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A Systematic Review of Cognitive Behavioral Interventions in Advanced Cancer

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Abstract

Objective—To systematically review cognitive behavioral interventions for people with advanced cancer.

Methods—A literature search was conducted using Medline©, CINAHL©, and Psych-info©. Inclusion criteria: Studies were included in the review if they met the following criteria: (1) the design was a randomized clinical trial (2) the study tested a cognitive behavioral therapy, including psycho-educational, alternative and complementary therapies (i.e. acupuncture, relaxation), expressive, support and skill building interventions, (3) participants were adults (18 years of age or older) with advanced cancer and the (4) outcomes were directly related to the patient with advanced cancer.

Results—11 studies met the inclusion criteria. Of the studies in the review: treatment effects were not statistically significant in most studies, methods were not consistently described, and samples had limited racial/ethnic diversity.

Conclusion—The interpretation of the effectiveness of the CBI's was limited by major challenges to the internal validity of the studies included in the review. The lack of data about the efficacy of CBI's to support people with advanced cancer is a gap in the current knowledge base.

Practice Implications—Given the needs of people living with advanced cancer well-designed studies are needed to test interventions that will improve outcomes for people living with advanced cancer.

1. Introduction

The American Cancer Society (ACS) estimates that 11.6 million people are living with a cancer diagnosis in the United States (U.S.) [1]. Virnig and colleagues [2] estimated that depending on the type of cancer, the percentage of people who are initially diagnosed with advanced cancer ranged from 5%-42%. For example, approximately 5% of people diagnosed with prostate cancer and up to 42% of people with lung cancer are found to have metastatic disease at presentation. People living with advanced cancer are a diverse

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population that includes, people who are: (1) newly diagnosed and are receiving active anti-cancer treatment, (2) cancer survivors who have been diagnosed with recurrent disease and (3) finally, there are people who are in the most advanced stage of their illness with a life expectancy of days or months. Because of the evolution in cancer treatment, a person may live for years after a diagnosis of advanced cancer [3] and have different needs over the trajectory of the disease. Therefore, it is important to identify the needs of people with advanced cancer and develop interventions to support their journey.

When compared with a person with early stage or localized disease, people with advanced cancer often experience a greater number of physical, emotional, and spiritual symptoms. Physical symptoms such as pain [4–10], dyspnea, constipation [11], fatigue [8, 12], and sleep pattern disturbances [13] are a significant part of the experience of living with advanced cancer. Emotional symptoms include, anxiety, depression, and grief for actual or potential losses [14–18]. Kolva and colleagues [19] found that 12 % of the total sample experienced clinically significant anxiety that impaired functioning. Depression is ranked as one top symptoms in patients with advanced cancer [17] The incidence of depressive syndromes in people with advanced cancer has been estimated to range from 56% [20] to high as 77% [21]

Many of the symptoms experienced in late advanced cancer can be confused with or masked by cancer symptoms [15,21]. Depression and anxiety have also been identified as a symptom cluster, that is, two symptoms that occur together. Teunissen and colleagues [20] found that 29% of the participants in their study of hospitalized patients with advanced cancer had anxiety and depression as co-morbid conditions.

Spiritual needs in people with advanced cancer have been identified as hope, gratitude, receiving love, forgiveness [23], creating meaning and purpose [23–26], connecting with family, friends, spiritual community [23] or deity from their faith tradition [27], a belief in the concept of something bigger that oneself” [28], and lastly spiritual and religious practices [29]. Spiritual symptoms include expressions of existential distress, loss of meaning, the need for forgiveness, and isolation from family, friends, community and religious iconography [23, 29].

Although many people living with cancer express psychosocial needs, such as the availability of community resources, assistance with preparation of an advance directive and support with financial concerns [30], people living with advanced cancer may have more complex and urgent needs such as legal representation to appoint guardians for minor children, how to access life insurance policies, funeral planning and creating a will.

Increasingly cognitive-behavioral Interventions (CBI’s) are being offered to cancer patients to support them with the full range of symptoms and psychosocial needs as described above. CBI’s are therapies that are designed to decrease symptoms and foster the belief that one has control over thoughts, beliefs, attitudes, and skills to facilitate coping [31–34, 26] during the treatment for cancer and along the survivorship journey.

CBI’s are guided by theories from psychology, behavioral science and education including, instrumental or operant conditioning [32, 35]; social learning theory [36–37], self-efficacy theory [36, 32], adult education [38–39], and stress and coping theory [40]. Three major types of interventions have been identified: cognitive, behavioral and educational.

Each type of intervention addresses specific mechanisms theorized to improve coping. The mechanism of change in cognitive interventions (CI) is the identification and modification negative thoughts, beliefs and expectations [36, 13, 32, 9]. Cognitive restructuring [34], problem solving [41, 11], guided imagery [13], and meaning-making interventions are example of CI's. [16]. Behavioral interventions are designed to increase the use of adaptive behaviors and decrease the use of maladaptive behaviors to achieve outcomes [32]. Learned behaviors stay in one's coping repertoire because the learning is based on rewards and punishments for behavior [8]. Providing patients with a new set of environmental stimuli that reinforce positive behavior is the mechanism of change in behavioral interventions [42]. Behavioral interventions include activity pacing, social reinforcement, pleasant activity scheduling, and establishing strategies that will assure medication adherence [32, 8].

Pyscho-educational interventions have been effective in the relief of physical and emotional symptoms in people with cancer [38, 8, 43] and have been used in two ways. Firstly, research studies are testing the effect of psycho-educational interventions as single interventions. Secondly, psycho-educational interventions are commonly found as a component of a CBI protocol with other cognitive and behavioral interventions [7, 41]. When included as a component of a CBI, educational interventions address knowledge gaps related to the anatomy and physiology of symptoms and other aspects of disease education [38, 8,], and the theoretical underpinnings of the intervention [8].

To date, the efficacy of CBI's for relieving physical symptoms [41, 38, 6]; reducing emotional distress [34, 33], and enhancing social support and self-efficacy[31] in people with early stage cancer has been well documented. However fewer CBI's have been tested in people with advanced cancer resulting in few interventions that address physical, emotional, spiritual and psychosocial needs of people with advanced cancer. In a busy community-based practice or cancer center the focus of care is on the management of the cancer-related treatment. Even in the best clinical settings, the person living with advanced cancer may have needs that cannot be addressed in a 15–30 minute visit. Cognitive behavior interventions could be one option to help a person living with advanced cancer.

The purpose of this study is to evaluate and critically review the evidence on the effectiveness of CBI's for physical, emotional and spiritual symptom management for patients with advanced cancer. The review is organized by a framework recommended by Ropka & Spencer-Cisek [6], Brown [45] and Devine [38] for the synthesis and critical appraisal of the quality of the evidence from the literature. An appraisal of the evidence will be integrated throughout and include a critique of selected characteristics of the studies, interventions, and outcomes of the interventions from the studies included in the review [6, 46]. Finally, the paper will conclude with recommendations for research and practice.

Methods

A literature search was conducted using Medline©, CINAHL©, and Psych-info©. The databases were searched for Randomized Clinical Trials (RCT) testing CBI's designed to enhance the management of physical, emotional, and spiritual symptoms by altering thoughts, feelings, beliefs, and skills in a person with advanced cancer that were published between 2001–2011. The MeSH©(Medical Subject Headings) and key words that guided the search included neoplasms, advanced, cognitive-behavioral, cognitive therapy, psycho-educational interventions and adults. Hand searches were done of the citations in the reference lists of relevant articles [38, 47, 36, 7, 11, 12].

We chose to focus on RCTs for patients with advanced cancer for the review for three reasons. Firstly, they are considered the highest level of evidence. Secondly, randomization serves to control many of the threats to internal and external validity [47], and finally a review of RCT's is considered the gold standard for systematic reviews. Studies were included in the review if they met the following criteria: (1) the design was a randomized clinical trial (2) the study tested a cognitive behavioral therapy, including psycho-educational, alternative and complementary therapies (i.e. acupuncture, relaxation), expressive, support and skill building interventions, (3) participants were adults (18 years of age or older) with advanced cancer and the (4) outcomes were directly related to the patient with advanced cancer.

An article was excluded from the review if (1) the paper was a review article, (2) presented a meta-analysis, (3) discussed methodological concerns (i.e. analytic approaches for RCT's); (4) the sample combined early stage (Stage I–II) and advanced cancer patients (Stages II–IV), (5) did not include advanced cancer patients, (6)reported only caregiver outcomes and (5) tested pharmacological interventions alone. Although, there is certainly some overlap in symptom management concerns in all cancer patients, we thought it was important to exclude studies that included both early and late stage subjects because patients with advanced cancer and their caregivers also have different issues that may impact symptom severity and symptom management. We also made a decision to focus on patient outcomes of CBI interventions. The issues that patients with advanced cancer face may differ from the psychosocial needs of the patients' caregivers. Focusing on patient outcomes strengthens the internal validity of the review by maintaining consistency in both the unit of analysis and outcomes across the studies in the review.

2. Results

The literature search yielded thirty-one studies testing CBI's on people with advanced cancer. The study abstracts were retrieved and after review it was determined that eleven studies met the inclusion criteria.

In Table 1 selected characteristics of the studies in the review, including randomization allocation, characteristics of the study participants, intervention, and retention rates are presented. All of the studies in the review initiated allocation to treatment group by randomization after the completion of baseline measures. The most common allocation procedure was the use of manual or computer-assisted randomization schema then stratified to clinical site and the most common method used to implement allocation concealment were sealed or opaque envelopes. The most common unit of randomization was the individual patient.

Only one study used a different unit of randomization. In the study of Moorey and colleagues [22] the nurse was the unit of randomization. The nurses who delivered the CBI were randomized to either the experimental or the control group. They were further stratified by home care team (determined by geographic location of the patient). All of the patients in the caseload of the nurses enrolled in the study received the baseline measures. This method of randomization was described as "cluster randomization". Patients then received their usual treatment from the hospice home care team; if they were under the care of a CBI trained nurse this nurse included CBI focused on emotional problems.

One of the quality indicators is the description of the research team members who generated the allocation sequence, enrolled participants, assigned participants to treatment condition and the methods for blinding to the outcomes of group assignment [46]. The studies contained in this review were not consistent in their description of these areas in an RCT design. Only four studies included any information on the description of research team members who generated the allocation sequence and the use of blinding to group assignment. One study provided information on the team member who assigned participants to treatment conditions and no studies provided a description of the team member who enrolled subjects. Any of these variations in blinding could have introduced bias that impacted study retention, group equivalence, and the results of the studies.

Table 1 describes the sample characteristics of the studies included in the review. Samples sizes ranged from 28–882. The majority of the participants in the studies included in the review were described as White or Caucasian (range 78%-100%). Studies published in 2010 and 2011 were more likely to have a greater racial/ethnic diversity in the sample, however the majority of the participants in the more recent studies were also White.

The majority of the study samples include multiple cancer types. In the eleven studies the subjects had seven specific cancer types (listed from most common to least common): breast (8 studies), lung/thoracic (5 studies), prostate (2 studies), colon (3 studies), ovarian (2 studies), head/neck (1 study), and hepatobiliary (1 study). Other descriptions of the cancer type included gastrointestinal cancer sites such as the esophagus, pancreas and stomach (2 studies), "other " (3 studies), and GU/GYN cancer (2 studies). One study did not include a description of the specific cancers sites of the people in the study.

Advanced cancer was not consistently defined across the studies reviewed. Six studies defined advanced cancer as stages III–IV. The participants in two additional studies were enrolled in hospice home care programs. Patients in hospice programs generally have a life expectancy of six-months or less. One study described the participants as having relapsed, refractory or recurrent solid tumors or lymphoma [44]. Goodwin and colleagues' criteria for advanced breast cancer included metastasis beyond the breast and ipsilateral axilla[49]. Finally, another study described its participants as having advanced cancer without any additional description.

Table-1 describes the retention rates of the studies included in the review. Across the studies evaluated, retention was difficult to describe for two reasons: Firstly, there was no standard method used to define or calculate retention. Secondly, in many of the studies the reader was required to manually calculate retention rates from either the narrative description of the study or the data tables. Retention rates for subjects allocated to the experimental and usual care group ranged from 27.9%–95% and 21.9%–83.2%, respectively. The two most common causes of attrition were a subject's physical deterioration and the death of a participant, respectively.

Quantifying the frequency/percentage of people lost to attrition because of deterioration in physical status was difficult because the studies lacked of a common taxonomy to describe study attrition for reasons other than death. Authors reported many reasons for study attrition such as lost to follow-up, declined participation, withdrawal from study(with no other explanation given), patient choice, patient too ill to travel, and overwhelmed caregiver. The percentage of people who died before completing the study ranged from 1.8% to 22.8%. Research studies in patients with advanced cancer have traditionally had low retention rates, primarily due to death of the patients [50] and it was felt it was important to try to capture that information in this review. We are not able to adequately weigh the right balance of burden to benefit when it is difficult to determine retention rates.

Another criteria for the evaluation of a RCT is a description of how the researcher accounted for missing data. One method used is the intention-to-treat (ITT) analysis or intention-to-treat framework that guides an analysis [51]. The data from all subjects randomly allocated to each arm of the trial are analyzed together as the data set for that treatment arm, regardless of whether they received or completed the intervention prescribed. ITT's are considered a higher level of analysis because they provide a mechanism to summarize the impact of an RCT and determine if one arm is more efficacious even in trial with missing data[46]. All subjects with at least on observation or data point post-randomization were included in the analyses. Seven of the 11 studies included in this review used an intention – to- treat analysis to account for missing data[4,9,11, 22,41,44,49]. Feasibility and pilot study status limited the use of ITT in two studies [16, 26] and finally, two studies did not describe any methods to handle missing data [12,30].

The interventions and outcomes of the trials included are summarized in Table 2. Two units of intervention were identified in the CBI’s: individuals and groups with advanced cancer. The most common unit of the intervention was the individual (n=6). Hospice enrolled patients or patient/caregiver dyads were the unit of intervention in three studies [8, 11, 22]. One study conducted with home hospice patients initially described family involvement, but no caregiver data or outcomes were reported [22]. In two studies interventions were also delivered to groups of people with advanced cancer [16, 49]. The number of participants in the groups ranged from 8–10.

Most of the interventions described in this review were delivered by specially-trained registered nurses or advanced practice nurses to individual cancer patients (n=5). Other personnel who delivered interventions included psychologist/psychiatrist[16, 44, 26, 52], social workers, spiritual care provider, physical therapist [52] In one study the discipline of the person who delivered the intervention was not identified [9].

The most common interventions were cognitive, those directed towards identification of dysfunctional thoughts and the use of strategies to modify dysfunctional or irrational thoughts (n=8) [4,8, 11–12, 22, 26, 44, 52]. One study included a vague description of the CBT as “ CBT focused on emotional problems” without an additional description of the components of the intervention [22]. Cognitive interventions found in the review were cognitive reframing (also referred to as cognitive restructuring), problem-solving [11, 26, 4], goal-setting[11, 26], and meaning-centered interventions [16, 26]. Two studies in this review used meaning-centered interventions. Meaning-centered interventions are cognitive interventions focused on reviewing impact and meaning of cancer diagnoses; exploring past significant life events and successful ways of coping as related to the advanced cancer experience, identifying sources of meaning (attitudinal, creative, experiential) and discussing life priorities in the context of living with the diagnosis of advanced cancer and a limited prognosis [16,26]. Keefe and colleagues included behavioral skills such as relaxation techniques, positive imagery, and activity pacing as strategies to be used to manage pain[8]. These behavior skills were reinforced with behavioral skills rehearsal, creation of a maintenance plan for continued use of the skill after completion of the study [8]. All of the studies’ (n=11) interventions included patient and/or family caregiver education. The education provided was related the theoretical underpinnings of the intervention [44], symptom management in advanced disease [8, 12, 4], organization of personal finance, insurance, community resources and legal issues [52], or used as the method to deliver the intervention or its components [4, 8,16,22, 41, 49, 26, 52, 22].

Table-2 includes a description of intervention frequency and duration. The content, duration, and frequency of the interventions were not consistently provided in the published articles. Of the studies that provided information about duration and frequency of contact, the sessions were delivered over a period of weeks, ranging from 1–8 weeks [8, 12, 26, 11, 52, 44,] and the number of contacts over the period of the study ranged from a single contact [11] with the interventionist to as many as 10 contacts over the intervention period. Keefe and colleagues’ [8] description of the timing, duration, and frequency of the intervention was an exemplar for the level of detail that is important to present in a report of a CBI in the literature: units of intervention (individual, dyads or group of three or more), exact number of contacts/sessions with research team, types of contacts (face-to-face, telephone, or other media), the mean duration of each contact/session, and the mean number of days from first to the last session. One of the hallmarks of the RCT design is to control all aspects of the study so that all confounding variables that may impact the relationships between the variable of interest are controlled for. The lack of consistency in the description of the frequency and duration of interventions makes it difficult to really determine the intervention that was delivered. In other words, drawing a parallel from pharmacological studies, it is difficult to determine the dose that was delivered. In the oncology literature patient-focused interventions that are individualized or tailored to unique characteristics or needs of the patient/family are presented as the gold standard [53]. A tailored intervention is designed around multiple dimensions that are salient to a person, such as a particular symptom or concern, the number and length of sessions desired, race-ethnicity or gender [13]. In this review three studies tested a CBI focused on the management of symptoms or areas of concern self-selected by the participants[26, 12, 9]. For example, one study in the review was designed so that participants could choose the number (range 1–4) and the duration of the individual sessions led by a psychologist [26]. Tailored interventions may increase bias introduced because of a lack of standardization and impact the statistical significance of the study. On the other hand, tailoring an intervention to the a person’s unique needs lead to the attainment of a skills that will be successfully incorporated into their “toolkit” to cope with the physical, emotional, spiritual and psychosocial challenges of living with advanced cancer. All of the studies in the review measured at least one physical, emotional or spiritual outcome variables.

Physical Outcomes

Symptom severity and pain intensity were key outcomes. The most common were physical symptoms or related to concepts such as symptom intensity. The most common symptom management outcome was pain intensity [4, 8, 11–12]. The effect of the interventions on other physical symptoms was also evaluated such as dyspnea [11–12], constipation (11–12] insomnia and fatigue [11, 44], nausea and vomiting; and anorexia [11].

Pre and post-treatment differences in symptom management were mixed. On one hand, participants in the studies in the review experienced reductions in symptom distress, fatigue, insomnia [11–12, 44]. In contrast, the patients in other studies in the review did not experience improvement in symptom severity or level of pain or dyspnea [4,8, 11]. For example, McMillan and colleagues reported findings from their problem-solving intervention designed to help hospice home caregivers to improve patient symptom management outcomes[11]. The patient outcomes were QOL, pain, dyspnea intensity, constipation, and total symptom distress. The intervention yielded no improvement in intensity of pain, dyspnea or constipation, or quality of life, but there was a decrease in perceived symptom distress.

All of the people enrolled in McMillan’s study [11] were and many of the people in Keefe’s study enrolled in a hospice program [8] and it may be possible that they were already receiving services or support with symptom management and the intervention’s effects were diminished.

Two studies in the review tested the efficacy of CBT on immune system functioning [9,44]. Again the outcomes were mixed. One study found that the CBI had no impact on immune functioning [44] In contrast Steel and colleagues[9] measured the level of peripheral blood leukocytes (PBL) and found an increase in circulating PBL’s. However, any interpretation of the results are limited because two of the studies were has sample sizes too small to detect an effect size and high rates of attrition. Steele and colleagues [9] experienced 50% attrition from their sample between the initial and the 3-month follow-up data collection.

Many of the studies in the review had outcomes related to the mood disorders of depression and anxiety. Depression was an outcome variable in five studies. The findings of many of studies in the review suggest that CBI’s are effective in lowering the post-treatment depression scores in the treatment group [45, 9]. However, there were studies within the review that found no difference in depression scores between the treatment or control group [22, 26]. In Moorey and colleagues' study [22] the depression scores for the EC and UC group decreased over time, but the decrease was not statistically significant. Similarly, Henry and colleagues [26] found that their Making Meaning Intervention (MMI) had no impact on depression, anxiety or other measures of psychological distress at 1 and 3 months post-treatment. We do not have information about the number of sessions received by the participants to make an interpretation of the effect size.

The patient population may have also impacted the outcomes. Moorey and colleagues' study was conducted with hospice patients, also considered as having advanced cancer, but they were enrolled hospice. Hospice patients usually have a poorer functional status with Karnofsky performance status scores less than 50 [54,55] and approximately one third of people are enrolled in hospice within the last week of life [5]. Physiologically many of the symptoms of depression are similar to those of a person who is actively dying such as fatigue, social withdrawal, increasing hours of sleeping, and loss of appetite. Similar to the pain and other symptom outcomes described above, the effect of the intervention may have also been impacted by counseling or spiritual care services received during the period of hospice care.

Quality of life was another outcome of note [4, 8–9, 11, 41,44,52]. Three studies found significant improvement in quality of life [4,9,52]. The majority of the studies in the review with quality of life as an outcome found no change in this measure from baseline to post-intervention [8, 11, 41] or decrease in QOL from baselines [44].

Two studies explored the impact of CBI's on spiritual outcomes of spiritual well-being [16] and existential distress [26] using Meaning-centered therapy. MCT is designed to help patients with advanced cancer enhance a sense of meaning, peace, and purpose in their lives [16]. Breitbart and colleagues [16] facilitated an 8-week MCT group intervention found that the group receiving the meaning-centered intervention experienced statistically significant improvements in spiritual well-being and sense of meaning. The individuals receiving the MMI from Henry and colleagues realized short-term benefit from the MMI with enhanced meaning, but only trends toward improved quality of life and existential well-being [26].

4.0 Discussion and conclusion

4.1 Discussion

This paper critically reviewed the evidence on the use of CBI's in patients with advanced cancer. We identified four major themes in this review: (1) a limited number of randomized clinical trials testing CBI's in people with advanced cancer, (2) treatment effects were not statistically significant in most studies (3) the study methods were not consistently described, and (4) there was very little racial/ethnic diversity in the samples. Each of these themes will be discussed below.

With regard to the first theme, we found a limited number of randomized clinical trials testing CBI's in people with advanced cancer. A researcher who considers conducting RCT's in this population must consider a major ethical concern, random assignment. Random assignment to the experimental or control group, one of the hallmarks of the RCT, means while all of the participants will receive the current standard of care, only the participants in the experimental group will receive the intervention. People living with advanced disease have many needs of all types and it may be considered unethical to withhold a treatment (albeit an experimental one), especially from the most severely ill of the advanced cancer patients, those enrolled in hospice[56]. While the RCT with an experimental and control group is the gold standard[47], perhaps a comparative type of RCT study such as Breitbart et al., 2010 that was contained in this review[16] where the efficacy of two interventions are being compared with standard care, may resolve this issue.

Expanding on the second theme, treatment effects were not statistically significant in most studies. The current review described how CBI's affected multiple outcomes (immunological, physical, emotional, spiritual, financial, and legal). Each type of CBI's has specific mechanisms theorized to improve coping or symptom management and therefore it is possible that CBI's may have a treatment effect on certain outcomes [35–40]. Other authors have also found that statistically significant outcomes were not consistent [47–48]. Statistically significant tests ranged from 22% for depression to 28% for general affect [47].

Pertaining to our third theme, the content, duration, and frequency of the interventions were not consistently provided in the published studies. Limited description of the intervention dose significantly impacted our ability to interpret results of the studies. Similar threats to internal validity of CBI studies have been found in the literature such as Devine's review of psycho-educational intervention for pain management in patients with cancer [43].

The fourth theme identified was the lack of racial/ethnic diversity of the participants in the studies selected for the review. Remarkably there were studies in the review that had no description of racial/ethnic composition of the sample. African Americans, Hispanics and Asians have not been included in clinical trials in sufficient numbers to evaluate the effectiveness of interventions for these populations. Chambers' and colleagues also identified a lack of racial-ethnic diversity in their systematic review of psychosocial interventions for men with prostate cancer [48]. Developing studies that meet the needs of people from diverse racial-ethnic groups is an important part of care for people living with advanced cancer.

4.2 Conclusion

We conducted a critical appraisal of randomized clinical trials testing the efficacy of CBI's in people with advanced cancer. The lack of data about efficacy of CBI's to support people with advanced cancer is a gap in the current knowledge base. The interpretation of the effectiveness of the CBI's was limited by major challenges to the internal validity of the studies included in the review. Individuals living with advanced cancer require support throughout the cancer journey from diagnosis to end-of-life care. Well-designed studies are needed to test interventions that will improve patient and caregiver outcomes for people living with advanced cancer.

4.3 Research and practice implications

RCT's to test CBI's in people with advanced cancer should continue with careful consideration for feasibility and efficacy with specific advanced cancer populations. If proposing an RCT raises ethical and methodological concerns in individuals with a lower functional status, then appropriate, well-designed quasi-experimental or comparative designs could be used to test the efficacy of the CBI's in these individuals.

Treatment effects were not statistically significant in most studies. Future research studies should explicitly describe content, duration, and frequency of the intervention and examine associations between a specific treatment dose and patient/family outcomes to increase confidence in the interpretation of the treatment effects of CBI's.

Finally, racial/ethnic diversity was limited in the study samples described in this review. Recent US census data suggesst that racial-ethnic composition of our population is changing. Over the next 20–30 years the number of people who self-identify as a member of a racial-ethnic minority will increase, especially the Hispanic population [57]. Globally, there are significant demographic shifts occurring as well. Therefore, it will become imperative to conduct research studies to test the efficacy of CBI's on individuals, dyads, and groups from diverse racial/ethnic groups and, if needed, tailor interventions to make CBI's more culturally appropriate.

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Table 1

Study characteristics

Author	Randomization Allocation	Subjects	Intervention	Retention rate
Bakitas, et al., 2009[4]	Stratification by clinical site & disease Blocked within strata	**N**=322 **EG:** N=161 **UC:** N=161 **Cancer type** GI N=133 (41%) Lung N=117(36%) Breast N=33(10%) GU N=39(12%) **Race-ethnicity*** White N=275(85%) 275/322 Other N=4 (1%) 1% Missing 43(13%)	**EG**: Psychoeducational Intervention-Case Management and Education **UC:** Standard of care at clinical sites	**EG:** 90% **UC:** 83.2%
Breitbart, et al., 2010 [16] **EG=Experimental group** **CG=Control group**	A group of 8–10 was formed and then randomized to treatment condition.	**N**=90 **EC**=49 **CG**=41 **Cancer type** Prostate N= 17(18.9%) Breast N=14 (15.6%) Colorectal N= 8(13.3%) Lung N= 8(13.3%) **Race-ethnicity** Caucasian N=72(80%) African-American N=7(7.8%) Hispanic N=4(4.4%) Other N=7(7.8%)	**EG:** Meaning-centered Group intervention (MCGP) **CG**: Supportive Psychological care (SPT)	**EG**: 34.7% **CG:** 21.9%
Goodwin, et al. 2001[49] **EG=Experimental group** **UC=Usual care**	Randomization ratio of 2:1 Stratification to one of seven clinical sites.	**N**=235 **EG**=158 **UC**=77 **Cancer type** **Breast** N=235 (100%) **Race-ethnicity** No description	**EG:** Weekly supportive-expressive therapy support group for one year **UC:** Cancer Care from oncology providers.	66.7% (for total sample) Proportion of group therapy sessions attended of 5208 possible in a year.
Keefe, F.J., et al., 2005 [8] **EG**=Experimental group **UC**=Usual care	Randomization to group assignment	**Patients** N=78 **Partners** N=78 **Cancer type**	**EG:** Partner-guided coping skills training in pain management **UC:** Standard outpatient care or hospice homecare	95.1% (for total sample)

Author	Randomization Allocation	Subjects	Intervention	Retention rate
		Lung, breast and prostate no information provided on frequency (percentages) by cancer diagnosis **Race-ethnicity*** Patients White N=78% **African American** N= 21% **Partners:** **White** N= 79% African American N=19.7% ***As reported in the paper**		
McMillan & Small [11] **EG=** experimental group **UC**=Usual care	Randomized to one of three groups at baseline by using computerized randomization procedure by phone.	**N**=329 caregivers of hospice patients Group 1 n=109 Group 2 n=109 Group 3 n=111 No description of racial/ethnic composition of sample or cancer type	**1** EG: UC+ Coping Skills intervention **2** UC + emotional support **3** UC: Standard Hospice care	EG=27.9% UC+ emotional support= 29.3% UC=36.7%
Meyers et al., 2011 [41]	Randomization assignments were Generated using 3:1 weighted scheme, blocked by site	**N=**441 dyads EC: N=324 UC: N=117	**EG:** Cope problem solving intervention **UC:** Usual care in clinic	**EG:** 31.5% **UC:** 27.2%
Miller et al., 2007 [52]	Pocock and Simon Balance scheme Stratified by cancer type, ECOG Performance status, and age.	**N**=115 **EG**=57 **UC**=58 **Cancer type** Colorectal 38% Head& neck 17% Lung 15% Brain 12% Other 18% **Race-ethnicity** No description of race-ethnicity	**EG:** Multidisciplinary Intervention for social support, financial concerns, legal issues **UC:** Usual care in clinic	89.5 % (for total sample)
Moorey et al., 2009 [22] **EG**: Experimental group **UC:** Usual care	Nurse randomization was stratified by team	N=80 **EG:** N=45 **UC**: N=35 **Cancer type** Breast N=9(11.25%) Colon N= 4(4%) Head & Neck N=9(11.25%) Lung N=20(25%) Ovary N=7(8.75%) GI	**EG:** CBT model guided intervention **UC:** Standard hospice care	**EG:** 35% **UC:** 51.4%

Author	Randomization Allocation	Subjects	Intervention	Retention rate
		N= 12(15%) Other cancer type N=19(23.75%) **Race-ethnicity*** White N=69(86.25%) Asian N=2(2.5%) Black (Caribbean Or African) N=4(5%) Mixed race/other N= 5(6.25%)		
Savard et al., 2007 [44] **EG**: Experimental group **UC**: Usual care	Stratified according to cancer clinic and Then randomly assigned to group	**N**=45 **EG**=25 **UC**=20 Gender: 100% women **Race/ethnicity**: 100% Caucasian **Cancer site**: Breast only N=37 EG=21 UC=16 Gender: 100% women **Race/ethnicity:** 100% Caucasian **Cancer site:** Breast	**EG:** 8-Weekly Sessions **UC:** Usual care in clinics	**EG:** 84% **UC:** 80%
Sherwood et al., 2005 [12]	Random assignment stratified by By recruitment site	**N**=124 **EG**=62 **UC**=62 **Cancer type** Breast 33% Lung 18% Other 49% **Race/ethnicity** Caucasian 94% African-American 5% Native American 1%	**EG:** 5 sessions over an 8 week period **UC:** Usual care in clinic	68% (for total sample)
Steel et al., 2007 [9] **EG**: Experimental group **UC**: Usual care	Randomized to Treatment group.	**N**=28 **EG**=14 **UC**=14 **Cancer type** Hepatocellular N=23 Gallbladder N=4 Cholangiocarcinoma N=1 **Race-ethnicity:** 79% Caucausian 7% Latino 2% African American	**EG:** CBT Education Supportive Expressive SSRI's **UC:** Education from Nursing Coordinator	50% (for total sample)

Author	Randomization Allocation	Subjects	Intervention	Retention rate
		3.5% Native Ameircan 3.5% other		

Table 2

Study interventions and outcomes

Author	Unit of intervention	Interventionist	Interventions	Outcomes	Findings
Bakitas, et al., 2009[4]	Individual	Advanced Practice Nurses	**Number of sessions**: 4 structured educational and problem-solving sessions **Duration**: 30–41 minutes Monthly telephone follow-up (or until participant death)	QOL Symptom Severity Mood Resource utilization	EC group had higher scores for quality of life and mood. No improvement in symptom intensity. No difference in resource utilization
Brietbart, et al., 2010[16] **EC**=Experimental group **QOL**=Quality of life **SWB**=Spiritual well-being **SOM**=Sense of meaning **PF**=Psychological functioning	Groups (8–10)		**Number of sessions**: 8-weekly sessions **Duration:** 90 minutes	SWB SOM PF	Significant improvements in SWB, SOM, anxiety and desire for death.
Henry, et al. 2010[26] **QOL**=Quality of Life **EWB**=Emotional well-being	Individual	Psychologist	**Number of sessions:** 4 sessions **Duration**: 30–90 minutes	Life Meaning Anxiety Depression Self-efficacy	Significantly enhanced meaning in life in the short term No impact on depression or anxiety No effect on self-efficacy
Keefe et al., 2005[8]	Patient-caregiver dyad	Registered Nurses	**Number of sessions**: 3 sessions **Duration:** 20–90 minutes	**Outcomes** QOL PWB SWB UP WP	**Findings** No significant treatment effects for patients' ratings of QOL PWB, SWB, UP or WP.
McMillan & Small (2007) [11] **QOL**=Quality of Life **PWB**=Physical well-being **SWB**=Social well-being **UP**=Usual pain **WP**=Worse pain	Patient/Caregiver Dyad	Trained nurses	**Number of sessions**: Not described **Duration:** Not described.	**Outcomes** Pain intensity Dyspnea Constipation Symptom Distress QOL	**Findings** EC had a positive effect on overall symptom distress, but not on the symptom severity of individual symptoms of pain, dyspnea, or QOL
Meyers, et al., 2011[41]	Patient Caregivers	Trained educator	**Number of sessions**: 3 sessions Over 30 days **Duration**: Not Described.	**Patients** QOL SPS	**Patients** Decrease in QOL Decline in problem solving skills
Miller et al., 2007[52] **QOL**=Quality of life **SPS**=Social Problem Solving	Individual	Psychologist Social Worker	**Number of sessions**: Two sessions **Duration**: 90 minutes	Overall QOL QOL social domain	Increased QOL Significant improvements found in social domains of financial and legal issues. Low correlation between overall QOL and social domain of financial concerns and legal issues
Moorey et al., 2009 [22]	Individual	Nurse	**Number of sessions:** Not described **Duration:** Not described	Anxiety Depression Adjustment to cancer Cancer coping Social support Functional Status	Lower anxiety scores over time No effects for depression, mental adjustment to cancer, or cancer coping.

Author	Unit of intervention	Interventionist	Interventions	Outcomes	Findings
					Reduction in perceived social support from significant other over time, but no group effect.
Savard et al., 2007 [44] **ANX=anxiety** **CY**=Cytokines **DEP**=Depression **FAT**=Fatigue **F/U**=Follow-up **INS**=Insomnia **LYM**= lymphocytes **NK**=natural killer cells **QOL**=quality of life	Individual	Psychologist	**Number of sessions**: 8 weekly sessions 3 boosters sessions administered every 3 weeks following the end of treatment **Duration:** 60–90 minutes	DEP ANX INS FAT QOL LYM NKC CY	Significant reductions in DEP, ANX, INS and FAT from pre to post treatment. Reduction not maintained between post-treatment & follow-up for DEP only Significant differences in QOL at post-test or follow-up. No significant effect on LYM population. Significant time effect for NK activity. NK activity increased from post-treatment to 3 month f/u. NK decreased to post-treatment level at 6 month follow-up.
Sherwood et al., 2005 [12]	Individual	Registered nurse	**Number of sessions:** 5 contacts over 8 week period Contact made every two weeks **Duration:** Not described.	**Symptom severity**	**Symptom severity** Lower symptom severity
Steel et al., 2007 [9] FXW=Functional well-being FWM=Family well-being HRQL=Health-related quality of life PBL=Peripheral blood leukocytes PWB=Physical well-being SWB=Social well-being EWB=Emotional well-being GQOL=Global quality of life	Individual	Not stated	**Number of sessions**: 3–4 face-to face sessions 5–6 telephone sessions **Duration:** Not described	HRQL • PWB • FWB • SWB • EWB • GQOL Depression Anxiety PBL Survival	HRQL Reduction in PWB and FXW scores. Increase in SWB, EWB, FWB, And GQOL Reductions in depression and anxiety Increase in PBL's Longer survival