Abilities subscale, the BSHS - Generic subscale, and PROMIS CAT measures of anxiety, anger, social role participation, and quality of life (Table 2). At baseline, there were no significant differences between the TCBP and control groups for any of the tertiary outcomes, except for the PROMIS Health score, which was significantly lower in the TCBP group (estimated treatment difference = −0.36, 95 % CI = −0.72, −0.01, P = 0.0461) (Table 3).

The unadjusted analysis (Table 3) showed no significant differences between the TCBP and control groups for the BSHS - Functional Abilities subscale, the BSHS - Generic subscale, PROMIS CAT Anxiety, PROMIS Social Roles, or PROMIS Quality of Life at any time point. However, the PROMIS CAT Anger score was significantly lower in the TCBP group compared to the control group at the 5-month follow-up (estimated treatment difference = −5.51, 95 % CI = −10.96, −0.05, P = 0.0479).

The adjusted analysis (Table 4) did not reveal any significant differences between the TCBP and control groups for the BSHS - Functional Abilities subscale, the BSHS - Generic subscale, PROMIS CAT Anxiety, PROMIS CAT Anger, PROMIS Social Roles, or PROMIS Quality of Life at any time point.

The clustering analysis, which accounted for potential correlations among participants recruited from the same source, yielded some additional findings (Tables S1 and S2). In the adjusted clustering analysis, the TCBP group had significantly lower BSHS - Functional Abilities scores (estimated treatment difference = −3.71, 95 % CI = −5.99, −1.43, P = 0.0014) and significantly higher PROMIS Social Roles scores (estimated treatment difference = 2.34, 95 % CI = 0.01, 4.68, P = 0.0498) compared to the control group at the 2-month follow-up. The TCBP group also had significantly lower PROMIS CAT Anxiety (estimated treatment difference = −2.65, 95 % CI = −5.06, −0.23, P = 0.0315) and PROMIS Health scores (estimated treatment difference = −0.22, 95 % CI = −0.40, −0.04, P = 0.0146) at post-treatment compared to the control group. Additionally, the PROMIS Quality of Life score was significantly higher in the TCBP group compared to the control group at post-treatment (estimated treatment difference = 0.29, 95 % CI = 0.01, 0.56, P = 0.0391) in the unadjusted clustering analysis.

These findings suggest that the TCBP intervention had some beneficial effects on functional abilities, social role participation, anxiety, overall health, and quality of life at various time points, when accounting for potential correlations among participants recruited from the same source. However, these effects were not consistent across all analyses and were not sustained at the 5-month follow-up. The intervention did not demonstrate significant effects on the BSHS - Generic subscale or anger in the adjusted or clustering analyses.

Table 3
Unadjusted Treatment Effects - Linear Regression Model.

Outcomes	BaselineCoefficient* (P Value)	Post TreatmentCoefficient* (P Value)	2-mo Follow UpCoefficient* (P Value)	5-mo Follow UpCoefficient* (P Value)
Pain Severity	−0.32 (0.3953)	−0.95 (0.0559)	−0.31 (0.6150)	−0.26 (0.6762)
Self-Efficacy	−5.03 (0.2023)	2.02 (0.6888)	−1.55 (0.7405)	2.09 (0.7387)
Pain Interference (PROMIS Impact)	1.66 (0.1650)	0.35 (0.8233)	−1.74 (0.2747)	1.99 (0.3469)
PTSD Checklist - DSM-IV	−0.98 (0.3969)	−1.96 (0.2432)	−1.04 (0.5021)	−0.16 (0.9235)
PROMIS Depression CAT	0.08 (0.9624)	−1.10 (0.6411)	0.11 (0.9638)	−1.87 (0.4965)
Pain Catastrophizing	−1.54 (0.5225)	−3.52 (0.2437)	−3.47 (0.2730)	−0.93 (0.8211)
Burn Specific Health Scale-Brief Functional Abilities	0.53 (0.7275)	−0.62 (0.7707)	−0.43 (0.8537)	1.44 (0.5219)
Burn Specific Health Scale-Brief Generic	0.87 (0.8093)	−1.15 (0.8088)	−1.82 (0.7017)	−3.03 (0.5602)
PROMIS CAT Anxiety	0.07 (0.9708)	−1.97 (0.4188)	−0.78 (0.7299)	−0.75 (0.7750)
PROMIS CAT Anger	−1.91 (0.2913)	−3.61 (0.1478)	−2.55 (0.3417)	−5.51 (0.0479)
PROMIS Health	−0.36 (0.0461)	−0.31 (0.1644)	−0.29 (0.2129)	0.06 (0.8152)
PROMIS Quality of Life	−0.03 (0.8909)	0.29 (0.2189)	−0.14 (0.5541)	−0.23 (0.4264)
PROMIS Social Roles	−1.76 (0.3005)	−1.36 (0.5512)	−0.28 (0.9134)	−1.60 (0.5176)

* Treatment Effect Coefficient

Table 4
Treatment Effects Adjusted for Baseline, Adherence, and Missingness - Linear Regression Model.

Outcomes	Post TreatmentCoefficient* (P Value)	2-mo Follow UpCoefficient* (P Value)	5-mo Follow UpCoefficient* (P Value)
Pain Severity	−1.24 (0.0007)	0.34 (0.5523)	−0.22 (0.7433)
Self-Efficacy	9.42 (0.0545)	8.97 (0.1097)	8.65 (0.1995)
Pain Interference (PROMIS Impact)	−2.22 (0.0879)	−2.81 (0.0521)	2.20 (0.3515)
PTSD Checklist - DSM-IV	−2.00 (0.0790)	−0.99 (0.5347)	0.61 (0.6570)
PROMIS Depression CAT	−2.36 (0.1563)	−0.64 (0.7743)	−2.06 (0.4465)
Pain Catastrophizing	−5.41 (0.0318)	−3.63 (0.3281)	1.52 (0.7158)
Burn Specific Health Scale-Brief Functional Abilities	−1.28 (0.5611)	−3.71 (0.1975)	1.55 (0.5082)
Burn Specific Health Scale-Brief Generic	0.71 (0.7866)	0.83 (0.8454)	−1.38 (0.7496)
PROMIS CAT Anxiety	−2.65 (0.1062)	−1.11 (0.5827)	1.15 (0.6064)
PROMIS CAT Anger	−0.01 (0.9969)	0.29 (0.9219)	−4.45 (0.1501)
PROMIS Health	−0.22 (0.1842)	−0.05 (0.8550)	0.25 (0.3637)
PROMIS Quality of Life	0.03 (0.8926)	−0.17 (0.5248)	−0.19 (0.5865)
PROMIS Social Roles	2.75 (0.0841)	2.34 (0.3305)	0.77 (0.7399)

* Treatment Effect Coefficient

3.6. Acceptability and usability outcomes

Participants in both the TCBP and control groups reported high levels of satisfaction and acceptability with the online intervention. On a scale from 0 to 10, participants rated the helpfulness of the program in their recovery as 7.87 ± 2.42 for the TCBP group and 7.35 ± 2.30 for the control group immediately post-treatment. These ratings remained stable at the 2-month (TCBP: 7.70 ± 1.58; control: 7.67 ± 1.90) and 5-month follow-ups (TCBP: 7.47 ± 2.52; control: 7.54 ± 2.20). Most participants in both groups (95–100 %) indicated they would recommend the program to a friend or family member with pain. Participants found the online platform easy to use, with ratings ranging from 8.42 to 9.57 on a 0–10 scale across both groups and all time points. It is important to note that the TCBP group had a higher dropout rate compared to the control group at post-treatment and follow-up assessments (Fig. 2). This discrepancy between the reported satisfaction levels and the dropout rates suggests that the missing data may not fully capture the satisfaction and acceptability of the intervention among all participants. It is possible that participants who dropped out of the study or did not complete the assessments might have had lower levels of satisfaction or acceptability that are not reflected in the available data.

In addition to the self-reported measures of acceptability and usability, we also examined the completion rates for the intervention modules as an objective measure of usability. In the TCBP group, 53 % of participants (25 out of 47) completed all 7 modules, while 64 % (30 out of 47) completed at least 4 modules. In the control group, 90 % of participants (44 out of 49) completed all 7 modules, and 90 % (44 out of 49) completed at least 4 modules. These completion rates suggest that participants in the control group had higher engagement and were more likely to complete the intervention modules compared to those in the TCBP group.

4. Discussion

This RCT compared the effectiveness of an online cognitive behavioral intervention for individuals with burn pain, TCBP, against an attention control group. While the study yielded some significant findings, it is important to acknowledge the challenges faced and the non-significant results. Retention rates were lower in the TCBP group compared to the control group, which may have impacted the ability to detect significant differences between groups. Many of the primary, secondary, and tertiary outcomes did not show significant differences between the TCBP and control groups across the various time points and analyses. After adjusting for key variables, individuals in the TCBP group reported greater reductions in pain severity and pain catastrophizing post-treatment compared to individuals in the control group. However, these effects were not sustained at the two-month and five-month follow-up assessments. The TCBP group also demonstrated some improvements in pain interference, functional abilities, self-efficacy, and social role participation at two months, but these effects were not consistent across all analyses and were not maintained at five months.

Reductions in pain severity and pain catastrophizing following TCBP are consistent with other digital cognitive and behavioral interventions for chronic pain. For example, a recent meta-analysis of seventeen asynchronous digital and electronic interventions for individuals with mixed chronic pain conditions found that both types of interventions are associated with short-term (< 3 months) improvements in pain severity and catastrophizing [33]. In line with our findings, the same meta-analysis concluded that existing electronic and digital interventions for chronic pain were not associated with significant changes in pain interference or long-term reductions in pain severity. In contrast to the current findings, past digital and electronic interventions for individuals with mixed chronic pain conditions have produced short-term improvements in both depressive symptoms and self-efficacy

[33]. While some of these online CBT interventions included similar didactic content and were comparable in length to TCBP, they used waitlist control groups as their comparison condition [17,34].

The lack of existing online psychological interventions targeting chronic burn pain prevent any direct comparisons of the current study's clinical outcomes. While in-person psychological interventions for burn pain have shown promise in reducing pain and psychosocial distress [35,36], these interventions have not been translated to online, self-guided, formats. While the reductions in pain severity and pain catastrophizing following TCBP are encouraging, several factors may explain the lack of group differences in pain interference, mental health symptoms, and self-efficacy following TCBP. First, unlike other web-based interventions, TCBP did not include any clinician contact or feedback. Results from a recent meta-analysis of thirty-six internet-delivered CBT-based interventions for chronic pain found that clinician guidance is associated with greater effects for pain severity, interference, and anxiety compared to no clinician guidance [37]. Clinician contact within most online interventions for chronic pain has promoted adherence and encouraged the application of didactic content to a patient's day-to-day life. Although clinician guidance among existing studies often varies in format (e.g., SMS, phone call) and frequency (weekly, monthly), it may be a valuable treatment component. Second, unlike many RCTs testing digital cognitive and behavioral interventions for chronic pain, the current study used an active control group consisting of general burn recovery information. Use of active control groups for either digital or in-person delivery of CBT for chronic pain has traditionally been associated with either null or very small effects for emotional distress [11,37].

In the current study, the low module adherence (i.e., completing 5 of the modules) and module completion rates (i.e., all 7 modules) in the TCBP group highlight the challenge of maintaining participant engagement in online interventions for individuals with burn injuries. Consistent with the results of the current study, existing online interventions targeting other common problems following burn injury (e.g., acute stress symptoms; adverse changes in one's body image), have also reported relatively high levels of dropout, ranging from 40 % to 81 % [20,21]. One explanation for these high dropout rates might be the lack of personalized support and interaction with healthcare professionals. Previous research has shown that therapist-guided internet interventions for depression and anxiety disorders tend to have lower dropout rates compared to self-guided interventions [38,39]. Incorporating regular therapist support, such as through messaging or video conferencing, may help to improve participant engagement and reduce attrition in online interventions for burn survivors.

The higher dropout rates in the TCBP group compared to the control group may be attributed to several factors. First, the control group received general burn recovery information, which might have been perceived as more relevant and engaging to a broader range of participants. In contrast, the TCBP group received specific pain management strategies, which may have been less appealing or applicable to some participants. Second, the TCBP intervention required more active engagement and practice of skills, which could have been more demanding and time-consuming compared to the control group's more passive information consumption. Future studies should consider strategies to enhance the relevance and engagement of pain management interventions, such as tailoring content to individual needs and preferences, and providing more interactive and supportive features to encourage adherence.

Although TCBP's effects on key health outcomes were modest, the current study possessed several strengths. First, the study recruited patients from various sources and across the nation. Secondly, TCBP was compared to an active control group focused on psychoeducational information related to burn injuries. TCBP received high ratings of acceptability and usability, as did the control educational program. Most participants found the online intervention helpful, easy to use, and would recommend it to others with chronic pain, suggesting that digital platforms can be an effective and well-received method for delivering pain management interventions to burn survivors. And finally, unlike many digital and electronic interventions for pain management, the current study examined long-term outcomes following treatment.

Further refinement of digital interventions designed to address chronic burn pain are warranted based on our findings. Chronic burn pain remains a common but frequently overlooked problem for many individuals with a history of burn and is often associated with several adverse mental health related consequences [40]. Existing cognitive and behavioral interventions for chronic pain have been applied to many chronic pain populations [33,37], but have not examined adults with chronic burn pain. Incorporating individuals with chronic burn pain as patient stakeholders early in the design of the intervention, including eliciting their feedback on the utility of the intervention and pilot testing the intervention on a smaller group of patients may enhance the treatment's accessibility and effectiveness. Additionally, given that treatment expectations are a strong predictor of treatment adherence for online psychological interventions [41], including the use of strategies that seek to promote behavior and attitude change, such as motivational interviewing, may increase the effectiveness of future iterations of digital CBT interventions for burn pain. Finally, the addition of clinician guidance in-between sessions may also enhance or prolong treatment-related effects.

4.1. Limitations

The current study has several limitations that should be acknowledged. First, the high intervention module dropout rates in the TCBP group underscore the challenges of maintaining participant engagement in online interventions for individuals with burn injuries and may limit the generalizability of the findings to the broader population of individuals with chronic burn pain. This may have introduced bias into the study results and limited the generalizability of the findings. Participants who completed the intervention modules and assessments might have been more motivated or engaged than those who dropped out, potentially leading to an overestimation of the intervention's effects. To improve participant retention in future studies, researchers should consider implementing strategies such as providing incentives, sending regular reminders, offering personalized support, and reducing the burden of participation (e.g., shorter assessments, more flexible schedules). Future iterations of this intervention may also benefit from considering ways to enhance user engagement, such as more interactive content, personalized feedback, or the integration of motivational strategies. Additionally, conducting qualitative research to understand participants' reasons for dropping out could provide valuable insights for designing more engaging and user-friendly interventions.

Secondly, more robust measures of patient adherence beyond intervention modules completed are warranted and could have been used to determine whether the degree of participant engagement moderated treatment effects. Our analysis accounted for module adherence, defined as completing at least 5 modules. However, a limitation of our study is that we did not collect more detailed engagement metrics beyond module completion. Future studies could benefit from tracking additional measures such as time spent on modules, interaction with content, or self-reported engagement to provide a more comprehensive understanding of how participants interact with the program to better understand their impact on treatment efficacy.

Furthermore, the sustainability of treatment effects was not maintained at the two-month and five-month follow-ups, indicating a need for strategies to prolong treatment effects. This could potentially be addressed in future studies through the implementation of booster sessions or the development of more robust self-management tools for participants to use after the initial intervention period.

Finally, the current study consisted of many individuals whose burn injury occurred a decade or more prior to their participation in the study. Given that psychosocial factors are known to predict the

transition from acute to chronic pain [17], early psychosocial interventions may lead to improved pain and mental health related outcomes.

4.2. Conclusions

This RCT compared the effectiveness of an online self-management program, "Take Charge of Burn Pain" (TCBP), against an attention control group for individuals with chronic burn pain. While the study yielded some significant short-term improvements in pain severity and pain catastrophizing, the overall impact of the intervention was limited, and the long-term effects were not demonstrated. The TCBP group showed greater improvements in pain interference, functional abilities, self-efficacy, and social role participation at the two-month follow-up compared to the control group, but these effects were not consistent across all analyses and were not maintained at the five-month follow-up. Participant retention and engagement emerged as significant challenges, with higher attrition rates in the TCBP group compared to the control group, although this difference was not statistically significant. Despite these limitations, participants in both groups reported high levels of satisfaction and usability with the online intervention platform. The potential of self-guided online psychological interventions to enhance pain coping strategies for burn survivors remains promising. However, future research should focus on refining these interventions to improve participant retention, incorporate personalized support, and explore the use of brief intervention formats. By addressing these challenges, we can work towards developing more effective and engaging online interventions to support individuals living with chronic burn pain.

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Declaration of Competing Interest

The authors have no conflicts of interest to declare.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.burns.2024.107336.

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