


Feasibility and acceptability of telephone-delivered cognitive-behavioral-based physical therapy for patients with traumatic lower extremity injury

Claudia A. Davidson¹  | Rogelio A. Coronado¹ | Susan W. Vanston¹ | Elizabeth G. Blade¹ | Abigail L. Henry¹ | William T. Obremskey¹ | Stephen T. Wegener² | Kristin R. Archer³

¹Department of Orthopaedic Surgery, Vanderbilt University Medical Center, Nashville, Tennessee

²Department of Physical Medicine and Rehabilitation, Johns Hopkins School of Medicine, Baltimore, Maryland

³Department of Orthopaedic Surgery and Department of Physical Medicine and Rehabilitation, Vanderbilt University Medical Center, Nashville, Tennessee

Correspondence

Kristin R. Archer, Department of Orthopaedic Surgery and Department of Physical Medicine and Rehabilitation, Vanderbilt University Medical Center, Nashville, TN.

Email: kristin.archer@vumc.org

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Abstract

Purpose: To determine feasibility and acceptability of a telephone-based Cognitive-Behavioral-Based Physical Therapy program for patients following traumatic lower extremity injury (CBPT-Trauma).

Methods: Patients were screened for high psychosocial risk factors and then completed the 6-week CBPT-Trauma program. Physical function, pain, and psychosocial outcomes were assessed at baseline and 6-months follow-up. Descriptive statistics assessed change in outcomes.

Results: Recruitment rate was 59%. Twenty-seven patients (73%) had a high psychosocial risk profile. Twelve patients completed the program and the follow-up assessment at 6 months and found the program to be very or extremely helpful to their overall recovery. All demonstrated a clinically meaningful increase in physical function. Six patients demonstrated a clinically relevant decrease in pain intensity, pain catastrophizing, and fear of movement. Seven patients reported a clinically meaningful increase in pain self-efficacy.

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Discussion: Findings suggest that recruitment is feasible for CBPT-Trauma program. However, engagement in the CBPT-Trauma study was low. For those that completed the program, patients were satisfied with the CBPT-Trauma program and experienced meaningful improvement in psychosocial factors and patient-reported outcomes. This open pilot study highlights the importance of targeted treatment for patients at high-risk for poor outcomes and the potential for increased access to services through telephone-delivery.

KEYWORDS

cognitive therapy, orthopedics, pain management, trauma

1 | INTRODUCTION

Acute orthopedic trauma is a major global health burden (Clay, Watson, Newstead, & McClure, 2012). In the United States (U.S.), acute trauma is the second greatest source of medical care expenditures costing approximately \$30 billion per year (Elliott & Rodriguez, 1996). Two-thirds of the annual estimated 2.5 million hospitalized trauma survivors have one or more extremity injuries, with the majority being moderately severe to severe (Dillingham, Pezzin, & Mackenzie, 1998; Pezzin, Dillingham, & MacKenzie, 2000; Rice, MacKenzie, & Jones, 1989). In motor vehicle accidents exclusively, 40% of treatment expenditures are due to lower extremity injuries (Dischinger et al., 2004). Traumatic lower-extremity injuries often result in chronic pain, long-term disability, and low rates of return to work (Ponsford, Hill, Karamitsios, & Bahar-Fuchs, 2008). One of the strongest predictors of chronic pain following traumatic injury, as well as long-term physical and psychological disability, is a high level of pain early in the recovery process (Archer, Devin, et al., 2016; Castillo, MacKenzie, Wegener, Bosse, & Group, 2006; Castillo, Wegener, Newell, et al., 2013; Clay et al., 2010; Rivara et al., 2008; Wegener et al., 2011; Williamson et al., 2009). Unmanaged pain leads to repeat hospitalizations, low satisfaction with healthcare, and delayed functional recovery and return to work (MacKenzie et al., 2006; O'Toole, Castillo, Pollak, MacKenzie, & Bosse, 2008).

There has been increasing evidence to support the importance of pain-related psychosocial factors, such as low pain self-efficacy, pain catastrophizing, and fear of movement, to poor pain and disability outcomes after traumatic orthopedic injury (Archer, Castillo, Wegener, Abraham, & Obremskey, 2012; Archer, Devin, et al., 2016; Castillo et al., 2006; Castillo, Wegener, Heins, et al., 2013; McCarthy et al., 2003; Nota, Bot, Ring, & Kloen, 2015). The Lower Extremity Assessment Project study first reported on the importance of low self-efficacy (the patient's confidence in being able to resume life activities) to long-term outcomes following traumatic lower-extremity injury (Bosse et al., 2002), with more recent evidence supporting the association between self-efficacy and pain at hospital discharge (Archer, Abraham, Song, & Obremskey, 2012). Archer et al. and others have also found that patients who display pain catastrophizing behavior (tendency to focus on, ruminate, and magnify pain sensations) and/or fear of movement are at risk for more severe pain and disability up to 2 years after trauma (Archer, Abraham, & Obremskey, 2015; Archer, Abraham, et al., 2012; Nota et al., 2015; Vranceanu et al., 2014). Overall, studies suggest that psychosocial risk factors, especially those related to pain beliefs and behaviors, are potential targets for cognitive and behavioral strategies that address maladaptive beliefs and avoidance of activities (Vranceanu et al., 2014; Zale, Ring, & Vranceanu, 2018).

Psychosocial interventions have the potential to be an effective and feasible management approach to address psychosocial factors and improve long-term outcomes in patients following traumatic lower-extremity injury

(Andersson, Dahlback, & Bunketorp, 2005; Berube, Choiniere, Laflamme, & Gelinias, 2016; Bisson, Shepherd, Joy, Probert, & Newcombe, 2004; Pirente et al., 2007; Zatzick et al., 2004). Cognitive behavioral therapy (CBT), a widely used psychosocial approach for patients with chronic pain and various musculoskeletal conditions (Dunne, Kenardy, & Sterling, 2012; Knoerl, Lavoie Smith, & Weisberg, 2016; Williams et al., 2002), has been efficacious in alleviating pain-related psychosocial symptoms in trauma survivors (Ashman, Cantor, Tsaousides, Spielman, & Gordon, 2014; Fann et al., 2015; Mehta et al., 2011; Qi, Gevonden, & Shalev, 2016; Sijbrandij et al., 2007; Visser, Gosens, Oudsten, & Vries, 2017). Castillo, Wegener, Newell, et al. (2013) examined the early effects of a psychosocial program focusing on self-management and peer support and found a significant treatment effect for depression at 6 months following severe extremity injury. However, this study reported a low rate of use of program components due to the program length, accessibility, and an underdeveloped program infrastructure. Other studies using time-intensive CBT interventions have identified retention issues as a barrier to effective uptake of psychosocial strategies (Visser et al., 2017; Vranceanu et al., 2015). Brief and accessible psychosocial treatments are needed in order to address these limitations.

Physical therapists routinely manage trauma survivors after hospital discharge and recognize the importance of addressing physical impairments as well as pain-related psychosocial factors in clinical practice (Keefe, Main, & George, 2018). Studies have demonstrated that physical therapists can learn and successfully implement the psychologically informed strategies needed to make meaningful differences in psychosocial risk factors and pain-related outcomes (Archer, Devin, et al., 2016; Archer et al., 2013; George, Fritz, Bialosky, & Donald, 2003; Hay et al., 2005; Klaber et al., 2005; Sullivan, Adams, Rhodenizer, & Stanish, 2006).

The purpose of this open pilot study was to determine the feasibility and acceptability of a Cognitive-Behavioral-Based Physical Therapy program for patients following traumatic lower-extremity injury (CBPT-Trauma). A telephone-delivery model was chosen to address the access and engagement barriers found in previous studies (Fann et al., 2015; Mehta et al., 2011). The CBPT-Trauma program was adapted from work done by Archer et al. in spine surgery patients (Archer et al., 2013, 2014; Archer, Devin, et al., 2016). The original CBPT program was designed to improve pain and disability outcomes through reductions in fear of movement and increases in pain self-efficacy in patients with chronic spine pain. For this study, an increased emphasis was placed on cognitive-restructuring strategies (i.e., identifying negative thoughts and replacing with positive thoughts) and strengthening exercises and mindfulness strategies replaced walking goals and pacing activities. In addition, educational material specific to physical and mental health recovery following traumatic injury was included, such as stages of bone healing, stress and recovery, and importance of social support. Results from this open pilot study will provide a better understanding of the role of psychologically informed rehabilitation in trauma survivors.

2 | METHODS

2.1 | Study design

This was a prospective open pilot study with 6-month outcome assessment. Ethical approval was obtained from the Institutional Review Board at Vanderbilt University Medical Center. The reporting of this study follows CARE guidelines for clinical case reports (Gagnier et al., 2014).

2.2 | Participants

From July 2017 to September 2017, consecutive English speaking patients were enrolled from Vanderbilt University Medical Center, a level I trauma center. Inclusion criteria for the study were as follows: (a) age 18–60 years; (b) operative fixation for at least one lower extremity orthopaedic injury; (c) initially admitted to trauma or orthopaedic trauma service; and (d) high psychosocial risk for poor outcomes. High psychosocial risk factors were defined by established cut-off scores on validated pain catastrophizing, fear or movement,

and pain self-efficacy questionnaires (score ≥ 20 on the Pain Catastrophizing Scale [PCS], ≥ 39 on the Tampa Scale for Kinesiophobia [TSK], and/or ≤ 40 on the Pain Self Efficacy Questionnaire [PSEQ]) (Ferreira-Valente, Pais-Ribeiro, & Jensen, 2011; Lundberg, Styf, & Carlsson, 2004; Neblett, Hartzell, Mayer, Bradford, & Gatchel, 2016; Park et al., 2016; Shah, Ghagare, Shyam, & Sancheti, 2017; Sullivan et al., 2006; Tonkin, 2008). Exclusion criteria for the study were as follows: (a) peri-prosthetic fracture in the femur; (b) upper or lower extremity amputations (> than greater toe or thumb); (c) non-ambulatory pre-injury; (d) moderate to severe movement dysfunction caused by a history of neurological disorder; (e) schizophrenia or other psychotic disorder; (f) current alcohol or drug abuse; and (g) inability to start the CBPT-Trauma program within 3 months of initial hospital discharge. Patients in need of a Legally Authorized Representative for consent and those that would have difficulty maintaining follow up (e.g., individuals incarcerated, experiencing homelessness, or limited phone access) were also excluded.

2.3 | Procedures

Screening and consent occurred during initial admission to the hospital and up to 2 weeks post discharge. After providing written consent, participants completed a series of validated questionnaires for determining high psychosocial risk (i.e., pain catastrophizing, fear of movement, and pain self-efficacy) and then a baseline questionnaire at approximately 2 weeks after initial hospital discharge. The baseline assessment collected questions on age, sex, race, marital status, education level, type of insurance, tobacco use, and height and weight for body mass index. Patients also completed a battery of validated questionnaires to assess physical function and pain. Clinical variables were abstracted from the medical record and included mechanism of injury and Injury Severity Score (ISS). After the baseline assessment, patients were scheduled for the first CBPT-Trauma session with the study physical therapist. This first session occurred within 2 weeks of the baseline assessment. Telephone intervention sessions occurred weekly for 6 weeks. Patients completed a paper intervention assessment at the end of the 6 weeks and a paper or web-based follow-up outcomes assessment at 6 months following initial hospital discharge.

2.4 | Intervention

The CBPT-Trauma program is a patient oriented cognitive-behavioral, self-management approach intended to improve physical function and reduce pain through reductions in pain catastrophizing and fear of movement and increases in pain self-efficacy (Table 1). The CBPT-Trauma program included six weekly phone sessions between the patient and a trained physical therapist (S.W.V.) and is adapted from prior work by Archer et al. in patients recovering from spinal surgery (Archer et al., 2013, 2014; Archer, Devin, et al., 2016). Each participant was given a manual to follow along with the physical therapist. The first session lasted approximately 45 min and subsequent sessions lasted 30 min. Sessions covered a range of topics including overview of their injury, managing stress, deep breathing, graded activity, goal setting, distraction techniques, balancing positive and negative thoughts, present-mindedness, relapse prevention, and a recovery plan (Beck, 1979; D'Zurilla & Goldfried, 1971; Scobbie, Wyke, & Dixon, 2009; Turner, 2001; Williams & McCracken, 2004). In addition, one session introduced strengthening exercises (leg, abdominal, back, and shoulder) and patients were provided with three different TheraBands. Each of these sessions built on each other, and the program was personalized to the patient's individual needs. After each session, the patient had a tailored home program based on their functional activity hierarchy and selected activity and exercise goals, as well as the cognitive or behavioral strategy reviewed during the session (see Table 1 for more detail).

TABLE 1 Summary of the CBPT-Trauma program content

Topics	Brief description
Session 1: Your Mind and Recovery	Review purpose of the program, conduct semi-structured patient interview, review patterns of injury, symptoms, diagnosis, and surgical treatment, review role of stress and support in recovery, share tips to reduce stress, introduce deep breathing as pain management strategy, set deep breathing goal Home Program: deep breathing
Session 2: Goal Setting	Review deep breathing goal and set new goal, complete graded activity plan and fear hierarchy, set activity goals based on hierarchy, and introduce distraction as a pain management strategy Home Program: deep breathing, functional activity goal(s), distraction strategy
Session 3: Balance your Thinking	Review breathing, distraction, and activity goals, set new goals, problem solve barriers to completing goals, introduce event-thoughts-feeling-action handout, identify negative thoughts that affect activity using worksheet, practice replacing negative thoughts with positive self-talk and complete worksheet Home Program: functional activity goal(s), deep breathing and distraction strategies as needed, replace negative thoughts with positive self-talk strategy
Session 4: Physical Recovery	Review breathing, distraction, positive self-talk, and activity goals, set new goals, problem solve barriers to completing goals, identify benefits and barriers to exercise and introduce strengthening exercises, and identify benefits of program so far Home Program: functional activity goal(s), deep breathing, distraction, and positive self-talk strategies as needed, strengthening exercises
Session 5: Present Mindedness	Review breathing, distraction, positive self-talk, strengthening exercises, and activity goals, set new goals, problem solve barriers to completing goals, introduce present-mindedness Home Program: functional activity and strengthening exercises goal(s), deep breathing, distraction, and positive self-talk strategies as needed, present-mindedness strategy
Session 6: Managing Setbacks	Review breathing, distraction, positive self-talk, strengthening exercises, and activity goals, problem solve barriers to completing goals, review present-mindedness and goal, introduce relapse cycle handout, complete managing set-back worksheet, and complete a recovery plan Instruct patient to complete assessment of the program Home Program: recovery plan worksheet

2.5 | Therapist training and fidelity

The CBPT-Trauma program was delivered by a physical therapist with over 15 years of experience working with patients with musculoskeletal conditions and 8 years delivering cognitive behavioral strategies in various post-operative populations. The physical therapist received formal training from a clinical psychologist (S.T.W.) in motivational interviewing and cognitive-behavioral skills. The intervention was monitored with the use of a therapist checklist which was completed at the end of each session to confirm if the cognitive-behavioral strategies were delivered as indicated. In addition, all sessions were audiotaped and reviewed by a clinical psychologist (S.T.W.) and a physical therapist with expertise in trauma rehabilitation (K.R.A.) to monitor adherence to the intervention protocol. Additionally, auditor checklists assessed the use and strength of basic motivational interviewing skills (i.e., open-ended questions, affirmation, reflection, and summary with consistent motivational interviewing spirit

(acceptance, compassion, evocation, partnership). The study physical therapist and investigative team met weekly to discuss any challenges in implementing the CBPT-Trauma program.

2.6 | Feasibility and acceptability

Feasibility measures included the number of patients enrolled, screened for high psychosocial factors, and who completed the CBPT-Trauma intervention. Acceptability was assessed with an intervention assessment that asked questions about the helpfulness of the overall program, decreases in pain and increases in activity due to the program, likeliness of recommending the program to a friend going through a similar injury, and benefits and importance of the CBPT-Trauma program. Open-ended questions were also provided to receive feedback from participants on lessons learned from the program and recommendations for ways to improve the program.

The primary clinical outcome was patient-reported physical function. To assess physical function, the Short Musculoskeletal Function Assessment (SMFA) Dysfunction Index and the Patient Reported Outcomes Measurement Information System (PROMIS) Physical Function computer adaptive test (CAT) were used. The SMFA is a shorter version of the 101-item Musculoskeletal Function Assessment. The Dysfunction Index subscale of the SMFA has 34 items that are rated on a 5-point Likert scale from *good function* (1) to *poor function* (5). A score is obtained by summing the responses to the items and then transforming the score ($\text{raw score} - \text{lowest possible raw score} / \text{possible range of raw score} * 100$) (Engelberg et al., 1996; Swiontkowski, Engelberg, Martin, & Agel, 1999). The SMFA is reliable, valid, and responsive in patients with musculoskeletal disorders and acute injuries (Engelberg et al., 1996; Swiontkowski et al., 1999). A clinically important difference (MCID) for the SMFA Dysfunction Index has been reported to range from 4.4 to 7-points in patients with traumatic lower extremity injury (Busse et al., 2009; Dattani et al., 2013).

The PROMIS physical function assesses a patient's ability to complete everyday activities that require physical action which can range from self-care to movements requiring multiple skills. The PROMIS physical function demonstrates good reliability and validity across diverse (race/ethnicity and age) groups and patients with osteoarthritis and traumatic upper extremity injury (Jensen et al., 2015; Kaat et al., 2017). An average T-score of 50 is representative of the general U.S. population with standard deviation (SD) of 10 (PROMIS PF scoring manual, 2017a) and a MCID of 8.41 has been established in patients with hip and knee joint pathologies (Hung, Bounsanga, Voss, & Saltzman, 2018).

Secondary outcomes included pain, pain catastrophizing, fear of movement, and pain self-efficacy. To assess these outcomes, PROMIS pain intensity v1.0 short form and pain interference v1.1 CAT, PCS, TSK, and PSEQ were used. PROMIS pain intensity assesses severity of pain experienced by patients. The first two items ask the patient to report pain intensity "in the past 7 days" and the last about "level of pain right now." PROMIS pain intensity demonstrates good test-retest reliability and concurrent validity with strong correlations established with valid disease specific measures, such as the Knee and Hip Injury and Osteoarthritis Outcome Score in patients with knee and hip pathologies as well as the Neck Disability Index in patients with neck pain (Bartlett et al., 2015; Moses et al., 2019; Padilla et al., 2018; PROMIS PI scoring manual, 2017b). Bartlett et al. (2015) suggests that a mean PROMIS score between 45 and 55 is within normal limits (0.5 SD) of the general U.S. population.

PROMIS pain interference assesses how pain impacts engagement with social, cognitive, emotional, physical, and recreational aspects of the patient's life. It has 56 items where each subsequent question is dependent on response to the previous (Amtmann et al., 2010; PROMIS Pain Interference scoring manual, 2017c). Various studies support good reliability and validity of PROMIS pain interference in multiple patient populations including those with chronic pain and arthritis (Bartlett et al., 2015; Broderick, Schneider, Junghaenel, Schwartz, & Stone, 2013; Cella et al., 2010; Stone, Broderick, Junghaenel, Schneider, & Schwartz, 2016). PROMIS pain interference is especially responsive to targeted pain interventions and has an MCID of 5.5 in low back pain patients (Amtmann et al., 2016; Askew, Cook, Revicki, Cella, & Amtmann, 2016).

The 13-item PCS assessed pain catastrophizing (Sullivan, Bishop, & Pivik, 1995). The PCS has a 5-point Likert scale with ratings from 0 to 4 where 0 is *not at all* and 4 is *all the time*. The PCS is reliable (Cronbach's alpha > 0.90) and has shown a correlation with pain, self-reported disability, negative affect, and pain-related fear in patients with musculoskeletal conditions (George, Calley, Valencia, & Beneciuk, 2011; Osman et al., 2000; Sullivan et al., 1995). Additionally, the PCS is sensitive to change following psychosocial interventions, with a 44.44% decrease in score indicating a MCID in patients with pain after injury (George et al., 2011).

The 17-item TSK was used to assess fear of movement (Kori, Miller, & Todd, 1990). Items on the TSK are measured using a 4-point Likert scale ranging from *strongly disagree* to *strongly agree*. The TSK has demonstrated good test-retest reliability in patients with musculoskeletal conditions and validity in patients with chronic pain (French, France, Vigneau, French, & Evans, 2007; Roelofs, Goubert, Peters, Vlaeyen, & Crombez, 2004). An MCID of 4 on the TSK has been reported in patients with chronic low back pain (Woby, Roach, Urmston, & Watson, 2005).

The 10-item PSEQ assesses the strength and generality of a patient's belief of whether they can complete a range of activities regardless of their pain. The PSEQ uses a 7-point scale ranging from 0 to 6 where 0 is *not at all confident* and 6 is *completely confident*. The PSEQ is internally consistent with good test-retest reliability and has good construct validity with regards to depression, anxiety, coping mechanisms, and patients experiencing chronic pain (Miles, Pincus, Carnes, Taylor, & Underwood, 2011; Nicholas, 2007). A MCID of 5.5 has been established in patients with chronic low back pain (Chiarotto et al., 2016).

2.7 | Data analysis

Data were managed and analyzed using IBM SPSS Statistics for Windows software, version 24 (IBM Corp., Armonk, NY, USA). Descriptive statistics were computed for baseline characteristics of the sample and outcome measures. Proportions were computed for feasibility and acceptability measures. Change in outcomes from baseline to 6 months after hospital discharge was assessed with descriptive statistics.

3 | RESULTS

Over a 2-month period, 149 consecutive patients were screened for eligibility. Sixty-three (42%) patients were potentially eligible and approached and 37 (59%) provided consent and moved to the screening phase. Out of 37 consented, 27 (73%) had high psychosocial risk factor(s). Two patients were withdrawn by the study team after screening due to exclusion criteria. Twelve patients remained in the study after six withdrew and seven were lost to follow-up prior to the start of the CBPT-Trauma program. Reasons provided for withdrawal included time constraints due to handling financial and legal issues related to the accident and housing issues which impacted ability to receive weekly phone calls. All 12 patients completed the six session CBPT-Trauma program, intervention assessment, and the 6 month follow-up assessment. No differences were found in baseline characteristics between patients with ($n = 12$) and without complete follow-up data ($n = 13$).

The characteristics of the eligible and enrolled sample are described in Table 2. Patients age ranged from 21 to 54 years and 67% were male. The majority of patients had high school education or less (58%) and were white (75%). Mechanism of injury associated with the traumatic lower-extremity injury included motor vehicle (50%), motorcycle (33.3%), pedestrian (8.3%), and fall >10 feet (8.3%). The ISS of patients ranged from 4 to 22.

3.1 | Acceptability of intervention

All 12 patients found the program to be very or extremely helpful to their overall recovery. Seven patients (58%) reported a meaningful decrease in pain and 11 (92%) reported a meaningful increase in activity due to the program.

TABLE 2 Baseline demographic and clinical characteristics of enrolled patients (N = 12)

ID	Age	Sex	Education	Race	Marital	Insurance	Tobacco	BMI (kg/m ²)	MOI	ISS
1	22	F	High school	Black or African American	Single	No	No	29.4	MVA	17
2	54	F	High school	Black or African American	Married	Private	No	28.3	MVA	5
3	44	M	Some college	White	Married	No	Yes	29.8	Motorcycle	4
4	36	M	High school	Black or African American	Single	Public	Yes	32.0	Motorcycle	4
5	32	M	College degree	White	Married	Private	No	24.4	MVA	19
6	36	M	High school	White	Married	No	No	29.2	MVA	5
7	23	M	Associate degree	White	Single	No	No	19.0	Motorcycle	21
8	21	M	High school	White	Single	No	Yes	15.0	Motorcycle	10
9	51	M	High school	White	Married	Private	Yes	33.2	Pedestrian	5
10	25	F	College degree	White	Single	No	No	25.8	MVA	13
11	36	M	High school	White	Single	Private	Yes	24.0	MVA	22
12	53	F	Associate degree	White	Divorced	Private	No	33.4	Fall	13

Note. BMI: body mass index; F: female; ISS: Injury Severity Score; MOI: mechanism of injury; M: male; MVA: motor vehicle accident.

The majority of participants (75%) found the CBPT-Trauma program to be somewhat or much more important in their recovery compared to other services since surgery. Seven patients (58%) reported that the benefits of the program far outweighed the effort they put into the program. All would recommend the program to a friend who has had lower extremity surgery. The most important components of the program from the patients' perspective were learning positive self-talk, ways to relax, and the importance of the relationship between mental and physical recovery. Patients also reported benefits from deep breathing, present-mindedness, and strategies to manage setbacks. The majority of patients reported that they wished the CBPT-Trauma program had started during the hospital stay or closer to their time of hospital discharge. Review of audiotapes found that the study therapist delivered 95% of CBPT components and at least 90% of motivational interviewing competencies in each session, indicating high fidelity to the intervention protocol.

All patients had a clinically significant decrease in their SMFA Dysfunction Index scores and 11 out of the 12 patients (92%) had a clinically significant increase in their PROMIS physical function scores from baseline to 6-month follow-up (Table 3; Figure 1).

At baseline, PROMIS pain intensity scores for patients 1, 3, 6, 7, 9, 10, and 12 were within reasonably normal limits (scores between 45 and 55 or 0.5 SD) of the general U.S. population's average (Table 4; Figure 2a). Patient 7 had a decrease in pain intensity of at least one SD at 6-month follow-up, while patient 6 had a slight increase in pain and patients 1 and 12 demonstrated no change (Figure 2a). Patients 4 and 11 were between \sim 0.5 and 1.0 SD worse than the general U.S. population average at baseline and both had a decrease in pain intensity by at least one SD at 6-month follow-up. Patients 2 and 8 were between \sim 1.0 and 2.0 SD worse than the general U.S. population average at baseline and both had a decrease in pain intensity by at least one SD at 6-month follow-up. For PROMIS pain interference at baseline, all patients demonstrated greater challenges engaging in various aspects of one's life due to pain ($>$ 0.5 SD of the average U.S population score of 50), except for patient 7 (Table 4, Figure 2b). Patients 1, 2, 3, 4, 8, 10, and 11 demonstrated a clinically significant decrease in pain interference at 6-month follow-up (Figure 2b). Slight increase in pain interference was noted for patients 6, 7, and 9 and no change was noted for patient 12.

TABLE 3 Baseline and 6-month physical function scores

Patient	SMFA Dysfunction Index			PROMIS Physical Function		
	T0	T1	Δ	T0	T1	Δ
1	44.1	26.5	-17.7 ^a	30.7	44.3	13.6 ^a
2	54.4	15.2	-39.3 ^a	31.8	42.3	10.5 ^a
3	27.2	7.4	-19.9 ^a	31.5	50.5	19.0 ^a
4	50.8	32.4	-18.4 ^a	21.3	41.7	20.4 ^a
5	38.2	22.8	-15.5 ^a	31.5	40.4	8.9 ^a
6	65.2	48.5	-16.6 ^a	26.7	36.0	9.3 ^a
7	55.2	28.7	-26.5 ^a	31.8	32.7	0.9
8	67.7	36.4	-31.3 ^a	23.4	39.8	16.4 ^a
9	49.2	11.8	-37.5 ^a	25.8	34.8	9.0 ^a
10	51.5	12.5	-39.0 ^a	25.8	48.9	23.1 ^a
11	43.4	9.1	-34.3 ^a	30.2	51.7	21.5 ^a
12	39.0	21.3	-17.7 ^a	26.0	38.0	12.0 ^a

Note. SMFA = Short Musculoskeletal Function Assessment (scores range from 0 to 100, with lower scores indicating better functioning; clinically relevant change = 4.4–7); PROMIS = Patient Reported Outcomes Measurement.

Information System (scores range from 0 to 100, with higher scores indicating better functioning; MCID = 8.41).

^aChange (Δ) in value from baseline (T0) to 6 months (T1) signifies clinically important difference.

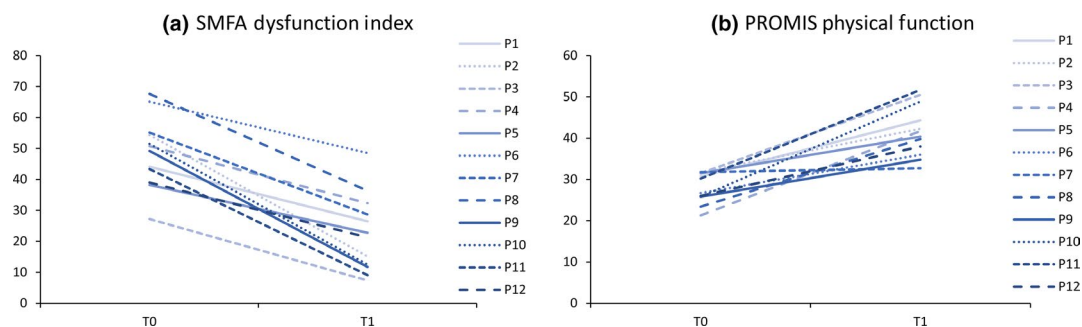


FIGURE 1 Changes from baseline (T0) to 6 months (T1) in physical function for patients 1–12: (a) Short Musculoskeletal Function Assessment (SMFA) Dysfunction Index (b) Patient Reported Outcomes Measurement Information System (PROMIS) Physical Function

Eight patients (66.7%) demonstrated high pain catastrophizing (i.e., PCS ≥ 20) at baseline (Table 4). Patients 2, 3, 7, 9, 10, and 11 demonstrated a clinically meaningful decrease in PCS scores at 6-month follow-up (Figure 2c). Patients 5, 6, and 12 had increases in PCS scores from baseline to 6-month follow-up. All patients demonstrated high fear of movement at baseline (i.e., TSK score ≥ 39), except patient 6 who had a score of 38 (Table 4). Patients 2, 3, 7, 9, 10, and 11 had clinically meaningful decreases in fear of movement at 6-month follow-up (Figure 2d). Patient 4 had no change in TSK score and patient 5 increased by one point from baseline to 6-month follow-up. Nine patients (75%) had low pain self-efficacy (i.e., PSEQ ≤ 40) at baseline (Table 4). Patients 1, 3, 5, 7, 9, 10, and 11 demonstrated clinically meaningful improvement in PSEQ scores, while patient 2, 8, and 12 had clinically meaningful decreases in pain self-efficacy (Figure 2e).

4 | DISCUSSION

The importance of psychosocial risk factors to poor long-term outcomes in patients with traumatic lower-extremity injury is well-established (Archer et al., 2015; Castillo et al., 2006; Castillo, Wegener, Newell, et al., 2013; Clay et al., 2010; McCarthy et al., 2003; Nota et al., 2015). However, research on accessible psychologically informed rehabilitation interventions is limited in this patient population (Vranceanu et al., 2015). Thus, the purpose of this open pilot study was to assess the feasibility and acceptability of a telephone-delivered CBPT-Trauma intervention in patients following traumatic lower-extremity injury who demonstrate a high psychosocial risk profile.

The feasibility results demonstrated that recruitment is feasible for a targeted CBPT-Trauma program, with 59% of eligible and approached patients providing consent during the early recovery period and 73% of consented patients screening positive for high pain catastrophizing, high fear of movement, and/or low pain self-efficacy. Our recruitment rate was lower than the 75% reported by Vranceanu et al. (2015) for a pilot trial of a mind-body skills based intervention in patients with acute musculoskeletal trauma, but higher than the 23% reported by Castillo, Wegener, Newell, et al. (2013) for an integrated self-management intervention in patients with severe traumatic extremity injury. In addition, our psychosocial screening rate was higher than the 43% reported in the trial by Vranceanu et al. (2015). Differences in recruitment and screening rates may vary by injury severity or timeframe from injury to the consent/screening process. Castillo, Wegener, Newell, et al. (2013) enrolled patients prior to hospital discharge, which was similar to our enrollment procedures of initial admission and up to 2 weeks post discharge, while Vranceanu et al. (2015) enrolled patients within 1–2 months of injury. Overall, a systematic review of recruitment rates for behavioral trials found a mean recruitment rate of 51.2%, which is similar to our trial (Trivedi et al., 2013). Stengel et al. (2017) reviewed orthopaedic trauma trials published in *Injury* over a 1 year period (June 2016 to June 2017) and found a median rate of 69%.

TABLE 4 Baseline and 6-month pain intensity and interference, pain catastrophizing, fear of movement, and pain self-efficacy scores

Patient	PROMIS Pain Intensity			PROMIS Pain Interference			PCS			TSK			PSEQ		
	T0	T1	Δ	T0	T1	Δ	T0	T1	Δ	T0	T1	Δ	T0	T1	Δ
1	52.3	52.3	0.0	62.6	52.2	-10.4 ^a	8	8	0	42	47	5	36	49	13 ^a
2	64.3	42.6	-21.7	69.6	52.2	-17.4 ^a	21	6.5	-14.5 ^a	42	34	-8 ^a	41	33	-8
3	49.9	45.7	-4.2	57.3	46.6	-10.7 ^a	8	2	-6 ^a	46	32	-14 ^a	37	58	21 ^a
4	57.5	40.5	-17.0	68.7	60.4	-8.3 ^a	34	31	-3	44	44	0	34	36	2
5	40.5	45.7	5.2	56.0	54.4	-1.6	5	11	6	42	43	1	31	37	6 ^a
6	54.4	56.3	1.9	56.9	64.3	7.4	20	25	5	38	35	-3	44	42	-2
7	52.1	38.3	-13.8	50.1	52.2	2.1	24	10	-14 ^a	46	35	-11 ^a	31	50	19 ^a
8	71.8	53.7	-18.1	72.1	63.6	-8.5 ^a	40	36	-4	45	41	-4	30	21	-9
9	45.7	40.5	-5.2	55.8	56.0	0.2	20	0	-20 ^a	45	40	-5 ^a	18	60	42 ^a
10	48.4	35.8	-12.6	65.6	52.8	-12.8 ^a	22	3	-19 ^a	54	40	-14 ^a	22	53	31 ^a
11	59.0	40.5	-18.5	71.6	56.0	-15.6 ^a	31	0	-31 ^a	40	28	-12 ^a	40	58	18 ^a
12	42.6	42.6	0.0	56.0	56.0	0.0	0	6	6	40	37	-3	45	30	-15

Note. PROMIS = Patient Reported Outcomes Measurement Information System Pain Intensity (scores range from 0-100, with higher scores indicating greater pain experienced by the patient); PROMIS Pain Interference (scores range from 0-100, with higher scores indicating greater consequences of pain in everyday life; MCID = 5.5); PCS = Pain Catastrophizing Scale (scores range from 0-52, with higher scores indicating greater pain catastrophizing; MCID = decrease by 44.44%); TSK = Tampa Scale for Kinesiophobia (scores range from 17-68, with higher scores indicating greater fear of movement; MCID = 4); PSEQ = Pain Self-Efficacy Questionnaire (scores range from 0-60, with higher scores indicating stronger self-efficacy beliefs; MCID = 5.5).

^aChange (Δ) in value from baseline (T0) to 6 months (T1) signifies minimal clinically important difference (MCID).

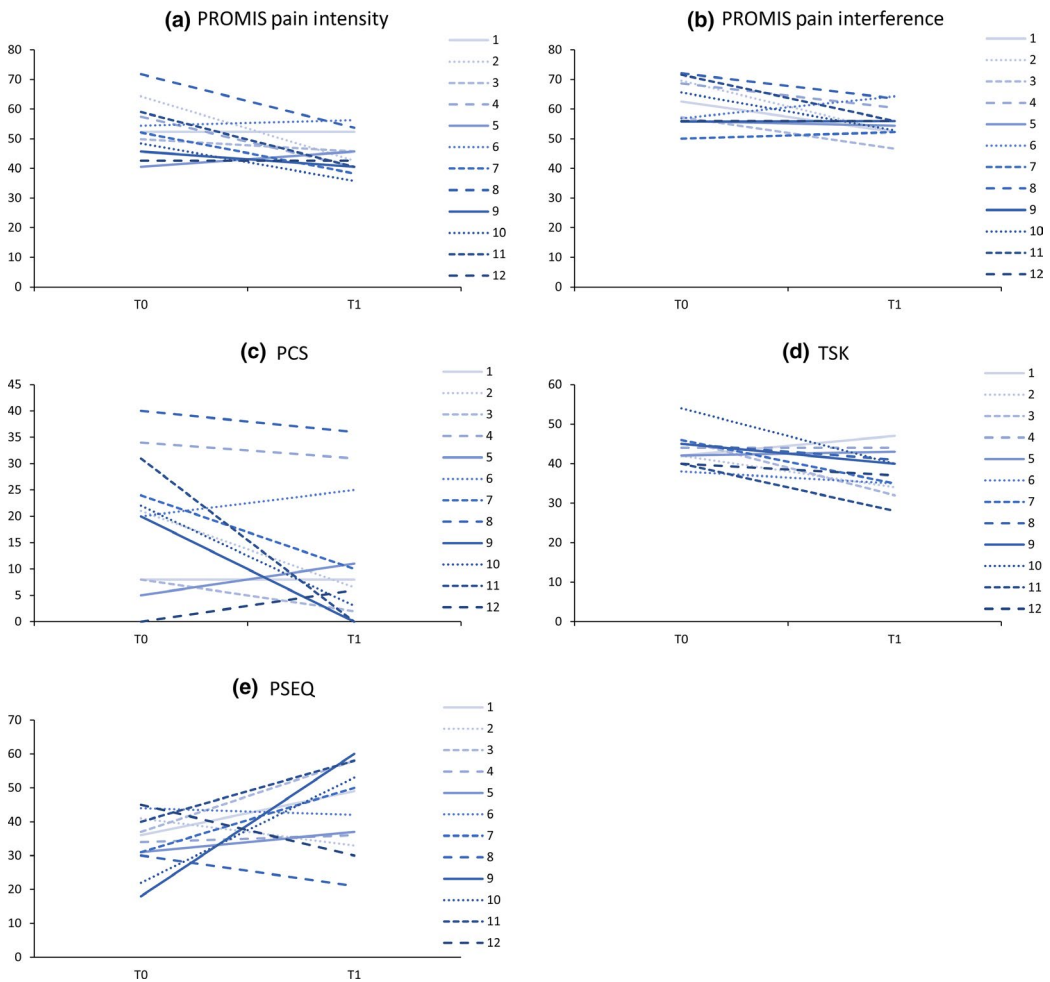


FIGURE 2 Changes from baseline (T0) to 6 months (T1) in secondary outcomes for patients 1–12: (a) Patient Reported Outcomes Measurement Information System (PROMIS) Pain Intensity, (b) PROMIS Pain Interference, (c) Pain Catastrophizing Scale (PCS), (d) Tampa Scale for Kinesiophobia (TSK) and (e) Pain Self-Efficacy Questionnaire (PSEQ)

One of the most important feasibility findings was that approximately 50% of patients did not start the CBPT-Trauma program after providing consent. Reasons provided by those who contacted our study team included time constraints and unstable housing as a result of their accident. Participants reported that they needed to focus on legal and financial issues first before taking care of themselves physically and emotionally. Additional work is needed to better understand how to engage patients at-risk for poor outcomes in the CBT-Trauma program, especially if it is delivered within the first few weeks after hospital discharge. Another option would be to enroll and initiate the CBPT-Trauma program later in the recovery period (i.e., between 2 and 3 months after hospitalization rather than 2–4 weeks). However, patients who participated in the 6-session CBPT-Trauma program reported that the strategies were helpful during the early recovery period, with the majority providing feedback that even earlier may be beneficial. In support of early targeted treatment, a review by Berube et al. (2016) recommends implementing psychosocial interventions as soon as possible after an injury to improve outcomes in patients with extremity trauma.

The CBPT-Trauma program appeared to be acceptable to patients based on intervention assessment results and improvement in patient-reported outcomes. All patients who started the CBPT-Trauma program completed

the 6 sessions and found the program to be very or extremely helpful to their overall recovery. The majority reported meaningful decreases in pain and/or meaningful increases in activity and found the CBPT-trauma program to be somewhat or much more important in their recovery compared to other services since surgery. These results are consistent with previous studies that have advocated for screening and applying targeted cognitive and behavioral strategies rather than implement a broad psychosocial management approach (Archer, Devin, et al., 2016; Bisson et al., 2004; George et al., 2003; Turner, Mancl, & Aaron, 2006; Vranceanu et al., 2015; Williams et al., 2002).

Improvement in patient-reported physical function appears clinically relevant, with all patients exceeding published values of clinical relevance for SMFA and/or PROMIS Physical Function CAT scores at 6-month follow-up (Barei, Agel, & Swiontkowski, 2007; Hung et al., 2018). This finding supports work by Vranceanu et al. (2015) that found a statistically significant difference in SMFA scores after a telephone-based mind-body intervention in patients with high levels of pain catastrophizing or anxiety following orthopaedic trauma. Both our intervention and that of Vranceanu and colleagues included relaxation strategies, cognitive restructuring, strategies to engage in physical activities, and problem solving, which have been shown to be effective for improving disability in patients with chronic pain (Ehde, Dillworth, & Turner, 2014). It is important to note that four patients in our study had improvement in physical function without meaningful changes in pain catastrophizing, fear of movement, or pain self-efficacy. One explanation may be that these patients experience changes in positive psychosocial characteristics that are not assessed in this study, such as increases in self-efficacy for return to usual activity or resilience, which then contributes to an improvement in physical function. Future work with the CBPT-trauma program should consider additional intermediary measures that assess a range of both risk and protective factors, such as resiliency, coping and anxiety, to better understand the underlying mechanisms of CBT-based strategies in this orthopedic patient population.

Approximately, half of our patients reported clinically meaningful improvement in pain following the CBPT-Trauma intervention. Smaller improvements in pain compared to physical function may be due to the low levels of pain found in this patient sample. The majority of patients had baseline pain intensity PROMIS scores that were within reasonably normal limits of the general U.S. population's average. Alternatively, since Vranceanu et al. (2015) also found small changes in pain at rest following a similar intervention, additional sessions may be needed to detect a robust pain effect. Future studies focusing on psychosocial interventions for trauma survivors may want to consider screening patients for moderate to high levels of pain as well as psychosocial risk factors.

The majority of studies assessing psychosocial interventions following traumatic injury have focused on improving psychological distress (Bisson et al., 2004; Castillo, Wegener, Newell, et al., 2013; De Silva et al., 2009). Inconsistent findings have been reported with some finding no significant effect on depression and anxiety, while others found potential benefit with regard to mental health. A systematic review by De Silva et al. (2009) noted that the overall absence of effect may be due to small sample sizes, low retention, brief nature of the programs, as well as the implementation of the psychosocial interventions in populations with large variability in risk profiles. Castillo et al. (2019) has recently demonstrated that classifying patients into risk and protective clusters using a multidimensional measure may allow for a more targeted approach to care in patients after orthopaedic trauma. The meaningful changes found in psychosocial characteristics (i.e., pain catastrophizing, fear of movement, and pain self-efficacy) in the majority of the patients in our study and in the work of Vranceanu et al. (2015) may be attributed to targeted screening using well-established and validated instruments.

Limitations that need to be considered include an open pilot study design that does not allow for statistical testing. We are unable to determine whether improvement in physical function, pain, pain catastrophizing, fear of movement, and pain self-efficacy were a direct result of the CBPT-Trauma intervention or due to natural recovery following traumatic injury. Randomized controlled trials are needed to compare the CBPT-Trauma intervention to usual care and/or an active comparator. In addition, 6 months is a relatively short time frame to assess clinically relevant outcomes following lower-extremity injury.

5 | CONCLUSIONS

Findings from our open pilot study suggest that implementing CBPT-Trauma, an early psychosocial rehabilitation program focusing on self-management and cognitive-behavioral skills, is potentially feasible and acceptable for patients after traumatic lower-extremity injury. The use of telephone delivery also has the potential to address barriers to care commonly reported in this patient population. Future work with the CBPT-Trauma program should consider patient engagement strategies to reduce attrition prior to the start of the intervention and additional intermediary measures that assess a range of both risk and protective factors to better understand the underlying mechanisms. Furthermore, a randomized controlled trial is needed to assess the efficacy of the CBPT-Trauma program compared to usual care or an active comparator. This open pilot study highlights the importance of targeted treatment for patients at high-risk for poor outcomes and the potential for increased access to services through telephone-delivery.

CONFLICT OF INTEREST

Dr. Kristin R. Archer would like to disclose financial associations with the American Physical Therapy Association, Pacira, Palladian Health, and Neuropoint Alliance, Inc. All other authors have no conflict of interest and no financial disclosures.

ORCID

Claudia A. Davidson  <https://orcid.org/0000-0002-7621-4406>

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