

# Efficacy of Psychosocial Interventions in Cancer Care: Evidence Is Weaker Than It First Looks

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## ABSTRACT

*With increasing sophistication, successive reviews find weaker evidence for the efficacy of psychosocial interventions to reduce distress among cancer patients. However, these appraisals may still be overly positive because of reviewers' uncritical acceptance of flaws in the design, analysis, and reporting of the results of such trials. Using randomized trials from high-impact journals, we show confirmatory bias, selective reporting of the most favorable of multiple outcome measures, suppressing of null results in subsequent citations of trials, and dropping of data for patients least likely to benefit from intervention. The conclusion that typical cancer patients do not benefit from interventions to reduce distress is strengthened when these endemic problems with the literature are taken into account. Required registering of the details of clinical trials and adherence to CONSORT reduces but does not eliminate bias in the literature.*

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## INTRODUCTION

We must not allow our commitment to improving the well-being of cancer patients to be compromised with an uncritical acceptance of exaggerated claims about the effectiveness of interventions that are based on poorly conceived, poorly conducted, and poorly reported clinical trials (1). If we believe that truly comprehensive cancer care must address not only biomedical outcomes but also patients' psychosocial needs and quality of life, we must be prepared to demonstrate that what we request for patients is effective and acceptable to them. Similarly, when we claim that the resources available for psychosocial care are inadequate, it is incumbent on us to show that additional resources will demonstrably improve patient outcomes. Our credibility and ultimately our ability to obtain resources for cancer patients depend on us meeting these standards.

Lepore and Coyne (2) argue that as randomized trials accumulate and reviews of them become more sophisticated, we are left with "no convincing evidence of broadly effective psychological interventions for reducing a wide range of distress outcomes in

cancer patients" (p. 90). Although hardly an optimistic assessment, the meta-analyses and reviews on which it is based still tend to gloss over serious deficiencies in the randomized trials on which these conclusions are based. Once we recognize these deficiencies, the basis for this pessimistic assessment is only strengthened.

With the possible exception of terminally ill patients (3,4), we do not believe that there is any inherent reason why adaptations of psychological interventions that have proved efficacious in other contexts would be ineffective in reducing clinically significant distress when it occurs in cancer patients. The greater challenges lie in adapting these interventions to the exigencies of routine cancer care and ensuring that they are effectively delivered to patients with demonstrable clinical need in the context of the competing demands of managing a life-threatening illness. Yet this remains an article of faith, not a conclusion we can support with a balanced review of the available literature for cancer patients.

At the present time, the best evidence is that a typical cancer patient receiving any of a variety of the psychosocial interventions will not obtain a benefit that is commensurate with the required investment of their time and effort. The available evidence does not justify routinely recommending these interventions to cancer patients, and it does not provide a credible basis for advocating for reimbursement by third-party payers. These conclusions hold in general for psychosocial interventions targeting distress but specifically for a year of weekly meetings of supportive expressive group psychotherapy (SEGP) (5), 10 sessions of cognitive-behavioral stress management (CBSM) (6), and the less intensive expressive writing (EW) (7). We recognize that these appraisals are at odds with the claims of proponents of these interventions, but our assessment is based on what would be obtained with main analyses of primary endpoints for all patients enrolling in trials evaluating these interventions (intention to treat), the widely accepted standard in the biomedical literature (8,9).

Adoption of the Consolidated Standards for Clinical Trials (8) by hundreds of medical journals and, more recently, *Annals of Behavioral Medicine*, *Journal of Consulting and Clinical Psychology*, and *Health Psychology* provides an impetus for higher standards for publishing results of clinical trials, and in this article we apply some of these standards in reevaluating claims that are being made for interventions to reduce distress among cancer patients. The original (10) and revised (8) CONSORT checklists were aimed at facilitating investigators' providing crucial information in reports of clinical trials. This information is necessary

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to allow readers to critically appraise the design and conduct of clinical trials and analysis and interpretation of the resulting data. CONSORT standards thus concern reporting, but they have the effect of guiding investigators in designing and implementing scientifically sound trials (11) as well. Noncompliance with a number of the CONSORT Checklist items has been empirically related to confirmatory bias in the reporting of trials (9).

Why is there a discrepancy between the investigators' own assessments of their work and ours? A "best foot forward" confirmatory bias is endemic in randomized controlled trials (RCTs) for psychosocial interventions in cancer care, with positive outcomes claimed for clinical trials even in their absence, and even in articles published after a journal's adoption of CONSORT (12). This bias pervades the larger psychosocial clinical trial literature as well. A review (13) of adult clinical trials published in the 1992 and 2002 *Journal of Consulting and Clinical Psychology* revealed low compliance with CONSORT Checklist items empirically associated with protection against confirmatory bias (9). We thus cannot take investigators' positive appraisals of their studies at face value, and we should be skeptical of meta-analyses and other reviews that uncritically accept investigators' claims. However, there are additional features of the conduct, analysis, and reporting of clinical trials that further serve to convey an inflated sense of the efficacy of interventions. These practices include post hoc selection of those outcome measures that put the efficacy of the intervention in the best light from a larger battery, ignoring the accumulation of negative trials and recasting past negative trials as being positive in subsequent publications, and post hoc dropping of patients from analyses who are likely to show the least benefit from having been randomized to the intervention. A systematic review of the literature is sorely needed but is beyond the scope and page limitation of this article. However, we illustrate these characteristics in clinical trials evaluating the three approaches previously noted. We should note that the articles on which we draw are from extramurally funded projects, they appeared in top-tier journals, and the interventions have been touted as promising means to improve the well-being of cancer patients, including in the articles on which we draw.

### Confirmatory Bias

In the abstract to their article, Classen et al. (5) reported that SEGP "can help reduce distress in patients with metastatic breast cancer" (p. 494). However, in primary analyses, no effects of this 1-year weekly experience were found on the Profile of Mood States (POMS), only on the combined avoidance and intrusive thoughts subscale of the Impact of Events Scale (IES), and this effect was small ( $d = .25$ ) by Cohen's (14) standards. Effects for general mood disturbance on the POMS were found only after the last POMS scores were discarded for patients who subsequently died within a year. The article states that the full range of IES and POMS subscales were analyzed in parallel primary and secondary analyses, but no results are reported other than for the total IES score and the general mood disturbance on the POMS. No mention of the Center for Epidemiologic Studies Depression Scale (CES-D), but a later article indicated that the CES-D had been administered and lamented that "substantive

psychological changes observed clinically seem to elude assessment" (4, p. 423). The omission of results for the CES-D in the original report of the trial is particularly noteworthy, given the importance that members of the investigative team attach to a reduction in depression as the means by which their intervention might improve survival (15). We are not alone in our negative assessment of SEGP (3,15). Edwards et al. (16) concluded in a review that included SEGP and other related therapies,

The five studies of group psychological therapies for women with metastatic breast cancer showed very limited evidence of benefit arising from these interventions. ... There may be some evidence of short-term benefit for some psychological outcomes, but in general these are not maintained even to a few months of follow-up. (p. 1)

Despite a title seemingly indicating a positive trial, Antoni et al. (6) presented data that indicate that CBSM failed to affect any of the summary scores or subscales of several measures of distress (CES-D, IES, and POMS). The components of this complex intervention package leave no doubt that the purpose of the intervention were to reduce distress: emotional expression; cognitive restructuring; and training in relaxation and guided imagery, assertiveness, interpersonal conflict resolution, and coping skills. The title of the article declared that the intervention enhances benefit finding, and in a later commentary, Antoni and Carver (17) stated, "One point of our article was that distress reduction is not the only meaningful goal for an intervention among cancer patients" (p. 458). Yet, within the original article they explicitly stated that the intervention was not designed to target benefit-finding. Furthermore, if one were to set out with improving benefit finding, it is unlikely that this particular constellation of intervention components would have been chosen.

Zakowski et al.'s (7) title would lead a reasonable reader to conclude that EW had reduced distress in cancer patients and that this study had isolated a potential mechanism by which the effect is obtained. The stated purposes of the study were to examine the efficacy of the EW for cancer patients, particularly patients with a high level of social constraints, which are restrictions on patients' ability to talk about their condition within their interpersonal relationships. Yet, there was no overall effect for the intervention on either the Brief Symptoms Inventory (BSI) or Intrusive Thoughts and Avoidance scales of the IES, and the pre-post differences in distress within the intervention group were actually smaller than initial differences between the intervention and control group. Overall, distress was remarkably stable across time ( $r = .78$  for the BSI), no overall effect was found for initial social constraint on subsequent distress, and so it appears that there was not a strong social constraint effect in need of buffering. Yet, the conclusion offered in the article was that although the intervention was not effective for "*all cancer patients [italics added]*" (p. 561), it was a useful tool for cancer patients whose interpersonal environments limited their ability to talk about their condition.

### The Nonaccumulative Nature of Null and Weak Effects

One important reason why the field does not come to terms with the results of clinical trials is that null findings tend to be

dropped and weak findings are made to look stronger in repeated references to these trials. A subsequent report of the Classen et al. (5) trial (18) identifies four outcomes: suppression of negative affect, restraint, repression, and emotional self-efficacy. The article cited the original article for a fuller description of the patients enrolled in the study without indicating that the earlier article was the primary outcomes article and without acknowledging the results of the analyses reported earlier. A reader could reasonably but incorrectly infer that the Giese-Davis et al. article (18) was a report of primary outcomes.

An article extending CBSM to prostate cancer patients, Antoni's lab group (19) declared "the efficacy of psychosocial interventions in reducing stress and negative affect and in improving the QoL [quality of life] of cancer patients has been demonstrated clearly" (p. 193). The article noted that CBSM has been provided to breast cancer patients but does not cite the null trial or report its results. The article described CBSM as having been designed to improve cancer patients' QoL through improvements in cognitive-behavioral stress management, but there is no mention of changes in distress, a more proximal outcome or mediator of effects of the intervention on QoL. A subsequent article (20) in which the strongest finding with a sample of women with AIDS was a reduction in Beck Depression Inventory scores ( $p < .05$ , one tailed) explained this effect in terms of components of CBSM targeting depression, and cited Antoni et al. (6) without noting its null finding.

Zakowski et al. (7) is too recent an article to measure its impact on the subsequent literature. However, taken together with previous studies (21–24), the study brings the box score for EW to 0–5 main effects on distress in cancer patients. One might consider whether the article should best end with a noting that this does not seem to be a promising intervention for cancer patients (for a review, see 25). It might even be appropriate for consent forms for any subsequent trials to note that five randomized trials have failed to identify any benefit of the intervention for cancer patients.

In explaining and elaborating on the rationale for particular CONSORT Checklist items, Altman et al. (8) suggested that the introduction to articles reporting clinical trials should justify the trial in relation to a systematic review of past trials (Item 2). Similarly, discussions of results should integrate a trial's findings with existing trials (Item 22). We suggest that negative findings get lost from such reviews and integrations. Furthermore, subsequent articles by the authors of clinical trials fail to report negative findings. The net effect is creation of a track record for interventions that is rife with confirmatory bias.

### **THE VARNISHED TRUTH: ALL THE RESULTS THAT FIT?**

#### **Must Investigators Precommit Themselves to Primary Outcomes and Specific Analytic Plans?**

In the larger clinical trials literature, there is an insistence that investigators commit themselves in advance to one or two primary outcome measures on which they will stake any claims

of efficacy for an intervention. The identification of an endpoint should be based on investigators being prepared to judge the efficacy of the intervention based on the effects on that particular outcome. Identification of a second primary outcome should not be a matter of a hedged bet, a second chance to claim efficacy, but rather a conviction that a distinct, second relevant effect of the intervention is found. Inclusion of multiple measures of the same endpoint or highly correlated outcome measures is suspect.

Based on a recognition that the spurious results that procrustean or opportunistic torturing of data will almost inevitably yield (26), that analyzing multiple endpoints and only report positive results is a common practice (27), and that a confirmatory publication bias had become endemic in the clinical trials literature (28), investigators are increasingly required by medical journals to register descriptions of their protocols at the point of starting a clinical trial so that departures from the designation and planned analyses of primary outcomes will be apparent (29). The CONSORT checklist that authors must now complete and submit with their manuscripts requires clear definition of endpoints and a reporting of all analyses performed, including whether they were prespecified or post hoc and exploratory (Items 6, 17, and 18). Although these standards would disallow what are common practices in psychosocial trials, it is recognized that the standards do not go far enough and that they only address part of the multiplicity of data analysis in clinical trials. Pocock (30) noted that further problems include investigators' selective emphasis of positive findings in repeated measurement over time and post hoc subgroup analyses (e.g., 5,6), and stopping of a trial based on positive results in interim analyses of accumulating data, rather than attainment of a predetermined sample size, preferably based on a priori power analyses.

The typical clinical trial offers immense possibilities for capitalizing on chance when primary endpoints, the single most critical time point, and analytic strategies are not prespecified. Thus, for outcome measures, Antoni et al. (6) had at least the CES-D, POMS (three subscales plus a General Affect Scale), the IES (avoidance, intrusive thoughts and total scale), optimism, and the Benefit Finding Scale, and these scales were available at three postintervention time points without explicit hypotheses or prioritization of these time points. Subgroup analyses that examined the main and interaction effects for high versus low depression and optimism for the three time points opened further possibilities.

Such post hoc subgroup analyses are pivotal for positive interpretations of the three trials we are reviewing, but more generally, high-profile articles in the behavioral medicine literature routinely emphasize subgroup analyses when they are positive in the face of negative primary analyses. In the broader clinical trials literature, this practice is uniformly criticized as inappropriate (31). There are usually large numbers of ways in which subgroups of patients can be specified and, therefore, lots of opportunities for capitalizing on chance. There is general agreement that such unplanned subgroup analyses are likely to yield spurious results (32,33), so that "only in exceptional circum-

stances should they affect the conclusions drawn from the trial” (34, p. 229).

Given a need for precommitment to specific analytic plans for one or two outcomes, how do we choose a priori among possible outcome measures for interventions designed to reduce psychological distress? Measures of psychological symptoms such as the CES-D or BSI would seem to have distinct advantages over the commonly preferred IES and POMS. Symptom measures such as the CES-D and BSI refer to clinically significant symptoms, and results of a trial can be compared to established cut points and results of many other intervention trials conducted with other patient populations. The IES has established cut points, but scores on it can be ambiguous. Notably, scores on the intrusive thoughts can reflect thoughtful concern about an ongoing stress process or the memorability of recent experiences, regardless of their stressfulness. Thus, college students completing the IES for the worse television show or movie that they have seen recently approximate the scores of cancer patients rating treatment and diagnosis (35). Scores on the POMS are based on endorsement of affect adjectives that reflect current mood as well as recall of past mood, and, given the subjective basis of a response, this scale may be particularly susceptible to gratitude for having received a free psychosocial intervention or disappointment over having been assigned to the control condition. Unfamiliarity with the interpretation has undoubtedly been one factor in investigators and readers of reports of clinical trials failing to appreciate a recurring finding. Namely, rather than being distressed, women with metastatic breast cancer entering trials evaluating SEGP (5,36) score in what is the normative range for college students (37).

### **What’s Wrong With Discarding Data for Patients Who Are Unlikely to Have Benefited From the Intervention?**

Clinical epidemiological and biomedical journals routinely require intention-to-treat analysis of outcomes, incorporating data for all patients enrolling in a trial, regardless of their degree of exposure to the intervention. In contrast, trials evaluating psychosocial interventions routinely exclude patients for whom data are incomplete or who might be expected to have benefited less from the intervention. There are numerous reasons for relying on intention-to-treat analyses, but some straightforward reasons are worth noting here. First, intention-to-treat analyses provide direct answers to the clinically important question, “On average, what benefit can patients expect from accepting this intervention outside of this clinical trial?” In answering that question, it is unrealistic to assume that patients accepting an intervention in routine care will attend all sessions or otherwise be compliant with what is expected of them. Second, intention-to-treat analyses preserve the baseline equivalence of groups that was presumably achieved by randomization, and these analyses help to ensure that bias is not introduced by selective retention of patients (38,39). Third, intention-to-treat analyses guard against unintentional or intentional bias in the discarding of data

for some patients whose results could potentially adversely affect the outcome of the trial.

Classen et al. (5) reported psychological outcome data for only 102 of the 125 women randomized into the study. Women variously lacked any outcome data because they were too ill to complete questionnaires or they withdrew from the study because of assignment to a control group, not liking the support group, or no reason given. Missing data are common in psychosocial trials with metastatic breast cancer patients. Thus, in other trials examining SEGP, Spiegel, Bloom, and Yalom (40) and Goodwin et al. (36) were able to obtain a complete set of assessments over the year of their intervention from only 52% and 62%, respectively, of the women participating in the study. However, an extraordinary feature of the Classen et al. report is the attention given to post hoc analyses for which the last assessment was removed for any women who died within a year following it. Data points were dropped for 59 women, and 10 women were excluded from analysis altogether because this adjustment removed the only data after baseline available for them. With this adjustment of the data, some positive effects for the intervention were found.

Butler et al. (4) provided a spirited justification for these analyses, arguing that *not* to make such an adjustment risked the Type II error of concluding the intervention was ineffective when it was indeed. Within a year prior to death, there is an increase in distress, regardless of whether patients are receiving an intensive intervention like SEGP, and this can obscure the benefits of the intervention that had been obtained up until that point. However, there are numerous reasons why such reanalysis will produce results that are not clinically useful or that are outright spurious (41). Because we cannot anticipate from baseline data which patients will die, results of such analyses cannot be used to make predictions about who will ultimately benefit from what is known at the outset of an intervention. Moreover, a systematic bias exists in this analytic strategy, in that such censoring of the data resulted in a steeper decline in mood for women in the intervention condition but a reversed slope for the women in the control condition. Apparently, more negative mood scores are removed in the intervention condition, whereas fewer negative mood scores are being removed in the control condition (41).

Antoni et al. (6) and Zakowski et al. (7) opted to analyze data only for patients providing assessments of mood at all time points of their studies. Their results, therefore, do not generalize to the full sample of patients initiating treatment, and exclusion of patients who do provide all assessments is likely to exclude disproportionately patients who received less than a full exposure to treatment or who were less otherwise adherent. Even if equal proportions of patients are dropped from the intervention and control groups, there are likely to be differences in the reasons for missing data from each of the groups that may lead to substantial biases in the data remaining for analysis (41,42). Furthermore, that there are no baseline differences between patients excluded versus retained provides no reassurance that bias has not been introduced, because some differences may not have been measured (such as subsequent exposure to the interven-

tion) and nonsignificant differences in baseline characteristics can still have substantial effects on the outcomes that are achieved (43).

### SUMMARY AND INTEGRATION

We have critically examined three studies from top-tier journals that are associated with claims for the efficacy of psychosocial interventions to reduce distress among cancer patients. We noted how any claims of efficacy depend on violating some basic standards for the reporting and interpreting of clinical trials. If we attempt to use results of such trials to advocate for psychosocial care for cancer patients, we can expect that these standards will be applied. Improvement in the quality of the literature will be facilitated by the requirement that articles being submitted for review be compliant with CONSORT and the likelihood that funding agencies and journals will soon follow the established policy for biomedical clinical trials and require registration of the details of psychosocial trials at their outset. However, for some time, the bulk of available trials will have been conducted and published prior to such reforms, and, anyhow, CONSORT and preregistry of trials still leave lots of opportunities for biased reporting of data as we have identified in the reports we review here. Readers thus need to sharpen and exercise their critical appraisal skills in examining a literature in which basic standards are not consistently enforced.

#### Why Should We Have Expected Positive Results?

Reports of RCTs for psychosocial interventions commonly open with claims about the diagnosis and treatment of cancer being distressing and even traumatic experiences. Yet the patients recruited to the trials we are discussing have not been remarkably distressed. We noted that SEGP attracts women with metastatic cancer whose mood falls within the norms for college students, and Antoni et al. (6) noted that the level of depression in their sample was within expectations for women from the community. Why should we expect efficacy to be demonstrated with patient samples that as a whole are lacking in clinically significant distress? Noting that most studies available for review recruit patients without regard to level of depression and that as a whole this literature provides evidence of, at best, a weak effect for such interventions, Sheard and Maguire (44) concluded that there is thus no evidence that providing psychotherapy to nondepressed patients prevents depression. This finding is consistent with our assessment that the typical cancer patient will not find substantial benefit from interventions of the kind we are reviewing.

A recent study (45) showed that cancer patients at a level of depressive symptoms comparable with what is found among depressed primary care patients benefit from problem-solving therapy, particularly when a significant other is involved in treatment. However, only a small proportion of cancer patients, perhaps 10% or less, would have the level of symptoms required for entry into this study, and an adequately powered study with such a sample would have to draw on a large multisite pool of patients. Although reasonable, such a study would involve a re-

jection of the implicit assumption that guides current psychosocial interventions for distress among cancer patients: All patients need these interventions. Even if a large number of cancer patients do not suffer the level of distress seen in this trial, at least transient distress is common. Would there be a virtue in maintaining regularly scheduled surveillance of cancer patients and intervening when distress develops? One study that adopted such a strategy (46) failed to show a benefit of intervention, probably in large part because so much of such distress resolves on its own in the context of routine care.

#### Beyond Efficacy: Acceptance and Sustainability in the Community

It would seem premature to discuss issues in the dissemination and implementation of interventions that are not convincingly demonstrating efficacy in RCTs. Yet it is nonetheless timely to ask, "Are these the kinds of interventions that would have high uptake and sustained use in the community?" Current standards for reporting the recruitment to clinical trials allow problems in their uptake to be obscured.

Moynihan, Bliss, Davidson, Burchell, and Horwich's (47) point about counseling would seem to apply more generally to psychosocial interventions targeting distress: "We make a plea for caution with regard to the blind faith that counseling will be gratefully received and will be effective despite a dearth of sound evidence" (p. 128). Apparently, breast cancer patients who screen positive for distress are no more interested in counseling than nondistressed breast cancer patients, with only a minority expressing an interest (48). There is rather consistent evidence that cancer patients prefer more support and communication from oncology clinical staff rather than mental health professionals and interventions designed to increase their access to quality, understandable information about their condition and its treatment to counseling and psychotherapy (49–52). Given this apparent strong preference, it might be useful for future RCTs examining psychosocial interventions for distress to compare them to improved access for patients to oncology professionals and tailored information regarding their condition, rather than simply to routine care. Regardless, future research needs to achieve a higher quality in the design, interpretation, and reporting of trials than we have seen heretofore.

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