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## Characteristics and Methodological Quality of 25 Years of Research Investigating Psychosocial Interventions for Cancer Patients

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### Abstract

The considerable amount of research examining psychosocial interventions for cancer patients makes it important to examine its scope and methodological quality. This comprehensive overview characterizes the field with as few exclusions as possible. A systematic search strategy identified 673 reports comprising 488 unique projects conducted over a 25-year time span. Although the literature on this topic has grown over time, the research was predominantly conducted in the United States (57.0%), largely with breast cancer patients (included in 70.5% of the studies). The intervention approach used most frequently was cognitive behavioral (32.4%), the treatment goal was often improving quality of life generally (69.5%), and the professionals delivering the interventions were typically nurses (29.1%) or psychologists (22.7%). Overall, there was some discrepancy between the types of interventions studied and the types of supportive services available to and sought by cancer patients. Strengths of this research include using randomized designs (62.9%), testing for baseline group equivalence (84.5%), and monitoring treatment, which rose significantly from being used in 48.1% to 64.4% of projects over time. However, deficiencies in such areas as examining treatment mechanisms and the adequacy of reporting of methodology, essential for useful syntheses of research on these interventions, remain to be addressed. Methodological challenges related to the complexity of this applied research, such as participants seeking treatment outside of research, contamination, and reactions to randomization, also were apparent. Future research could benefit from closer interactions between academic and voluntary sectors and expanding the diversity of participants.

### Key terms

cancer; psychosocial; intervention; treatment; quality of life

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## Interventions for Cancer Patients

At most recent report, more than 11 million Americans were living with cancer.<sup>1</sup> Cancer's diagnosis, treatment, and aftermath present challenges that can contribute to psychological morbidity and can compromise quality of life. Diagnosis involves many stressors and can provoke worries about functioning, social value, finances, burden on one's family, and death.<sup>2, 3</sup> Cancer treatments produce side effects, such as fatigue, nausea, and changes in appearance and functioning that can be difficult to cope with.<sup>4-7</sup> After treatment is complete, stressors involve continued medical follow-up; residual physical, interpersonal psychological, and spiritual effects; and practical issues, such as employment, finances, and insurance coverage.<sup>8</sup> If cancer progresses despite treatment, worries about the future predominate.<sup>9</sup> Late-stage cancer brings existential concerns<sup>10</sup> and potentially pain.<sup>11</sup> With the recognition of such difficulties, attention in recent decades has been directed at developing and testing interventions to improve the quality of life of individuals coping with cancer.<sup>12</sup>

Quality of life is subjective and multidimensional. Seven dimensions affected by cancer and its treatment are (1) physical concerns, (2) functional ability, (3) family well-being, (4) emotional well-being, (5) treatment satisfaction, (6) sexuality and intimacy, and (7) social functioning.<sup>13</sup> Accordingly, interventions aimed to improve the quality of life for individuals diagnosed with cancer are diverse and often feature multiple potentially therapeutic components targeted at multiple outcomes.<sup>2, 14</sup> Some types resemble common psychotherapeutic approaches, such as group cognitive-behavioral therapy,<sup>15, 16</sup> problem-solving therapy,<sup>17</sup> and psychodynamic psychotherapy.<sup>18</sup> However, various other approaches also have been tested. Some examples include: written expressive disclosure,<sup>19</sup> nurse-administered self-care self-efficacy enhancement<sup>20</sup> complementary and alternative medicine support,<sup>21</sup> movement and dance,<sup>22</sup> and audiotaped side effect management education.<sup>23</sup> Similarly, the range of outcome variables assessed in studies evaluating such interventions (e.g., depression, anxiety, body image, pain, fatigue, fear of recurrence, levels of perceived social support, sexual functioning, marital satisfaction, sleep disruption) reflects this multidimensionality in the conceptualization of quality of life.

Given the now considerable amount of research examining psychosocial interventions for cancer,<sup>24</sup> it is important to examine its scope and quality. Such an evaluation can characterize this literature, analyze trends over time, and identify directions for improvement. A comprehensive review also is useful in understanding what types of individuals, with what types of cancers, exposed to what types of psychosocial interventions have been subjected to empirical scrutiny. This can identify understudied populations and determine to what extent available resources for cancer patients have been evaluated.

Attention to methodological quality is also important. In prior reviews, the quality of investigations studying psychological therapies for cancer patients was deemed suboptimal. In Newell et al.'s evaluation of 155 randomized, controlled trials of psychological therapies for adult and child cancer patients, the median quality score was less than one-third of the maximum number of points possible.<sup>25</sup> The authors noted that this was likely related to poor reporting of methods. In Rehse and Pukop's<sup>26</sup> review of 37 published controlled studies investigating psychosocial interventions' effect on quality of life, studies scoring lower in methodological quality had smaller outcome effect sizes.

Studies of psychosocial interventions for cancer patients have been criticized for narrow inclusion criteria and for being too intensive to allow participation of those most in need<sup>27</sup> but such criticisms need to be empirically validated.<sup>28</sup> Some investigators have pointed out the dearth of non-European American samples and the typical low statistical power of research in this area.<sup>29</sup> Other research has noted the high levels of drop-out associated with psychosocial

interventions for cancer patients.<sup>30, 31</sup> Such methodological shortcomings may bias estimates of treatment efficacy.<sup>26, 32</sup> Closer attention to methodology and its impact, such as on participation rates, would help direct future inquiry, intervention development, and approaches to improve methodology.

A number of high-quality reviews and meta-analyses have investigated the efficacy of psychosocial interventions for cancer patients. For example, Meyer and Mark<sup>33</sup> conducted a meta-analysis of 45 randomized, controlled studies of psychosocial interventions with adult cancer patients published between 1979 and 1993; Devine and Westlake<sup>34</sup> reviewed 116 studies reported between 1976 and 1993 examining psycho-educational care for cancer patients; Newell and colleagues<sup>25</sup> reviewed randomized, controlled trials published between 1980 and 1998 evaluating the effectiveness of a psychosocial interventions aimed at improving cancer patients' psychosocial, side-effect, immune, or survival outcomes. In addition to reviews selecting studies with particular types of designs or levels of quality, more focused reviews have concentrated on patients with particular types of cancer, such as breast,<sup>35</sup> or stages of cancer, such as advanced,<sup>36</sup> particular outcomes, such as fatigue,<sup>37</sup> depression and anxiety,<sup>38, 39</sup> or survival,<sup>40, 41</sup> or particular types of interventions, such as physical activity,<sup>42</sup> or guided imagery.<sup>43</sup>

Previous reviews and meta-analyses predominantly have focused on evaluating the extent to which evidence supports interventions' efficacy. Methodological and reporting limitations often have led to studies being excluded from these reviews.<sup>25</sup> By contrast, rather than summarizing outcomes, the purpose of the present review was to characterize the evolving nature and scope of psychosocial cancer intervention research as a whole, with as few exclusions as possible. We therefore conducted a comprehensive synthesis of 25 years of published reports and unpublished dissertations evaluating psychosocial interventions designed to improve the quality of life of cancer patients. We analyzed characteristics of the reports, the participants, the treatments investigated and their delivery, the outcomes assessed, the methodological quality of these studies, and challenges noted by investigators conducting this research. We also examined trends over time in the amount of research being conducted and its methodological quality.

## Method

### Study Identification

Studies included in the review examined psychosocial interventions for adult cancer patients that: (1) reported outcomes on psychological, emotional, behavioral, physiological, functional, or medical status; (2) were first reported as a published article or an unpublished dissertation between January 1980 and December 2005; and (3) included 10 or more individuals per group. Studies examining interventions aimed at increasing adherence to anti-cancer treatment and focusing exclusively on caregiver outcomes were outside the purview of this review. Electronic databases (PsycINFO, PubMed, and Dissertation Abstracts International) were searched using key terms (e.g., *cancer, neoplasms, tumor, and psychosocial intervention, psychotherapy, psychological treatment, education, cognitive behavioral, relaxation, stress management, support group, self-help group, nursing intervention, biofeedback*; a full list is available from the authors upon request). The reference lists of included reports and of 94 prior reviews and meta-analyses also were examined. Descendancy searches were conducted on prior reviews (i.e., for subsequent articles citing them), and tables of contents of several journals (*Psycho-Oncology, Journal of Clinical Oncology, Cancer, Journal of Psychosocial Oncology, European Journal of Cancer, and Cancer Nursing*) were searched.

The sample included 673 reports comprising 488 projects, (a QUORUM flowchart and a complete listing of the reports is available from the authors). Separate reports based on the

same sample (e.g., separate articles reporting outcomes at 3-month and 12-month follow-up) were consolidated as a single project.

## Study Coding

Coding by the PI and two teams of thoroughly-trained graduate-level coders was guided by a detailed manual. Information from all project reports was used to provide comprehensive ratings. Coders met regularly to prevent coding drift, discuss coding dilemmas, and to reach consensus on independently-coded projects used for reliability estimation (which represented 9.2% of the total sample). Ten key continuous a priori coding items were examined for reliability. The average two-way mixed effect intraclass correlation<sup>44</sup> assessing the agreement for the ratings of the PI, Coder 1, and Coder 2 was .83 and for the ratings of the PI, Coder 3, Coder 4, and Coder 5 was .90. Ten key categorical a priori coding items were also examined. The average generalized kappa<sup>45</sup> assessing the agreement for the ratings of the PI, Coder 1, and Coder 2 was .72 and for the ratings of the PI, Coder 3, Coder 4, and Coder 5 was .61.

Items assessing the nature of the research involved characteristics of the principal investigator, the project's funding and publication status, location of data collection, aspects of the project's target sample, and the characteristics of those who participated. Intervention characteristics, such as its approach, ingredients, delivery, duration, and the outcomes measured, were also assessed.

Items assessing the quality of study methodology and reporting involved aspects of the sample description; the research design, including the quality of randomization, where applicable; intervention specification and provision; and data analyses, such as whether intention-to-treat analyses were conducted. These were adapted from a set of methodological quality items used in prior work<sup>46</sup>. Although consensus on essential areas of methodological quality has yet to be reached, and no one scale is considered appropriate for all research topic areas,<sup>47</sup> we included aspects of quality conventionally considered important. Due to the low feasibility of keeping participants and interventionists blind to treatment groups for psychosocial interventions, items assessing this were not included. Similarly, because outcomes in this area are predominantly based on self-report, assessments of blinding of outcome assessors also were not included. Aspects of reporting from the CONSORT,<sup>48</sup> such as noting the number dropping out of treatment, also were evaluated. Because combining different dimensions of methodological quality is not advised,<sup>49</sup> we report them separately.

Items assessing challenges in conducting this research had to do with possible biases introduced during recruitment, retention, and randomization, and unintended consequences, such as participants seeking treatment outside of the research study and contamination across intervention conditions.

## Results

### Study, Investigator, Report, and Sample Characteristics

There was a dramatic increase in the number of studies conducted over the 25-year period, from an average of 10 projects per year appearing in the 1980s, to 22 per year from 1995–1999, to 36 per year from 2000–2005. The majority of principal investigators was affiliated with a university (75.3%), held a Ph.D. (66.8%), and was female (59.85). The projects most often were funded by private foundations (40.4%) and federal agencies (34.3%), but a fairly high proportion (36.3%) did not report any funding support. The majority of studies was conducted in North America and the UK (74.5%) and written in English (98.4%), but the remainder was conducted in an additional 16 countries. A large proportion of the projects (87.1%) comprised at least one published report, but 65 out of 107 projects included dissertations that were

unpublished as of November, 2008. The cancer types included in the samples (assessed at the study level) were often breast (70.5%), lung (28.9%), colon/colorectal (20.9%), and prostate (18.4%). Patients in the samples were most often undergoing treatment (38.9%) or post treatment (13.5%) at the time they were recruited to participate.

### Participant Characteristics

The total number of participants studied in this group of projects was 46,665. Participant characteristics are displayed in Table 1. Although demographic characteristics were not always reported (e.g., age was reported for 90.8% of the projects, but marital and employment status only for 55.5% and 28.3%, respectively), the typical participant was female, in her mid-50's, White, married, and well-educated. Disease and treatment characteristics were reported in less than half of the projects, but when they were, patients tended to have early stage-cancer and to be approximately 18 months post-diagnosis.

### Intervention Characteristics

Characteristics of the interventions investigated are presented in Table 2.

**Goals**—Interventions were primarily directed at improving quality of life generally, but also at coping with treatment side effects and the physical effects of the disease. A relatively small proportion of interventions was developed to increase understanding of treatment options or exclusively to improve social relationships. Other stated treatment goals included improving memory or concentration, increasing compliance with medications, and altering tumor progression or length of survival.

**Target patient populations**—Although a minority of projects designed an intervention for any type of cancer patient, others focused on specific types, such as those undergoing a particular type of treatment (e.g., chemotherapy), or with a particular type of cancer. Particular cultural groups targeted in a small proportion of projects included African-American and Hispanic-American, Japanese, Chinese, Taiwanese, and Indonesian patients. Only a small number targeted adults of particular age groups (e.g., younger or elderly) or designed interventions specifically for cancer patients of a particular gender (beyond specifying patients with gender-specific cancers, e.g., prostate).

**Theoretical approach**—In almost one-third of the projects, the active treatment(s) involved a primarily cognitive, behavioral, or cognitive-behavioral approach (i.e., types of psychotherapy that focus on recognizing and altering problematic thoughts and behaviors and reducing negative emotions<sup>38</sup>). For example, one study included programs that involved: developing effective problem solving skills and identifying and challenging maladaptive thoughts; learning relaxation techniques; and utilizing resources such as family and friends and pleasurable activities to cope.<sup>50, 51</sup>

Approximately one-fifth of projects examined interventions that were primarily educational or informational (i.e., increasing knowledge and reducing uncertainty by providing information through print, audiovisual, or interpersonal channels<sup>38</sup>). Examples include an oncology clinic orientation<sup>52</sup> and information about treatment options,<sup>53</sup> side effects,<sup>54</sup> or psychosocial challenges.<sup>55</sup> Close to one-fifth of investigations primarily involved complementary and alternative medicine (CAM; i.e., medical and health care systems, practices, and products not considered part of conventional medicine practiced by allied health professionals;<sup>56</sup>) or mind-body approaches. Examples included exercise,<sup>57, 58</sup> massage,<sup>59</sup> acupuncture,<sup>60</sup> and meditation and yoga.<sup>61</sup>



Approximately one-tenth of projects included interventions that involved non-behavioral counseling or psychotherapy (i.e., psychosocial care provided by a qualified professional<sup>38</sup>). Examples of types of psychotherapy included interpersonal,<sup>62</sup> experiential-existential,<sup>63</sup> Rogerian,<sup>64</sup> and supportive/expressive.<sup>65</sup> A small proportion involved social support provided by non-professionals, typically fellow cancer survivors, such as a non-moderated e-mail support group,<sup>66</sup> online bulletin boards,<sup>67</sup> and telephone support.<sup>68</sup> Approximately one-fifth included a multimodal intervention that incorporated multiple therapeutic approaches. For instance, the Multidimensional Cancer Rehabilitation Program involved information, exercise, sports, expressing negative emotions, support and validation, breathing, relaxation, and stress management.<sup>69</sup> Other approaches not part of these categories, involved, for example, the American Cancer Society's *Look Good...Feel Better* program that uses professional cosmetologists to improve appearance<sup>70</sup> and exposure to a restorative natural environment.<sup>71</sup>

**Ingredients**—More than half of the interventions included therapeutic ingredients that involved stress and symptom management (i.e., relaxation training, guided imagery), and about half included education or information. Less than one-fifth each included physically-focused activities (i.e., exercise, stretching, nutritional counseling); psychotherapy; or expressive activities (i.e., writing, art, dance). Only a small proportion used spiritually-oriented activities (i.e., prayer and discussing spiritual concepts). Other ingredients included an audiotaped or written summary of the treatment consultation, a question prompt sheet for medical appointments, games (for distraction during chemotherapy), or access to a botanical garden.

The majority of studies with multiple intervention conditions included control conditions with little active care (no-treatment control, treatment as usual—which typically did not include psychosocial care—, or wait-list). For the active treatment conditions (i.e., not control or usual care) for which the length of treatment could be determined, the average number of planned sessions was 11.87 ( $SD = 32.48$ ), the average number of scheduled hours was 10.63 ( $SD = 17.77$ ; including self-administration at home if this was an explicit part of the intervention), and the average span of time over which interventions took place was 9.27 weeks ( $SD = 14.32$ ). More than half of the projects included interventions with components that were delivered to patients individually (occasionally including a spouse, family member, or caregiver also) and about one-third had components that were delivered to groups of patients. A small proportion of projects used the telephone to facilitate this delivery. Approximately one-third of projects each made use of written materials or non-interactive audiotapes or videotapes, but a smaller proportion used interactive computers or videos or the internet. Fewer than half of projects examined treatments that featured self-administered components.

**Individual conducting the intervention**—Professionals delivering the interventions were predominantly nurses or psychologists, whereas fewer were social workers, physicians, or psychiatrists. A minority of interventions was led by peers. Others included dietitians, physical therapists, occupational therapists, massage therapists, hypnotherapists, Reiki and Tai Chi masters, reflexologists, acupuncturists, counselors, yoga teachers, dance teachers, music therapists, exercise physiologists, chaplains, trained facilitators, family members, caregivers, or significant others.

**Outcomes assessed**—The mean number of different outcomes reported per project was 13.10 ( $SD = 10.58$ ). In keeping with the goals of maintaining or improving quality of life, mental health or psychological or emotional functioning outcomes were assessed in a majority of the projects. Physical symptoms also were assessed in a majority of projects. General quality of life measures (e.g., the Functional Assessment of Cancer Therapy Scale; FACT)<sup>72</sup> were used to assess outcomes in almost one-third of the projects, as were relationship/social/sexual/family functioning, improvement in the cancer treatment process, and survival/physiologic/medical measures. Cognitive/occupational functioning was assessed in a smaller proportion of

projects. Other outcomes, such as satisfaction with the intervention, were assessed in approximately one-third of the projects.

### Quality of Study Methodology and Reporting

The results of items assessing the quality of study methodology and reporting are displayed in Table 3. We compared the methodological quality of older versus more recent research in the dataset by dividing the sample of projects in half and contrasting the 241 projects first reported during 1980–1998 with the 247 projects first reported during 1999–2005.

**Sample description**—Overall, whereas most projects reported the initial number of participants in their sample, fewer than half reported the number approached to participate and fewer than half reported the number of dropping out of the intervention. Few provided information on the representativeness of their sample by comparing the characteristics of participants to non-participants. These comparisons typically involved demographic variables, such as age, education level, marital status, employment status, and disease- and treatment-related variables, such as stage of cancer and type of treatment. Occasionally, psychological variables, such as mood disturbance, also were included.

**Research design**—The majority of projects used randomized experimental designs, whereas a minority used non-randomized comparisons, and single-group designs. More than half of the randomized designs only stated their design to be randomized whereas fewer described their procedure and included methods to prevent subterfuge (i.e., concealing the allocation schedule from those making group assignments).

**Intervention provision and specification**—Where applicable (i.e., the intervention was delivered by a person), fewer than one-third of projects mentioned using manuals to standardize delivery. More than half, however, assessed intervention implementation by monitoring the integrity of treatment (e.g., noting the number of sessions attended, audiotaping and reviewing sessions, or having participants log their practice). A minority assessed implementation by measuring the immediate effects of treatment on intermediate variables through which interventions were believed to affect outcomes. For instance, in a study investigating the effects of cognitive-behavioral stress management training on the quality of life of prostate cancer patients, the investigators assessed the extent to which perceived stress management skills had improved.<sup>16</sup> Process analysis, which examines the means by which interventions are intended to have their effect, either by linking intervention elements or duration to outcome or examining mediating mechanisms (e.g., examining whether patients in education intervention groups acquired more information than peer-discussion intervention groups<sup>73</sup>), was not often pursued.

**Data analyses**—A majority of applicable multiple-group projects reported that intervention groups were compared at baseline for equivalence on select variables, but far fewer investigated if there was differential dropout of participants with certain characteristics from compared groups. Intent-to-treat analyses were performed in relatively few projects. The average number of participants per group included in the first follow-up point was 47.20 ( $SD = 65.14$ ,  $n = 406$ ), translating to an average power to detect a medium effect size of .78.

**Changes over time**—There was a significant increase over time in the proportion of projects that reported the initial number of participants in the sample. For randomized designs there was a significant improvement in the quality of the randomization  $\chi^2(3) = 7.93$ ,  $p < .05$ , with the proportions of projects including measures to prevent subterfuge rising significantly from 12.0% to 24.2%,  $\chi^2(1) = 7.66$ ,  $p < .05$ . The only aspect of intervention provision that improved significantly over time was intervention monitoring. There were also significant increases in

the proportion of studies that examined group equivalence at baseline and used intent-to-treat analyses.

### Exclusion Rates and Study and Intervention Participation Rates

**Recruitment strategy**—About a quarter of studies (23.8%) used the rigorous method of recruiting potential participants from *consecutive* patients, whereby all patients at a treatment center were screened or invited to participate. The most common source, however, was nonconsecutive patients (42.6%). Approximately a quarter of studies (25.2%) used referral or invitation by a medical care provider and 10.2% used advertisements. Other recruitment sources, such as tumor registries, lists of enrollees in other trials, support agencies, churches, and attendees of presentations in the community, were used in 16.4% of the projects.

**Eligibility criteria**—The vast majority (96.9%) of studies specified inclusion and exclusion criteria. Although the rationale for these criteria often was not explicitly stated, reports typically used criteria were related to the target population that the intervention was designed for (i.e., their type of cancer, type of treatment, particular symptoms) and sometimes medical or ethical contraindications for being involved in the intervention (i.e., inability to participate in physical activity for exercise interventions, lack of permission from one's physician, lack of awareness of one's diagnosis). Only 57 projects (11.6%) specified as an inclusion criterion that participants have evidence that an intervention would be indicated, such as pain, nausea, insomnia, or elevated levels of distress. Many exclusion criteria were logistical in that they specified, for example, living within a reasonable distance from the study site. Because many interventions involved education, developing skills, or some level of mental participation, exclusion based upon not being of sound mind (e.g., having cognitive impairment) was fairly common. Other exclusion criteria were related to controlling extraneous or nuisance variables (e.g., not participating in other studies, no prior cancer). There were also exclusions that involved having a psychiatric history, taking psychoactive drugs, or having clinically significant distress.

**Exclusion and dropout rates**—For only approximately 15% of the projects ( $n = 72$ ) was it possible to determine the proportion of potential participants who were excluded by such criteria, which was 34.3%, ( $SD = 28.3\%$ ; range 0–96.0%). For approximately one-third of the projects ( $n = 178$ ) it was possible to calculate the mean proportion of eligible participants not involved in the study, which was 27.4% ( $SD = 20.9\%$ ; range: 0–88.0%). Being involved entailed, at minimum, agreeing to participate and/or being enrolled and/or being assigned to an intervention group and/or completing baseline assessments and/or beginning treatment. For fewer than half of the projects ( $n = 215$ ) was it possible to calculate the mean proportion of participants dropping out of intervention, which was 11.3% ( $SD = 11.8\%$ ; range = 0–55.0%).

**Sample representativeness**—As was mentioned earlier, only a small proportion of studies ( $n = 36$ ) provided information on the representativeness of their sample by comparing the characteristics of participants to non-participants. These comparisons typically involved demographic variables, such as age ( $n = 23$ ), education level ( $n = 8$ ), marital status ( $n = 14$ ), employment status ( $n = 4$ ), and disease- and treatment-related variables, such as stage of cancer ( $n = 13$ ) and type of treatment ( $n = 10$ ). Only occasionally were psychological variables, such as mood, anxiety, or coping style, included ( $n = 8$ ). Taken together, these analyses provided an incomplete picture of the differences between participants and non-participants.

Although the majority of studies did not find an effect for age, in the ones that did, there was a tendency for participants to be younger than non-participants. Studies also tended to find that participants indicated more distress than non-participants. In a few studies the reasons for refusing mentioned by non-participants were noted; they typically involved conflicting



demands and lack of interest. For instance, a study of an intervention to enhance communication between patients about to undergo radical prostatectomy and their medical providers and partners, of 101 non-participants, 47% noted they were too busy and 14% were not interested; 12% also found the questionnaire too personal.<sup>74</sup>

Similarly, only a small proportion of studies ( $n = 13$ ) reported whether there was differential dropout of participants with particular characteristics from intervention and comparison groups. Overall, few significant interactions between intervention group and baseline characteristics in predicting dropout were noted, perhaps due to the low power.

### Unintended Events: Additional Treatment and Contamination

We also examined unintended events, whereby participants received additional assistance related to quality of life that was not planned by the research team, or contamination, whereby participants (in multiple group studies only) were exposed to elements that made another intervention condition distinctive. These phenomena are relevant to validity and may also provide insight into participants' reactions to research participation. Although projects did not often monitor or document additional assistance, 67 (13.7%) noted that it was received. Examples included support groups provided outside of the study, professional counseling or psychotherapy, antidepressant and anti-anxiety medications, vitamins, body work, yoga, exercise, meditation, and prayer.

Twenty-seven projects, or 7.3% of multiple-group studies, noted that there was some unintended contamination of interventions across groups, whereby (typically control) participants tried to gain access to therapeutic activities available to those in other trial arms, aside from usual care. Examples included control group participants joining an outside support group in a trial of two types of group psychosocial support; control group participants keeping track of side effects, when monitoring side effects was part of the experimental intervention; and a control participant obtaining a commercially-produced guided imagery tape in a study testing a version of such tapes.

## Discussion

This overview reveals the topography of the field of psychosocial intervention studies for adult cancer patients conducted over two-and-a-half decades. Research in this area increased dramatically, reflecting enthusiasm and support for providing empirically-based assistance and tools for individuals coping with cancer's diagnosis, treatment, and survivorship. This conclusion concurs with that of a recent Institute of Medicine (IOM) Report which asserted there is a "wealth" of psychosocial resources (i.e., information on cancer-related treatments, peer support, counseling/psychotherapy, medical supplies, transportation, family and caregiver support, assistance with activities of daily living, legal services, financial and insurance advice, benefits counseling, and financial assistance) currently available to cancer patients.<sup>12</sup>

The IOM report also documented the great extent to which these resources are provided by non-profit cancer support organizations in the voluntary sector. Although the 25 years of research summarized here involved more than 46,000 cancer patients (not all of whom were in active treatment conditions), just a single non-profit organization among the dozens that exist, CancerCare, provided free counseling, education, support groups, referral, and financial assistance to 42,680 patients in 2005 alone.<sup>12</sup> Thus, although there were a few exceptions whereby evaluations of services provided widely by non-profit organizations have been presented in the scientific literature (i.e., The American Cancer Society's *Look Good...Feel Better*<sup>70</sup> and *Reach to Recovery* programs<sup>75, 76</sup> and the Wellness Community<sup>77</sup>), the majority of research focusing on university-based-investigator-designed interventions stands in contrast to the services available to, and being used by, cancer patients. A discrepancy between the

types of interventions evaluated by researchers and those most commonly used in actual practice, has been documented in other areas, such as treatment for alcohol use disorders.<sup>78</sup> This means that clinicians seeking information on evidence-based interventions have this available for only a subset of existing treatments. Closer interactions between academic and voluntary sectors could provide new insights for both. These might involve including evidence-supported elements in the services provided by non-profit organizations and rigorously evaluating interventions widely used by non-profit cancer support organizations.<sup>8</sup> Further inquiry into potential reasons for this discrepancy, such as whether the time and resources required discourage their widespread implementation is also warranted.

### Investigator, Report, and Sample Characteristics

Although this overview was able to capture research conducted in a number of countries, this work has predominantly been conducted in the United States and in samples of breast, lung, or prostate cancer patients who are white and well-educated. Just as patients with different types of cancer may require different types of psychosocial interventions, differences in the types of treatments available, the meaning of cancer, and cultural mores about disclosure of disease may create differences in the types of interventions needed worldwide and their efficacy. Recognition that the great majority psychological inquiry has been dominated by U. S. samples, investigators, editors, and journals, and the disconnect between the conditions under which the rest of the world's population lives, has led to calls to expand the scope of the field of psychology in general.<sup>79</sup> These calls are relevant to psychosocial oncology research, also. Encouraging initiatives to address health disparities in cancer in terms of income, ethnic minority status, and health insurance coverage within the United States are now underway.<sup>80</sup>

Although there is a great deal of support from federal governmental agencies (both American and non-American) for research on psychosocial interventions for cancer, a good portion of this work is supported by private foundations. This speaks to public enthusiasm for this work, but it may also contribute to research being focused on cancers for which there is the most public advocacy. For instance, although lung cancer samples made up the second-largest proportion after breast cancer samples in our dataset, their representation in this research literature was by far less, and out of proportion to the rates at which breast versus lung cancer affects the population.<sup>81</sup>

As indicated by the 107 projects that involved at least one doctoral dissertation, this is a fruitful area for budding investigators. More than half however, remained unpublished, prompting the question of whether these were of lower quality, had findings that were null or unpalatable, or if their authors simply had other priorities. Although a full exploration of their foci, methodological quality, and results is beyond the scope of this review, the projects consisting of unpublished dissertations were significantly less likely to use randomized designs (61.5% versus 83.3%,  $\chi^2 = 5.78$ ,  $p < .05$ ), suggesting that at least on some indices, they were less rigorous.

### Intervention Characteristics

Interventions often used cognitive behavioral approaches, involving developing coping skills and stress and symptom management, and educational approaches, in line with the notion that cancer patients' distress likely stems from coping with the many practical and tangible difficulties that cancer diagnosis, treatment, end of life, and survivorship entail. Interventions focused on information about illness and treatment are preferred by patients.<sup>82</sup> Of interest was the number of projects subjecting CAM or mind body approaches to empirical scrutiny. The National Center for Complementary and Alternative Medicine at the National Institutes of Health, established in 1998, has increased support for this type of research. This growing interest was reflected in significant increase in the percentage of projects studying CAM

approaches from 12.4% to 24.3%,  $\chi^2 = 11.38, p < .01$ . Cancer patients avail themselves of such treatments,<sup>83, 84</sup> often without their doctors' recommendation, at higher rates than those without cancer, making testing their efficacy important. Spiritual approaches, not represented prominently in the interventions tested here, also are commonly sought out by patients.<sup>85</sup>

Interventions were frequently designed specifically for patients with a particular type of cancer or type of cancer treatment. However, inclusion criteria did not often specify that eligible participants be experiencing a particular difficulty or meet a particular screening criterion. This may be based on the seemingly reasonable assumption that side effects associated with particular treatments are common, and that being diagnosed with or treated for cancer prompts informational or psychosocial needs. For interventions addressing particular types of outcomes, such as depression and anxiety, screening for those at risk may produce stronger results<sup>39</sup>. However, there also may be benefits for those who are not currently experiencing particular difficulties in preventing or minimizing future problems<sup>86</sup>.

Fewer than 5% of interventions included patients that were in the palliation stage of treatment. The intervention approaches used typically were not specific to palliative care (e.g., massage, acupuncture, aromatherapy, hypnosis, relaxation training) save for one dissertation investigation that involved a family hospice intervention (involving physical care with pain and symptom control, crisis intervention, respite care, 24-hour on-call coverage, education and anticipatory guidance on home care, grief, time of death, funerals, and legal matters, counseling, and follow-up bereavement care).<sup>87</sup> Although engaging dying populations in research may be challenging, the lack of investigation on this type of comprehensive end-of-life care represents an important gap in the literature.

Quite an array of outcome variables was considered, in line with the multidimensional conceptualization of quality of life. Survival/physiologic/medical outcome variables also were considered in almost a third of projects, reflecting an expanding emphasis on biobehavioral measures.<sup>88</sup> Although disruptions in work during and after treatment often are noted by cancer patients,<sup>12</sup> cognitive or occupational outcomes were not often assessed. The effects on work and finances largely have been neglected in this literature. Participant satisfaction was considered in 18.6% of projects, supporting the notion that investigators are interested in receiving feedback on the acceptability of their interventions to cancer patients. Other reviews have noted high levels of satisfaction with cancer support groups.<sup>89</sup>

### Quality of Study Methodology and Reporting

Strengths of this literature as a whole include using predominantly randomized designs, testing for group equivalence, and monitoring treatment. However, deficiencies in other areas, such as examining treatment mechanisms and the adequacy of reporting of methodology, essential for useful syntheses of this area, remain to be addressed. Aspects of methodological quality that improved over time were: specifying the number of participants at baseline, including measures to prevent subterfuge of the allocation process in randomized designs, monitoring the integrity of intervention delivery, examining group equivalence at baseline, and using intent-to-treat analyses.

A small minority of studies conducted process analyses that considered the mechanisms by which an intervention might have its effects, either by linking the dose of treatment received to outcomes or examining purported mediating pathways between interventions and outcomes. For example, an investigation testing a multimodal psychosocial group intervention for breast cancer patients showed that, after adjusting for age, type of surgery, receipt of chemotherapy or not, time since surgery, and baseline distress, changes in satisfaction with information received predicted follow-up levels of distress.<sup>90</sup> In an investigation of group psychotherapy, although the number of sessions attended was not related reductions in total mood disturbance,

<sup>91</sup> the extent of expressing existential themes was.<sup>92</sup> Such inquiry is recommended as a priority for future research.<sup>2</sup>

### Exclusion Rates and Study and Intervention Participation Rates

Given that fewer than one-quarter of projects selected their participants from the full population of patients at a particular treatment center (consecutive patients), and that the majority of projects relied on other methods, it is likely that there is some selection bias in the recruitment of participants. On their face, the exclusion criteria used in this literature seemed reasonable from scientific and logistical points of view. However, in other areas of research, commonly-used exclusion criteria, when applied hypothetically to real-world samples of treated patients, have been demonstrated to indirectly lead to under-representation of minorities, as well as patients with low-incomes and with more severe problems.<sup>93</sup> Further research would need to examine the participant characteristics associated with commonly-used exclusion criteria to determine if this might also be the case for psychosocial oncology. Finally, because it was not examined in a large proportion of projects, and not extensively examined in those for which it was studied, the differences between participants and non-participants in this research base remain poorly understood. This, however, may pose few difficulties in terms of the external validity of this work, as in practice only interested and able patients will take part in such interventions. <sup>2</sup> Exploring innovative modes of intervention delivery, such as via the internet, <sup>94, 95</sup> videoconferencing,<sup>96</sup> or with workbooks<sup>97</sup> for those without access to computers, may increase the accessibility to those who have less flexible schedules or the inability to travel to treatment centers.

Reflecting the low overall rates of cancer patients in clinical research, and the especially low rates for minorities, new funding initiatives are directed at improving enrollment rates in trials.<sup>98</sup> A new framework for accrual to clinical trials that takes into account community, system, provider, and patient factors is beginning to be applied and tested. For instance, one effort involved educating the public about the importance of clinical trials, establishing trust through a radio show and sponsoring community events, providing valet parking, educating hospital staff and providers about the project, and giving attention to productive communication strategies.<sup>99</sup>

### Unintended Events: Contamination and Additional Treatment

Because so few projects reported on participants obtaining additional unplanned assistance and contamination across intervention groups, it is difficult to estimate their prevalence, but even the low overall rates give cause for some concern that balancing the goals of research and participants is complex. Assessing unintended contamination and factoring it into analyses is one solution. While coding the projects summarized here, numerous difficulties were noted. These often had to do with participant preferences for one of the contrasted intervention groups over another. For instance, in a study of a CAM-oriented intervention for breast cancer patients “many...responded to the advertisements because of an interest in CAM therapies, and did not want to be in the standard group.”<sup>100, p. 63</sup> In a randomized trial of psychosocial support for patients with breast cancer “off-study support groups became an increasing problem,...as recognition of the potential benefits of support groups grew..., patients became unwilling to accept randomization.”<sup>101, p. 53</sup> Difficulties such as these highlight the utility of examining the perspectives of potential recipients of psychosocial interventions for cancer patients. For instance, in contrast to the few documented interventions that included spiritual elements and the majority that had closed group membership, patients themselves indicate interest in having spiritual concerns addressed and drop-in formats.<sup>82</sup>

The findings of this overview must be viewed in light of potential limitations such as the possibility that there were reports that were not included because of the reliance on only three

bibliographic databases, difficulty locating particular reports, and language limitations. A final limitation is that, although the overview captures research conducted over a wide time span, newer interventions have not been captured, limiting the extent that the trends documented apply to the literature published more recently. Novel techniques, such as meaning-making interventions<sup>102</sup> and intimacy-enhancing interventions,<sup>103</sup> and approaches such as a dignity-conserving emphasis in palliative care<sup>104</sup> and counseling interventions that focus on the family<sup>105</sup> represent promising new directions.

## Conclusion

This comprehensive characterization of the literature investigating psychosocial interventions for cancer patients documented its dramatic growth, and its wide scope with respect to treatment approaches, target difficulties, and types of patients. Because of the disconnects between interventions that are reported on in the research literature and the services that are sought by, and available to, cancer patients, and discrepancy between the characteristics of research participants and the population of individuals with cancer, future research could benefit from closer interactions between academic and voluntary sectors and expanding the diversity of participants. A primary focus of psychosocial interventions has been on quality of life, but that focus should continue to expand to address the effects on work and financial stability. The field also could benefit from an increased focus on the mechanisms by which psychosocial interventions may have their effects and deliberate study of ways to improve diverse recruitment and retention. Important questions for further study include whether these interventions should be targeted to individuals experiencing specific difficulties or if, based on their potentially preventive value, most cancer patients could be helped by them.

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**Table 1**

## Participant Characteristics

Characteristic	Mean	SD	n
Demographic characteristics			
Age (years)	54.1	7.2	443
Female (%)	<b>71.1</b>	29.6	452
White (%)	81.2	23.3	173
Years of education	13.7	3.1	75
College attenders (%)	54.2	22.8	149
Employed (%)	52.2	21.5	138
Married (%)	71.1	12.3	271
Income (in \$1,000)	48.5	20.3	10
Low income (%)	53.4	37.6	4
Disease and treatment characteristics			
% stage 0	1.3	4.1	139
% stage I	34.4	27.0	124
% stage II	36.4	24.4	121
% stage III	11.8	19.0	137
% stage IV	11.4	25.0	146
% treated with surgery	84.2	30.4	210
% treated with radiation	52.3	34.3	197
% treated with chemotherapy	63.0	33.9	222
Time since diagnosis (months)	18.1	18.5	113

**Table 2**  
Intervention Characteristics and Outcomes Assessed

	<i>n</i>	%
Goal of intervention		
Improved quality of life	339	69.5
Improved coping with treatment side effects and relief from physical effects of disease	106	21.7
Increased understand of treatment options and improved satisfaction with treatment decisions	24	4.9
Improved social relationships	1	.2
Other treatment goal	18	3.7
Target patient populations		
Particular gender <sup>a</sup>	6	1.2
Particular type of cancer <sup>a</sup>	225	46.0
Particular age <sup>a</sup>	8	1.6
Particular stage or type of treatment <sup>a</sup>	301	61.7
Particular cultural or language group <sup>a</sup>	10	2.0
Other target <sup>a</sup>	74	15.2
No particular target	58	11.9
Type, theoretical orientation, or approach		
Cognitive, behavioral, or cognitive behavioral therapy <sup>a</sup>	158	32.4
Education/information <sup>a</sup>	100	20.5
Non-behavioral counseling or psychotherapy <sup>a</sup>	52	10.7
Social Support (by non-professionals) <sup>a</sup>	28	5.7
Complementary or alternative mind-body approaches <sup>a</sup>	90	18.4
Multimodal intervention <sup>a</sup>	95	19.5
Other <sup>a</sup>	21	4.3
Waiting list, control group, or treatment as usual <sup>a</sup>	323	66.2
Intervention ingredients		
Developing coping skills <sup>a</sup>	176	36.1
Education/information <sup>a</sup>	235	48.2
Expressive activities <sup>a</sup>	61	12.5
Physically focused activities <sup>a</sup>	84	17.2
Psychotherapy <sup>a</sup>	73	15.0
Stress/symptom management <sup>a</sup>	241	49.4
Social support <sup>a</sup>	168	34.4
Spiritual <sup>a</sup>	8	1.6
Other <sup>a</sup>	76	15.6
Standard care <sup>a</sup>	93	19.1
Mode of Delivery		
Individual <sup>a</sup>	279	57.2
Group <sup>a</sup>	167	34.2

	<i>n</i>	%
Telephone <sup>a</sup>	61	12.5
Interactive computer/internet/video <sup>a</sup>	17	3.5
Non-interactive audiotapes/video <sup>a</sup>	158	32.4
Written materials <sup>a</sup>	187	38.3
Self-administered/directed <sup>a</sup>	206	42.2
Other <sup>a</sup>	17	3.5
Not applicable (control conditions) <sup>a</sup>	250	51.2
Not indicated <sup>a</sup>	11	2.3
Individual conducting the intervention		
Nurse <sup>a</sup>	142	29.1
Physician <sup>a</sup>	38	7.8
Psychologist <sup>a</sup>	111	22.7
Psychiatrist <sup>a</sup>	18	3.7
Social worker <sup>a</sup>	41	8.4
Peer <sup>a</sup>	28	5.7
Other <sup>a</sup>	206	42.2
Not applicable (control conditions) <sup>a</sup>	303	62.1
Outcomes assessed	79	16.2
Mental health/psychological or emotional functioning <sup>a</sup>	404	83.8
Cognitive/occupational functioning <sup>a</sup>	79	16.2
Relationship/social/sexual/family functioning <sup>a</sup>	154	31.6
Improvement of the cancer treatment process <sup>a</sup>	121	24.8
Physical symptoms <sup>a</sup>	288	59.0
Quality of life <sup>a</sup>	141	28.9
Survival/immune/physiologic/medical measures <sup>a</sup>	137	28.1
Other outcomes	166	34.0

<sup>a</sup>Categories not mutually exclusive.

Table 3

Quality of Study Methodology and Reporting

	1980-1998		1999-2005		All	
	n	%	n	%	n	%
Sample description						
Reported number approached to participate	88	36.5	112	45.3	200	41.0
Reported number initially participating*	210	87.1	232	93.9	442	90.2
Compared characteristics of participants to eligible non- participants	17	7.1	19	7.7	36	7.4
Reported number dropping out of treatment	101	41.9	116	47.0	217	44.5
Research Design						
One group post test only	10	4.1	7	2.8	17	3.5
One group pre and post test	36	14.9	58	23.5	94	19.3
Nonequivalent control group without matching or statistical control	26	10.8	13	5.3	39	8.0
Nonequivalent control group with matching or statistical control	9	3.7	4	1.6	13	2.7
Randomized experiment	150	62.2	157	63.6	307	62.9
Other design/design not indicated	10	4.1	8	3.2	18	3.7
Quality of randomization, for randomized experiments (n = 307) <sup>*b</sup>						
Randomization implied but not stated	2	1.3	1	0.6	3	1.0
Method only stated to be randomized	88	58.7	81	51.6	169	55.0
Randomization procedure described but no measures to prevent subterfuge included	42	28.0	37	23.6	79	25.7
Randomization procedure described and measures to prevent subterfuge included	18	12.0	38	24.2	56	18.2
Intervention provision and specification						
Manuals used to guide treatment (where applicable, n = 607 intervention conditions)	87	27.3	93	32.5	182	30.0
Intervention implementation assessed						
Intervention monitored <sup>d***</sup>	116	48.1	159	64.4	275	56.4
Assessed immediate effects of intervention <sup>d</sup>	26	10.8	28	11.3	54	11.1
Additional intervention monitored	37	15.3	41	16.6	78	16.0
Contamination monitored (where applicable, n =368)	20	8.2	25	10.1	45	12.2
Process analyses conducted						
Linked intervention elements or duration to outcome <sup>d</sup>	38	15.7	37	15.0	75	15.4
Examined mediating factors <sup>d</sup>	29	12.0	25	10.1	54	11.1

	1980-1998		1999-2005		All	
	n	%	n	%	n	%
Data Analyses						
Groups compared for equivalence at baseline (where applicable, n = 375)**	155	79.0	163	90.5	317	84.5
Interaction between treatment condition and dropout status (re: study treatment or follow-up on pretreatment variables examined, where applicable n = 365)	4	1.1	9	2.4	13	3.6
Intent-to-treat analyses conducted***	21	8.7	44	17.8	65	13.3

<sup>a</sup> Categories not mutually exclusive.

<sup>b</sup> df = 3.

\*  $p < .05$ .

\*\*  $p < .01$ .

\*\*\*  $p < .001$ .