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ORIGINAL ARTICLE

Feasibility, engagement, and acceptability of a behavioral pain management intervention for colorectal cancer survivors with pain and psychological distress: data from a pilot randomized controlled trial

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Abstract

Purpose Colorectal cancer survivors report pain and psychological distress to be burdensome long-term cancer consequences. Quality cancer survivorship care includes interventions for managing these symptoms. Yet, no studies have tested the efficacy of an accessible behavioral intervention for colorectal cancer survivors with pain and comorbid psychological distress. This paper reports on the feasibility (i.e., accrual, attrition, and adherence to study procedures), engagement, acceptability, and descriptive outcomes of a telephone-based coping skills training (CST) intervention.

Methods This randomized pilot trial assigned colorectal cancer patients (N=31) to 5 sessions of CST or standard care. CST sessions focused on cognitive-behavioral theory-based coping skills tailored to colorectal cancer symptoms of pain and psychological distress. Participants completed assessments of pain severity, self-efficacy for pain management, health-related quality of life, and psychological distress at baseline, post-treatment, and 3-month follow-up.

Results Data indicated strong feasibility, evidenced by high completion rates for intervention sessions and assessments (93% completed all sessions; M=48.7 days; baseline=100%; post-treatment=97%; 3-month follow-up=94%). Participants demonstrated robust engagement with CST (M days per week with reported skills use=3.8) and reported high protocol satisfaction (M=3.6/4.0). Descriptive statistics showed self-efficacy for pain management and health-related quality of life improved for all participants.

Conclusion Findings suggest that a telephone-based CST intervention has strong feasibility, evidenced by accrual, low attrition, and adherence to intervention sessions and assessments. Likewise, participant engagement and acceptability with CST were high. These data provide a foundation for larger randomized efficacy trials of the telephone-based CST intervention.

Keywords Telephone-based coping skills training · Pain-coping skills · Psychological distress · Cancer pain · Colorectal cancer

Introduction

Early detection strategies and treatment advances have resulted in over 1 million colorectal cancer survivors in the United States [1]. Survivorship is an increasingly important phase along the cancer continuum, as many colorectal cancer survivors endorse long-term negative physical and psychosocial consequences of their disease. Pain and psychological distress (i.e., anxiety and depression) are described by survivors as especially burdensome long-term symptoms [2–4].

Pain is a significant problem that does not improve with time for patients with colorectal cancer [4]. Stoma procedures are common for these patients and can cause unique pain experiences, worry, and isolation from normal activities [4].

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Colorectal cancer patients with persistent pain also are more likely to report psychological distress for years post-treatment [5, 6]. Research shows that colorectal cancer survivors with pain are more likely to be depressed and anxious compared to those not experiencing pain [3, 7]. The burden of these symptoms negatively impacts the overall health-related quality of life (QoL) for colorectal cancer patients [5, 8]. Patients with colorectal cancer report needing more information and viable treatment options for managing pain and distress during survivorship [9–12]. There is a notable deficit in our survivorship care paradigm and a critical need to develop novel and accessible behavioral interventions specifically tailored to address colorectal cancer symptoms (i.e., pain and psychological distress), enhance self-efficacy for symptom management, and improve overall health-related QoL.

Numerous guidelines for quality survivorship care (e.g., American Society of Clinical Oncology and National Comprehensive Cancer Network) recommend the inclusion of behavioral interventions for pain management and psychological distress [12]. However, to date, most interventions are primarily medical in nature (e.g., analgesic therapy for pain management) [13]. Further, when offered, behavioral interventions are delivered almost exclusively in-person at major medical centers [14]. For patients with colorectal cancer, travel is particularly challenging as their specific cancer-related symptoms can make it difficult to be away from the home (e.g., problems finding public restrooms) [5]. Additionally, behavioral interventions for cancer survivors typically target only one symptom (e.g., pain) or area of functioning [15, 16]. Accessible behavioral interventions designed to target interrelated symptoms unique to colorectal cancer patients (e.g., stoma-related and abdominal pain and psychological distress related to stoma noises/smells) have the potential to efficiently reduce survivors' symptom burden, enhance self-efficacy for symptom management, and improve overall health-related QoL. Yet, no studies have tested an accessible behavioral intervention uniquely tailored for colorectal cancer survivors with pain and comorbid psychological distress.

To address these gaps in the literature, we designed a cognitive-behavioral theory-based intervention targeting interrelated symptoms (i.e., pain and psychological distress) in colorectal cancer survivors. Study sessions involved the application of cognitive and behavioral coping skills to the unique symptom management needs of colorectal cancer survivors. The coping skills training was delivered in a highly accessible way via telephone. Most telephone-delivered interventions for cancer survivors are educational in nature or limited to email/text messages to provide health-related information and health behavior reminders [17, 18]. To our knowledge, this is the first telephone-based behavioral intervention for colorectal cancer survivors that delivers systematic training in cognitive and behavioral coping techniques for pain and comorbid psychological distress.

We conducted a pilot randomized controlled trial (RCT) to assess our cognitive-behavioral theory-based intervention that delivers training in coping strategies specifically tailored to address the unique symptom management needs of colorectal cancer survivors. Colorectal cancer survivors with pain and comorbid psychological distress were recruited and randomized into either: telephone-based coping skills training (CST) or standard care. This paper reports on the feasibility (i.e., accrual, attrition, and adherence to study procedures), engagement, acceptability, and descriptive outcomes of CST to provide a foundation for subsequent larger randomized efficacy trials.

Methods

Participants

Participants (N=31) were men and women who had been diagnosed with colorectal cancer in the past 4 years. Eligibility criteria included (1) ≥21 years old, (2) completed active cancer treatment, (3) reported pain and psychological distress at ≥3 on a 0-10 scale since completing cancer treatment, and (4) English-speaking. Exclusion criteria included (1) cognitive impairment or severe psychiatric condition based on chart review, (2) receipt of pain coping skills training <6 months, or (3) initial diagnosis of metastatic cancer. Participation was not discontinued due to changes in disease course or treatment.

Procedure

Procedures complied with ethical guidelines and received Duke University Institutional Review Board approval (Pro00063330). Recruitment took place from 2015-2018 at the Duke Cancer Institute. Participants were identified using electronic medical records. A letter signed by the oncologist and principal investigator was sent to the patient to introduce the study. Patients were contacted by study staff for eligibility screening and consent.

After completing the baseline assessment, participants were randomized with a 1:1 allocation ratio to receive (1) CST or (2) standard care. A random number assignment procedure was conducted by a study member with no participant interaction. Participants were blinded to study hypotheses and completed assessments online to reduce demand characteristics and assessor bias. Participants completed post-treatment and 3-month follow-up assessments. Participants received $15 per completed assessment. Study statisticians were not involved in data collection. Analyses were conducted after the completion of data collection.

Intervention conditions

Telephone-based coping skills training (CST)

The CST condition received five 45-60 minute sessions of a cognitive-behavioral theory-based protocol that taught cognitive and behavioral coping skills to manage colorectal cancer pain and comorbid psychological distress. These strategies enhance patients' abilities to cope by improving behaviors, thoughts, and feelings about pain and distress. The therapist and patient discuss the patient's specific symptoms to tailor the session content to the patient's unique symptom needs. The CST intervention is informed by our group's prior work and factors from Social Cognitive Theory that positively impact self-efficacy for symptom management (e.g., mastery and vicarious learning) [19]. The CST intervention is an adjunct treatment that complements the treatments from medical providers (e.g., medications and mechanics of colostomy bag).

Session 1 Participants were introduced to progressive muscle relaxation (PMR), provided with rationale for its use as a pain control technique (i.e., decreases body tension and distress), and guided through a practice exercise. PMR involves concentrating on signals of muscle tension and using them as cues to relax. PMR effectively decreases pain and psychological distress in cancer patients [20, 21]. The therapist offered problem-solving around any negative physiological, cognitive, and/or affective reactions to the PMR practice, especially as it relates to the colorectal cancer pain experience (e.g., stoma-related pain). Participants were provided with a guided audio-recording of PMR and asked to practice daily.

Session 2 Participants were taught an activity pacing method (i.e., activity-rest cycle) for scheduling activity and rest that allows them to be productive and active, but avoid increased pain. Activity-rest cycling can decrease physical symptoms and psychological distress in patients with cancer [22, 23]. Pleasant activity scheduling was then taught, which is a form of behavioral activation that encourages engagement in enjoyable activities. Pleasant activity scheduling can decrease pain and improve mood in patients with cancer [24, 25]. The therapist helped problem-solve any concerns, including anticipated facilitators (e.g., goals) and barriers to at-home practice (e.g., worry about stoma noises/smells). Participants were asked to practice these skills daily.

Session 3 Participants were taught cognitive restructuring to recognize how some thoughts can negatively influence their pain. Specifically, participants were encouraged to explore how negative pain-related thoughts (e.g., "My cancer pain is ruining my life!") not only impact their pain and ability to cope with pain but also their psychological well-being. Cognitive restructuring is a well-established method for increasing mood and reducing pain in patients with cancer [26–28]. The therapist assisted with problem-solving any difficulties with this skill and encouraged daily practice.

Session 4 Imagery was taught during the fourth session. The therapist encouraged the participant to reflect on pleasant scenes and/or their own memories of such scenes. The therapist then guided the participant through several imagery practices and encouraged home practice. The therapist provided assistance problem-solving around negative responses (i.e., physiological, affective) to this skill. Imagery has been shown to lead to significant reductions in pain and anxiety and improvements in mood in patients with cancer [29, 30].

Session 5 The final session incorporated a review of all coping skills, as well as the use and benefits of each coping skill for managing colorectal cancer pain and psychological distress. Participants were also taught a brief applied relaxation exercise—mini-relaxation practice. The therapist worked collaboratively with the participant to set goals for continued skills use and to problem-solve anticipated obstacles.

Standard care control

The standard care control condition received informational pamphlets related to survivorship health and cancer center services. Topics included nutrition, physical activity, smoking and alcohol, and survivorship care. This information was mailed to the participant following randomization.

Measures

Background and medical information

Background and medical information included age, race, marital status, employment status, availability of health insurance, education, household income, and personal and family history of colorectal cancer.

Feasibility

The feasibility of the study design and CST intervention was assessed via accrual, attrition (≤20%), and adherence (≥80%) to study procedures (i.e., intervention sessions and assessments).

Engagement

Participants' intervention engagement was assessed by the interventionist prior to each session by asking about skills used in the past 7 days (e.g., "How many days in the last seven have you used progressive muscle relaxation?"). Adequate engagement was demonstrated by self-reported skill use on

≥3 days during the week prior to a session [31, 32]. Participants were also asked how often since their last session had they used skills and/or ideas from this program on a scale of 0=not at all to 4=almost every day.

Acceptability

The 10-item Client Satisfaction Questionnaire was used to assess acceptability post-treatment [33]. Items are rated on a 4-point scale from 1=low acceptability to 4=high acceptability. Item scores are averaged to obtain a total score. Acceptability was demonstrated by participants reporting ≥80% (*M*=3.2/4.0) satisfaction with the intervention.

Pain severity

Pain severity was assessed by the 4-item Pain Severity subscale of the Brief Pain Inventory (BPI) [34]. Participants were asked to rate their pain in the last 7 days at its "worst," "least," "average," and "right now" using an 11-point scale ranging from 0=no pain to 10=pain as bad as you can imagine. Item scores were averaged to obtain a total score representing pain severity. This subscale has been recommended for use in all chronic pain clinical trials [35, 36].

Self-efficacy for pain control

Self-efficacy for pain control was measured using the Self-Efficacy for Pain Management subscale of the Chronic Pain Self-Efficacy Scale [37]. This subscale contains 5 items that assess patients' certainty about their degree of pain control. Response options range from 10=very uncertain to 100=very certain and are averaged. This scale has shown good reliability and has been used in patients with cancer [37, 38].

Health-related quality of life (QoL)

Health-related QoL was assessed using the 27-item Functional Assessment of Cancer Therapy-General (FACT-G), version 4.0 [39]. The FACT-G includes four QoL domains (i.e., physical, social/family, emotional, and functional well-being). Response options range from 0=not at all to 4=very much and are summed to calculate a total score with higher scores indicating better QoL. This scale has demonstrated sound psychometric properties [39].

Psychological distress

The 18-item Brief Symptom Inventory (BSI-18) was used to measure psychological distress [40]. To reduce participant burden, the BSI-18 was condensed to include 11 items; this approach has been used in prior research [41]. Response options range from 0=not at all and 4=extremely. Item scores were summed and converted to area T-scores, with higher scores indicating worse distress. The BSI-18 has demonstrated good internal consistency and strong reliability and structural validity in cancer patients [42].

Statistical analyses

This paper reports on the feasibility (accrual, attrition, and adherence to study procedures), engagement, acceptability, and descriptive outcomes of the CST intervention from the pilot RCT. Consistent with guidelines for pilot studies, we did not conduct formal statistical analyses testing between-group differences [43, 44]. Instead, we computed descriptive statistics for the study outcomes using the Statistical Package for the Social Sciences Version 26 (SPSS 26).

Results

Feasibility

Accrual

Of the 98 patients assessed for eligibility, 52 did not meet inclusion criteria, 12 declined participation, and 3 were unreachable for formal screening (see Fig. 1 for CONSORT diagram). We enrolled 31 patients in 21 months. Following the baseline assessment, all participants were randomized to either CST (*n*=14) or standard care (*n*=17). Table 1 displays demographic and medical data.

Attrition

Of the 31 participants randomized, 94% completed the study (*n*=29). Two participants in the standard care condition were lost to follow-up. Overall, attrition was remarkably less than the set cut-off of 20%, indicating this study design and intervention protocol were feasible.

Adherence

Ninety-three percent of participants in the CST condition completed all 5 intervention sessions (*n*=13). One participant declined the intervention sessions due to time constraints and stress. These data are well above the set cut-off of 80% adherence to intervention sessions. The mean amount of time for patients in the CST condition to complete the protocol was 48.7 days (SD=23.3), suggesting the 5-session protocol can be completed in 1.5 months or one session per week, which is within the expected time of 5 to 8 weeks.

All participants (100%) assigned to the CST intervention completed the baseline, post-treatment, and 3-month follow-up assessments. In the standard care condition, 100% of

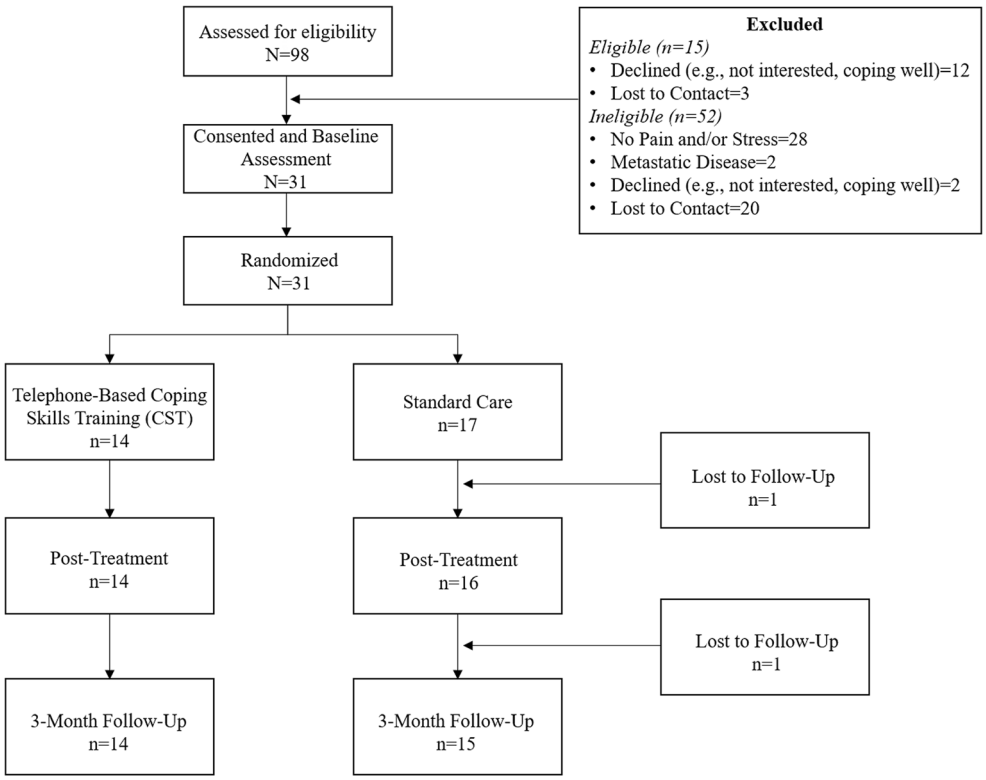

Fig. 1 CONSORT diagram

participants completed the baseline assessment, while 94% (n=16) and 88% (n=15) completed the post-treatment and 3-month follow-up assessments, respectively. These data exceed the set cut-off of 80% adherence to study assessments.

Engagement

Participants randomized to CST demonstrated strong engagement, evidenced by skills practice assessed prior to each applicable intervention session (i.e., 2-5). Across all sessions, the majority of skills were practiced at or above our set cut-off of 3 days during the prior week (see Table 2). By session 5, participants reported using any skill or idea from the program "almost every day" (*M*=3.78 [SD=.73]).

Acceptability

Participants found the CST intervention to be highly acceptable with a mean satisfaction rating of 3.6/4.0. This was above the set cut-off of 80% (*M*=3.2/4.0) satisfaction with the intervention. Qualitative feedback from participants was overwhelmingly positive. One participant noted "everything about the program was helpful." Many participants described PMR and activity-rest cycle as the most useful skills. Table 3 outlines additional qualitative feedback.

Descriptive results

Data from completed assessments revealed that pain severity was low across all timepoints in both CST (baseline *M*=2 [SD=2]; post-treatment *M*=3 [SD=2]; 3-month follow-up *M*=2 [SD=2]) and standard care (baseline *M*=2 [SD=2]; post-treatment *M*=2

Table 1 Participant characteristics and summary of self-report data (*N*=31)

	M (SD)	*N* (%)
Age	59.5 (10.5)	
Gender (% male)		19 (61.3%)
Race		
White		30 (96.8)
Black		1 (3.2)
Relationship status		
Married/life partner		23 (74.2)
Single		5 (16.1)
Divorced		2 (6.5)
Widowed		1 (3.2)
Cancer type		
Rectal		15 (48.4)
Colon		16 (51.6)
Time since initial diagnosis (months)	39.6 (29.09)	
Time to complete sessions (days)	48.8 (23.3)	

Note. *M*, mean; SD, standard deviation

Table 2 Days of coping skill use during week prior to session

Skill	Session 2 *M* (SD)	Session 3 *M* (SD)	Session 4 *M* (SD)	Session 5 *M* (SD)
Progressive muscle relaxation	3.31 (2.36)	3.85 (2.03)	2.15 (1.52)	2.62 (2.36)
Activity-rest cycle	--	4.54 (2.33)	4.38 (2.22)	4.77 (1.88)
Pleasant activity scheduling	--	5.62 (1.45)	5.08 (1.98)	5.00 (1.63)
Cognitive restructuring	--	--	5.54 (1.45)	5.08 (1.61)
Imagery	--	--	--	3.23 (2.31)
Mini-relaxation	--	--	--	4.38 (1.30)

Note. *M*, mean; SD, standard deviation

[SD=2]; 3-month follow-up *M*=1 [SD=2]). Mean values for self-efficacy for pain control were moderate at baseline, and notably, not equivalent across conditions (CST *M*=69 [SD=23] vs. standard care *M*=62 [SD=20]). In both the CST and standard care conditions, self-efficacy for pain control modestly improved at post-treatment (CST *M*=71 [SD=24] vs. standard care *M*=66 [SD=23]) and 3-month follow-up timepoints (CST *M*=72 [SD=27] vs. standard care *M*=65 [SD=25]. Similarly, overall health-related QoL demonstrated some improvement across timepoints for both CST (baseline *M*=80 [SD=14]; post-treatment *M*=80 [SD=16]; 3-month follow-up *M*=83 [SD=15]) and standard care (baseline *M*=76 [SD=12; post-treatment *M*=80 [SD=13]; 3-month follow-up *M*=77 [SD=15]). Psychological distress was low at baseline for all participants and remained low across follow-up timepoints in both CST (baseline *M*=.49 [SD=.49]; post-treatment *M*=.66 [SD=.50]; 3-month follow-up *M*=.51 [SD=.38]) and standard care (baseline *M*=.74 [SD=.56]; post-treatment *M*=.56 [SD=.48]; 3-month follow-up *M*=.43 [SD=.52]). Given the pilot nature and small sample size of this study, we did not assess change between conditions on outcome variables [43, 44].

Discussion

Behavioral interventions are an efficacious, non-medication treatment option for cancer-related symptoms [12]. Although many researchers have focused on addressing the individual physical and psychological symptoms of cancer patients, there is less work targeting persistent cancer-related pain and co-morbid psychological distress during the survivorship phase of care. Furthermore, few interventions have targeted the

Table 3 CST participant feedback

Topic area	Feedback
Therapist	• "Speaking with a knowledgeable, pleasant person weekly was reaffirming."
	•"[What I liked the most was] the therapist's compassionate attitude and disposition."
Delivery modality	• "I liked the phone sessions."
	• "[What I liked most was] doing the therapy over the phone."
Intervention content	• "Everything about the program was helpful."
	• "Having the chance to ask questions and describe my personal situation made the study more meaningful to me…the CD with the relaxation exercises was also very helpful because those are the concepts I need to work on the most. I don't have to worry that I'm going to forget the methodology."
	• "The ability to talk to someone about one's issues is always a help but adding some specific aids to reduce both physical and psychological pain and fear of pain gives one a boost not only in directly dealing with concerns but allows one to refocus on the degree to which the issues can be ameliorated."
	• "Giving [me] options to make it through the day."
	• "I liked the muscle relaxation part."
Barriers/areas for improvement	• "The least helpful aspect of the study was more a factor of the timing. My good practice routine was interrupted because of the holidays."
	• "I wonder if spacing the calls out a little more would help; I could [have] used more time between calls to incorporate the exercises into my daily routine."
	• "The only thing I would suggest is to add a follow-up with patients to see how the coping skills have translated."

unique psychosocial concerns of colorectal cancer patients (e.g., stoma-related pain and distress) using a highly accessible delivery modality (i.e., telephone). This is the first study to assess the initial feasibility, engagement, acceptability, and descriptive outcomes of a telephone-based behavioral intervention tailored specifically for survivors of colorectal cancer with comorbid pain and psychological distress.

Thirty-one of 98 colorectal cancer survivors met eligibility criteria and consented to be enrolled in this pilot study. Fourteen participants were randomized to the CST intervention, while 17 participants were randomized to standard care. Ninety-four percent of participants completed the study (n=29). Across all study participants, 100% completed the baseline assessment, 97% completed the post-treatment assessment (n=30), and 94% completed the 3-month follow-up assessment (n=29). These data suggest participants were agreeable to randomization and completing study assessments. This provides a strong foundation for conducting subsequent, larger efficacy trials of the CST protocol using a similar randomized design. Such trials are critically needed, given colorectal cancer patients' reports that treatment options for managing pain and psychological distress are lacking during survivorship [9–11].

We found the CST intervention to be feasible, with all but 1 participant completing the 5-session protocol. The time to complete the CST protocol was approximately 1.5 months (M=48.7 days), which suggests that intervention sessions can be completed weekly across a relatively brief timeframe. It is plausible that delivery of session content via a readily available method (i.e., telephone) enhanced the feasibility of the CST intervention for patients who may be struggling with competing health, family, and work-related demands and barriers specific to colorectal cancer (e.g., burdensome travel due to gastrointestinal symptoms) that make it difficult to attend in-person appointments. This is one of the first telephone-based behavioral interventions for colorectal cancer survivors that delivers formal training in cognitive and behavioral coping techniques [17, 18]. Findings from this pilot RCT offer compelling support for the use of this modality to deliver multi-session symptom management protocols to colorectal cancer patients.

Our results also suggest that the CST intervention was highly engaging and acceptable. Engagement with CST content was robust, evidenced by participants reporting the use of skills and/or ideas from the protocol on at least 3 days during the previous week. Similarly, mean self-reported satisfaction with the protocol was within the "high satisfaction" range. Qualitative feedback corroborated these self-report data wherein all participants described the coping skills as helpful. These results suggest that carefully tailored intervention content was relevant and useful to participants. This is notable given data suggesting this patient population has reported non-medication treatment options for managing pain and psychological distress are limited and suboptimal [9–11]. Qualitative feedback regarding areas for improvement (e.g., spacing out sessions and adding follow-up sessions) is valuable and should be used to guide future work.

As this was a pilot study primarily focused on assessing feasibility, engagement, and acceptability, we did not conduct formal statistical analyses testing between-group differences. However, descriptive statistics showed that the CST protocol produced a signal for hypothesized change in several pain-related outcomes, including self-efficacy for pain management and overall health-related QoL. These findings should be interpreted cautiously, though, due to the small sample size and modest change across timepoints. Notably, we did not observe much improvement in pain severity and/or psychological distress among those randomized to CST. Symptom eligibility screening was completed at a different timepoint than the baseline assessment, which likely accounts for the lower, sub-clinical levels of pain and distress reported at baseline. Future work should assess symptom levels closer to the intervention timeframe (e.g., past week) and ensure that treatment starts soon after screening. Further, given the low levels of pain and distress observed at baseline, it is possible that participants who opted into our study were already coping well with their colorectal cancer symptoms. Our CST intervention might be better suited for patients reporting at least clinically significant levels of pain and psychological distress at the time of baseline and intervention [31].

The pilot work presented here should be considered in light of several limitations. First, our sample size was small; a larger sample would provide adequate power for testing group differences and detecting minimum clinically important differences in pain and psychological distress. Second, eligibility criteria may have been too inclusive, yielding a relatively heterogeneous sample with low levels of baseline symptoms scores across relevant variables. Patients were not recruited based on their type of pain (e.g., stoma-related vs. neuropathy), however, this should be considered for future work. Future studies should consider using validated cut points for clinically-relevant levels of pain and psychological distress and assessment close to the intervention timeframe to ensure that enrolled patients are those in most need of coping strategies [31].

Our study had many strengths, including a randomized controlled design and central goal to address critical symptom (i.e., pain and psychological distress) management needs unique to colorectal cancer patients during survivorship. Another strength includes the telephone-based intervention approach. Overall, this trial demonstrated that the study design and CST intervention protocol are highly feasible, engaging, and acceptable to colorectal cancer survivors. To our knowledge, this is the first study evaluating a behavioral coping skills training intervention for colorectal cancer survivors with pain and psychological distress delivered via a highly

accessible and readily available modality. This telephone-based intervention has the potential to decrease survivors' symptom burden, lead to improvements in pain management self-efficacy and health-related quality of life, and ultimately reduce suffering caused by cancer and its treatment.

Author contribution All authors contributed to the study conception and design. Material preparation, recruitment, and data collection were performed by Sarah A. Kelleher, Ph.D., Tamara J. Somers, Ph.D., Hope E. Uronis, M.D., MHS, and Francis J. Keefe, Ph.D. Data analyses were performed by Sarah Kelleher, Ph.D., Joseph G. Winger, Ph.D., and Hannah M. Fisher, Ph.D. The first draft of the manuscript was written by Sarah Kelleher, Ph.D. and Hannah M. Fisher, Ph.D., and all authors commented on subsequent versions of the manuscript. All authors read and approved the final manuscript.

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Data availability N/A

Code availability N/A

Declarations

Ethics approval Procedures complied with ethical guidelines and received Duke University Institutional Review Board approval (Pro00063330).

Consent to participate Informed consent was obtained from all individual participants included in this study.

Consent for publication The authors affirm that human research participants provided informed consent for publication of the data included in this publication.

Conflict of interest The authors declare no conflict of interest.

References

1. Siegel RL, Miller KD, Goding Sauer A, Fedewa SA, Butterly LF, Anderson JC, Cercek A, Smith RA, Jemal A (2020) Colorectal cancer statistics, 2020. CA Cancer J Clin 70(3):145–164
2. Stark D, Kiely M, Smith A, Velikova G, House A, Selby P (2002) Anxiety disorders in cancer patients: their nature, associations, and relation to quality of life. J Clin Oncol 20(14):3137–3148
3. Lowery AE, Starr T, Dhingra LK, Rogak L, Hamrick-Price JR, Farberov M, Kirsh KL, Saltz LB, Breitbart WS, Passik SD (2013) Frequency, characteristics, and correlates of pain in a pilot study of colorectal cancer survivors 1–10 years post-treatment. Pain Med 14(11):1673–1680
4. Denlinger CS, Barsevick AM (2009) The challenges of colorectal cancer survivorship. J Natl Compr Cancer Netw 7(8):883–893 quiz 894
5. Arndt V, Merx H, Stegmaier C, Ziegler H, Brenner H (2004) Quality of life in patients with colorectal cancer 1 year after diagnosis compared with the general population: a population-based study. J Clin Oncol 22(23):4829–4836
6. Schag C et al (1994) Quality of life in adult survivors of lung, colon and prostate cancer. Qual Life Res 3(2):127–141
7. Zaza C, Baine N (2002) Cancer pain and psychosocial factors: a critical review of the literature. J Pain Symptom Manag 24(5):526–542
8. Shi Q, Smith TG, Michonski JD, Stein KD, Kaw C, Cleeland CS (2011) Symptom burden in cancer survivors 1 year after diagnosis: a report from the American Cancer Society's Studies of Cancer Survivors. Cancer 117(12):2779–2790
9. Arora NK, Reeve BB, Hays RD, Clauser SB, Oakley-Girvan I (2011) Assessment of quality of cancer-related follow-up care from the cancer survivor's perspective. J Clin Oncol 29(10):1280–1289
10. Beckjord EB, Arora NK, McLaughlin W, Oakley-Girvan I, Hamilton AS, Hesse BW (2008) Health-related information needs in a large and diverse sample of adult cancer survivors: implications for cancer care. J Cancer Surviv 2(3):179–189
11. Fairley TL, Pollack LA, Moore AR, Smith JL (2009) Addressing cancer survivorship through public health: an update from the Centers for Disease Control and Prevention. J Women's Health 18(10):1525–1531
12. Council, I.o.M.a.N.R (2006) From cancer patient to cancer survivor: lost in transition: An American Society of Clinical Oncology and Institute of Medicine Symposium. National Academies Press, Washington, D.C
13. Lussier D, Huskey AG, Portenoy RK (2004) Adjuvant analgesics in cancer pain management. Oncologist 9(5):571–591
14. Syrjala KL, Jensen MP, Mendoza ME, Yi JC, Fisher HM, Keefe FJ (2014) Psychological and behavioral approaches to cancer pain management. J Clin Oncol 32(16):1703–1711
15. Somers TJ, Abernethy AP, Edmond SN, Kelleher SA, Wren AA, Samsa GP, Keefe FJ (2015) A pilot study of a mobile health pain coping skills training protocol for patients with persistent cancer pain. J Pain Symptom Manag 50(4):553–558
16. Rini C, Porter LS, Somers TJ, McKee DC, DeVellis RF, Smith M, Winkel G, Ahern DK, Goldman R, Stiller JL, Mariani C, Patterson C, Jordan JM, Caldwell DS, Keefe FJ (2015) Automated Internet-based pain coping skills training to manage osteoarthritis pain: a randomized controlled trial. Pain 156(5):837–848
17. Badger TA, Segrin C, Hepworth JT, Pasvogel A, Weihs K, Lopez AM (2013) Telephone-delivered health education and interpersonal counseling improve quality of life for Latinas with breast cancer and their supportive partners. Psycho-Oncology 22(5):1035–1042
18. Lawler S, Maher G, Brennan M, Goode A, Reeves MM, Eakin E (2017) Get healthy after breast cancer-examining the feasibility, acceptability and outcomes of referring breast cancer survivors to a general population telephone-delivered program targeting physical activity, healthy diet and weight loss. Support Care Cancer 25(6):1953–1962
19. Bandura A (1997) Self-efficacy: The exercise of control. W. H. Freeman, New York
20. Cheung YL, Molassiotis A, Chang AM (2003) The effect of progressive muscle relaxation training on anxiety and quality of life after stoma surgery in colorectal cancer patients. Psycho-Oncology 12(3):254–266
21. Kwekkeboom KL, Wanta B, Bumpus M (2008) Individual difference variables and the effects of progressive muscle relaxation and analgesic imagery interventions on cancer pain. J Pain Symptom Manag 36(6):604–615
22. Murphy SL, Lyden AK, Smith DM, Dong Q, Koliba JF (2010) Effects of a tailored activity pacing intervention on pain and fatigue for adults with osteoarthritis. Am J Occup Ther 64(6):869–876
23. Keefe FJ, Ahles TA, Sutton L, Dalton JA, Baucom D, Pope MS, Knowles V, McKinstry E, Furstenberg C, Syrjala K, Waters SJ, McKee D, McBride C, Rumble M, Scipio C (2005) Partner-

guided cancer pain management at the end of life: a preliminary study. J Pain Symptom Manag 29(3):263–272
24. Sigmon ST, Nelson RO (1988) The effectiveness of activity scheduling and relaxation training in the treatment of spasmodic dysmenorrhea. J Behav Med 11(5):483–495
25. Telch CF, Telch MJ (1986) Group coping skills instruction and supportive group therapy for cancer patients: a comparison of strategies. J Consult Clin Psychol 54(6):802–808
26. Gaston-Johansson F, Fall-Dickson JM, Nanda JP, Sarenmalm EK, Browall M, Goldstein N (2013) Long-term effect of the self-management comprehensive coping strategy program on quality of life in patients with breast cancer treated with high-dose chemotherapy. Psycho-Oncology 22(3):530–539
27. Riddle DL, Keefe FJ, Nay WT, McKee D, Attarian DE, Jensen MP (2011) Pain coping skills training for patients with elevated pain catastrophizing who are scheduled for knee arthroplasty: a quasi-experimental study. Arch Phys Med Rehabil 92(6):859–865
28. Somers TJ, Blumenthal JA, Guilak F, Kraus VB, Schmitt DO, Babyak MA, Craighead LW, Caldwell DS, Rice JR, McKee DC, Shelby RA, Campbell LC, Pells JJ, Sims EL, Queen R, Carson JW, Connelly M, Dixon KE, LaCaille LJ, Huebner JL, Rejeski JW, Keefe FJ (2012) Pain coping skills training and lifestyle behavioral weight management in patients with knee osteoarthritis: a randomized controlled study. Pain 153(6):1199–1209
29. Abernethy A, Keefe F, Mccrory D, Scipio CD, Matchar D (2006) Behavioral therapies for the management of cancer pain: a systematic review. In: Proceedings of the 11th World Congress on Pain. IASP Press, Seattle, pp 789–798
30. Baider L, Uziely B, De-Nour AK (1994) Progressive muscle relaxation and guided imagery in cancer patients. Gen Hosp Psychiatry 16(5):340–347
31. Somers TJ et al (2016) A small randomized controlled pilot trial comparing mobile and traditional pain coping skills training protocols for cancer patients with pain. Pain Res Treat 2016:2473629
32. Burns DD, Spangler DL (2000) Does psychotherapy homework lead to improvements in depression in cognitive–behavioral therapy or does improvement lead to increased homework compliance? J Consult Clin Psychol 68(1):46–56
33. Attkisson CC, Zwick R (1982) The Client Satisfaction Questionnaire: psychometric properties and correlations with service utilization and psychotherapy outcome. Eval Program Plann 5(3):233–237
34. Cleeland CS, Ryan KM (1994) Pain assessment: global use of the Brief Pain Inventory. Ann Acad Med Singap 23(2):129–138
35. Turk DC, Dworkin RH, Allen RR, Bellamy N, Brandenburg N, Carr DB, Cleeland C, Dionne R, Farrar JT, Galer BS, Hewitt DJ, Jadad AR, Katz NP, Kramer LD, Manning DC, McCormick CG, McDermott MP, McGrath P, Quessy S, Rappaport BA, Robinson JP, Royal MA, Simon L, Stauffer JW, Stein W, Tollett J, Witter J (2003) Core outcome domains for chronic pain clinical trials: IMMPACT recommendations. Pain 106(3):337–345
36. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport BA, Rauschkolb C, Revicki DA, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S (2008) Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain 9(2):105–121
37. Anderson KO, Dowds BN, Pelletz RE, Edwards TW, Peeters-Asdourian C (1995) Development and initial validation of a scale to measure self-efficacy beliefs in patients with chronic pain. Pain 63(1):77–83
38. Porter LS et al (2008) Self-efficacy for managing pain, symptoms, and function in patients with lung cancer and their informal caregivers: associations with symptoms and distress. Pain 137(2):306–315
39. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, Silberman M, Yellen SB, Winicour P, Brannon J (1993) The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 11(3):570–579
40. Derogatis L (1975) Brief symptom inventory, clinical psychometric research. Clinical Psychometric Research, Baltimore
41. Peshkin BN, DeMarco TA, Graves KD, Brown K, Nusbaum RH, Moglia D, Forman A, Valdimarsdottir H, Schwartz MD (2008) Telephone genetic counseling for high-risk women undergoing BRCA1 and BRCA2 testing: rationale and development of a randomized controlled trial. Genet Test 12(1):37–52
42. Andreu Y, Galdón MJ, Dura E, Ferrando M, Murgui S, García A, Ibáñez E (2008) Psychometric properties of the Brief Symptoms Inventory-18 (BSI-18) in a Spanish sample of outpatients with psychiatric disorders. Psicothema 20(4):844–850
43. Eldridge SM et al (2016) Defining feasibility and pilot studies in preparation for randomised controlled trials: development of a conceptual framework. PLoS One 11(3):e0150205
44. Kraemer HC, Mintz J, Noda A, Tinklenberg J, Yesavage JA (2006) Caution regarding the use of pilot studies to guide power calculations for study proposals. Arch Gen Psychiatry 63(5):484–489