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Lessons to be Learned from 25 Years of Research Investigating Psychosocial Interventions for Cancer Patients

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Abstract

Conducting rigorous psychosocial intervention research with cancer patients has many challenges including encouraging them to join studies, asking them to engage in interventions or be part of control conditions, and to provide data over follow-up assessments. Here, we highlight valuable insights regarding such challenges provided by investigators studying psychosocial interventions for cancer patients. Handling these skillfully has important implications for the internal and external validity of this research and the ethical treatment of participants. Challenges noted in research reports included in a systematic review of 25 years of research (comprising 488 unique projects) investigating interventions designed to enhance cancer patients' quality of life were compiled. Among the difficulties mentioned was the fact that patients may not feel the need for psychosocial interventions and thus may not be interested in joining an intervention study. Patients who do feel the need for such interventions may be deterred from joining trials by the prospect of being randomized to a non-preferred group; if they do join a trial, participants may be disappointed, drop out, or seek compensatory additional assistance if they are assigned to a control group. Apart from randomization, other aspects of research may be off-putting to participants or potential participants, such as the language of consent forms or the intrusiveness of questions being asked. Potential remedies, such as research awareness interventions, monetary incentives, partnering with cancer support organizations, and using designs that take preferences into account merit consideration and further research inquiry.

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Keywords

neoplasms; patient selection; reproducibility of results; ethics

Conducting rigorous psychosocial intervention research with cancer patients has many challenges. Recruiting cancer patients to join studies, asking them to engage in interventions or to participate in control conditions for the sake of research, and to continue to provide data over the course of follow-up assessments involves planning, organization, skill, sensitivity, and resources, such as personnel and study infrastructure. In a comprehensive systematic review of 25 years of research (comprising 488 unique projects) investigating interventions designed to enhance cancer patients' quality of life, we noted evidence of such challenges¹. For instance, for the 178 projects for which this could be calculated, 27% of eligible participants did not become involved in the research; for the 215 projects for which this could be calculated, the proportion of participants dropping out of treatment was 11%. Investigators did not often monitor or document in their reports additional off-study assistance obtained by participants or contamination of intervention ingredients across treatment groups, so it is difficult to determine their true incidence. However, 14% of the studies reviewed did note that such additional assistance was received and 7% of the multiple-group studies stated that there was some contamination across groups. In coding this large group of study reports, numerous challenges related to the internal and external validity of the research and the ethical treatment of study participants came to light. Because these were often noted only parenthetically in study reports, we highlight here the valuable insights that these challenges provide (see Table 1) and discuss possible strategies for addressing them.

Patient Reluctance to be Part of Psychosocial Intervention Research

Successfully recruiting participants to enroll in studies investigating psychosocial interventions for cancer patients depends upon their perceptions of the value of and their need for psychosocial interventions. For instance, newly diagnosed breast, colorectal, gastric, or prostate cancer patients were invited to join a randomized trial of an individual psychological support intervention². Twenty-five percent of decliners reported that they had no need for any psychosocial intervention. Conversely, some participants have noted that their willingness to be involved in a study was rooted only in a desire to help others in a similar situation, but they had no need for psychotherapy themselves³. Evidence suggests that most cancer patients do not make use of psychosocial resources naturalistically. For instance, a survey of women with breast cancer listed in a tumor registry indicated that 82% were not currently in or had ever participated in any type of cancer support program⁴. Some study reports have noted low patient enthusiasm for psychosocial interventions when provided. In a trial of psychological therapy for patients with testicular cancer, recruitment was stopped after 2.5 years because of the low numbers agreeing to participate⁵. Whereas 16% refused completely, 44% of those approached were willing only to complete assessments but not to participate in the specific intervention offered, indicating that it was not the research *per se* to which they were adverse. The authors noted that early-stage outpatients, who refused at higher rates than did later-stage inpatients, may have been reassured by their good prognosis and, thus, were reluctant to make additional trips to the hospital. Other authors have noted the relatively small proportion of patients who choose to attend available hospital support programs, but maintain that this lack of interest may be due to misconceptions about the interventions offered and lack of knowledge about the benefits they might provide⁶. Regardless of whether or not patients' perception of lack of need for or interest in psychosocial interventions is realistic, the unwillingness of many cancer patients to participate in psychosocial interventions makes enrollment of study samples difficult.

Successful recruitment to studies of psychosocial interventions also depends on participants' feelings about and willingness to be involved in a research project. Reluctance to participate in research when in the throes of facing a life-threatening illness is, of course, understandable ⁷. In a study noted above ², 25% of those approached declined to participate, and 11% of these specified that they did not want to be involved in research. Other studies have reported low uptake rates (e.g., 33%, ⁸, with one multisite trial of psychosocial support for women with metastatic breast cancer randomizing fewer than 9% of patients who were eligible ⁹. Quite likely, rates of uptake in research depend upon patient demographic, psychological, and disease characteristics. For instance, we noted in our review that fewer than 5% of interventions included patients that were in the palliation stage of treatment ¹, and this may likely be related to the challenges of working with dying patients. However, some researchers have noted the feasibility of recruiting even very ill, metastatic cancer patients ¹⁰.

Research uptake may also be determined by aspects of study procedures. For example, the inquiries of some investigators may be perceived as intrusive, especially by patients for whom diagnosis and treatment already have resulted in a sense of a lack of control and a lowering of self-esteem. Of 101 men with prostate cancer who refused to take part in a study of an intervention to enhance communication between patients about to undergo radical prostatectomy and their medical providers and partners, 12% mentioned that they found the study questionnaire too personal ¹¹. Similarly, the wording of consent forms has been noted as a problem arising in recruitment to cancer supportive care trials ¹². Investigators may not be aware that such rituals of the research process, taken for granted and well-understood by researchers, can provoke discomfort and represent barriers to successful recruitment.

The majority of studies in this area use randomized trial study designs ¹. Although this methodology is rigorous from the perspective of establishing group equivalence and controlling for self-selection factors (which do seem to operate when patients can choose an active as opposed to a control treatment ¹³), it may elicit reluctance from potential participants. Some evidence documents that dislike of randomization is a barrier to enrollment in cancer clinical trials in general ¹⁴. Goodwin et al. (2000) noted in their trial that, as the availability of support groups outside the study and awareness of their potential benefits increased, potential participants were less amenable to being randomized, potentially to a control group. This difficulty has been mentioned by other investigators ¹⁵. Although from the investigators' perspective, the off-study support groups were not offering the same type of therapy, were not therapist-led, or long-term, the off-study support groups seemed to be perceived by patients to be of similar value, and thus represented attractive competitors ¹⁰.

Participant Disappointment Regarding Treatment Group Assignment

Although a proportion of studies investigating psychosocial interventions for cancer patients examine a single type of treatment and conduct pre- and post-treatment assessments of functioning, the majority are multiple-group studies that contrast active treatments to a control condition or compare two types of treatment (e.g., these made up 74% of the investigations in our prior review, Moyer et al., in press). A large proportion of these (e.g., 66% in our prior review) use control conditions that involve no treatment, treatment as usual, or a wait-list condition that has the option of receiving the active treatment after the study is complete. Not surprisingly, these contrasted conditions may be differentially attractive to participants. In a trial of a complementary/alternative medicine (CAM) therapy-oriented intervention versus a standard therapy control group, potential participants were drawn to the study because of an interest in CAM and were not interested in participating in the standard therapy ¹⁶. In an investigation that compared the effectiveness of a cognitive-

behavior therapy intervention to a no-therapy control condition in metastatic breast cancer patients 17, some participants, understandably, registered disappointment at having been randomized to the control group. Other authors have noted similar reactions 15, some despite diligent pilot work to develop a preparation and debriefing protocol for the randomization procedure 18. Conversely, other authors noted that they randomized participants to the intervention and control groups on a 3:1 ratio because they expected refusals to participate in their group intervention (a behavioral intervention for newly diagnosed cancer patients) to be particularly high 19. This was explained by noting that in Israel, where the study was conducted, receiving psychotherapy carried a stigma, especially among those with medical conditions. In a study that compared a coping skills intervention for cancer patients delivered in an individual versus a group format some participants were reluctantly assigned to the group format 8. These individuals then attended the intervention meetings only sporadically, compromising the group processes and jeopardizing the successful completion of the trial.

Some authors have noted effects on study outcomes that may result from such potential “resentful demoralization,” or negative reactions to being assigned to a non-preferred condition 20. During a randomized clinical trial of a mindfulness-based stress reduction (MBSR) program versus freely-chosen stress management activities for women with breast cancer, participants unintentionally learned their group assignment prior to completing baseline assessments 21. Although the groups were similar in terms of demographic and health status variables, those assigned to the MBSR condition had superior depression, trait anxiety, quality of life, sense of coherence, and sense of control scores. This pattern suggested that the differences in psychological variables were the result of participants’ awareness of their group assignment and their expectations about it. Conversely, results from another randomized trial of a cancer rehabilitation program that emphasized physical training, information, and coping skills did not find any evidence that potential reactions to being assigned to control groups influenced any of the outcome variables 22. In this trial, non-participants (who did agree to complete assessments) reported lower levels of most problems at baseline compared to participants, potentially indicating a reduced level of need for the intervention. Relative to these non-participants, control participants did not show differences in the proportion improving or deteriorating over time on three variables believed to be particularly sensitive to resentful demoralization: depressive symptoms, fighting spirit, and quality of life. Finally, other authors noted difficulty in obtaining full data from members of their control group in which they had higher numbers refuse to have a blood draw, perhaps because these participants felt that they were not receiving anything in return for being in the study 23.

When participants are disappointed with their group assignment they may be motivated to try to gain access elsewhere to the assistance that they hoped to obtain by joining the trial. Although this compensatory behavior may reduce the likelihood of identifying a true intervention effect and cloud the results of the study 22, it is an understandable response on the part of participants. Furthermore, it may be viewed as unethical in some situations to try to prevent this type of help-seeking. Some investigators noted that their institutional ethics committee required that participants assigned to control conditions be specifically made aware of other resources that they could access outside the study 17.

Treatment contamination, whereby participants assigned to control conditions gain access to active ingredients of the treatment under study, appears to be particularly common in trials of exercise interventions for cancer patients 24–26. Other examples of contamination included control group participants joining an outside support group in a trial of two types of group psychosocial support 27; control group participants keeping track of side effects, when monitoring side effects was part of the experimental intervention 28; a control participant

obtaining a commercially-produced guided imagery tape in a study testing a version of such tapes 29; control participants obtaining copies of a publicly-available videotape that was part of an intervention 30; and a participant assigned to standard care in a study of a computer-based nursing intervention enlisting the assistance of a clinical oncology nurse specialist after querying those who were receiving it 7. Occasionally, treatment contamination resulted from compassionate responses on the part of investigators; in a trial of psychotherapeutic support for gastrointestinal cancer patients undergoing surgery, a proportion of the control group (25%) requested that they be transferred to the experimental group and the investigators complied 31. It would seem that contamination is most likely when the treatment under study is one that may be easily accessed or approximated outside the study, such as exercise.

As more evidence accumulates about the usefulness of psychosocial interventions for cancer patients, and more patients join trials in the hope of gaining access to treatment, the use of no-treatment control groups has become ethically objectionable. In other areas of investigation, for instance, evaluations of treatment of alcohol use disorders, no-treatment control groups (in non-drug studies) are used fairly infrequently 32. However, designing appropriate attention-placebo conditions for behavioral interventions may be challenging. A study that used a 30-minute “chat” about issues unrelated to patients’ illness to control for the attention of a brief psychotherapeutic intervention found that it appeared to have some therapeutic value 33-34. Similarly, meeting repeatedly with an empathetic research assistant over the course of data collection unintentionally led some participants to report that they felt as if they had received an intervention 8. Finally, the authors of a trial of an educational intervention for newly-diagnosed cancer patients about to undergo radiotherapy concluded that although there was a significant effect on depression, that, because knowledge scores were not affected, that this effect was likely a non-specific effect of attention 35. Because of the recognized importance of social support to cancer patients 36, investigators are compelled to walk the fine line of providing supportive interactions to their research participants in the context of their participation in a trial while still creating distinct interventions with unique supportive components. Because of the particular importance of educational support to cancer patients 36, it is likely, however, that warmth and attention from research staff can be successfully distinguished from elements of support that are particularly relevant to the cancer experience.

Lack of Participant Adherence to Psychosocial Interventions

Psychosocial interventions vary in the amount of involvement and active participation that they require on the part of cancer patients. Whereas educational interventions entail very little, support groups involve much more emotional investment and effort, and psychotherapy may demand deeper self exploration 37. Similarly, patients vary greatly in the extent to which they are willing to become deeply involved in interventions and become engaged in psychological self-help work 38, 39, with some study participants actually showing resistance to it 8. In a computer-mediated social support group for women with breast cancer, 46% actively participated and wrote 4 or more messages whereas 54% did not actively participate and wrote 3 or fewer messages 40. In terms of predictors of level of participation, race and stage of cancer did not differentiate those who decided to actively participate from those who did not. For the active participants, 18 demographic, health, attitude, and social variables were explored as moderators. Those moderators that proved to be significant predictors of the number of words written were being Caucasian and having a higher energy level. In another study, adherence to exercise in trials was predicted by being male, level of extraversion, perceived control over ability to exercise, and normative beliefs about social network members’ support for regular exercise 41.

Cancer patients in trials of psychosocial interventions have also been noted to deliberately engage in other activities that may be helpful to them. Examples of additional assistance included support groups provided outside of the study^{9, 42, 43}; professional counseling or psychotherapy^{44, 45}; antidepressant medications, meditation, yoga⁴⁶; antianxiety medications⁴⁷; CAM techniques^{48–50}; exercise¹⁸; church groups⁵¹; breathing exercises, relaxation tapes⁵²; prayer⁵³; radio programs, television programs, and books⁵⁴; the internet⁵⁵; initiating additional contact among group members⁴⁴; and support received from members of patients' medical team^{3, 56}.

In some cases, additional assistance has, counter-intuitively, been found to be accessed more by intervention participants than by control participants. For instance, in a study examining a group psychotherapeutic intervention delivered as group conference call versus usual psychosocial care, no attempt was made to limit the control group members' access to supportive resources available in the community or through national organizations⁵⁷. The intervention participants used significantly more outside services (i.e., support groups, retreats, educational programs, booklets, and videos) than did control participants and rated the value of these outside services as significantly higher. It may be that the type of person who joins such a trial is also the type of person who would be likely to seek out numerous forms of assistance.

Furthermore, participants may drop out of treatment altogether. A study that examined predictors of completing a 12-week, twice-weekly structured exercise program found that participants completing the program were older, had completed treatment as opposed to still being in treatment, and had early-stage as opposed to later-stage cancer⁵⁸. In this study, one-quarter of the sample did not complete the program, giving reasons such as treatment side effects and work or personal factors. Another study that reported a 20% attrition rate from an electronic support group for women with breast cancer found that those who dropped out were less able to cope with anxiety, had higher levels of fatalism, less pain interference, and less posttraumatic growth⁵⁹. Dropout is problematic in and of itself, but when there is differential dropout from intervention and control groups this introduces the possibility of bias. For instance, in one study, when participants learned that they were assigned to the control group, 25% of them dropped out⁶⁰. Conversely, a study of an 18-week computer-based symptom management nursing intervention focused on symptom management, noted that 13 of 55 patient/caregiver dyads dropped out of the intervention condition because it took too much time⁷.

Participant Drop-Out of Follow-up Assessments

Missing follow-up data, especially when it is missing in non-random ways, can be problematic for interpretation of results. For example, some authors report differential follow-up rates from intervention and control conditions⁶¹, but further bias can be introduced if such differential group dropout is related to participant characteristics. The true effect of an intervention could be diminished or reversed if, for instance, distressed patients in the intervention group feel obliged to participate in follow-up assessments whereas distressed patients in the control group feel less obliged to do so⁶². A pattern of findings supporting this notion was documented in a study of home visits for patients with colorectal cancer⁶³. A marginally significant interaction between level of anxiety and intervention group and non-response on subsequent follow-up⁶² indicated that those who were more anxious were more likely to complete follow-ups.

Practical and Logistical Difficulties

A significant proportion, about one-third, of the research evaluating psychosocial interventions for cancer patients involves treatment delivered in group formats¹.

Interventions delivered in groups of other patients are thought to be particularly useful in that they can normalize the experience of cancer⁶⁴, reduce isolation⁶⁵, and make use of helpful psychological processes such as social comparison, informational and emotional social support, and the helper therapy principle, whereby individuals gain from assisting others⁶⁶. Forming groups of patients, however, has logistical challenges. Some authors have noted that in order to accrue participants rapidly enough to fill groups they needed to randomize participants in a ratio of 2:1 to intervention and control groups, necessitating an increase in total sample size; similarly, smaller participating centers in their multi-site trial could not recruit enough participants to fill groups¹⁰. Such delays can result in loss of potential participants due to incapacitation as time passes¹⁸. Conducting research with ill populations also means that some participants be lost due to morbidity or death (e.g.,⁷). The content of the intervention may also be affected by this. Some authors have noted that death of members in some but not all of the groups meant that the content of the discussions were quite different across them¹⁸. Physical deterioration due to advancing illness may also affect psychosocial outcomes. In a trial of supportive-expressive group therapy for women with metastatic breast cancer, there was a significant increase in levels of pain and distress documented in the last assessment before death⁶⁷ which may introduce some bias irrespective of condition.

Investigations of behavioral interventions share many of the challenges of investigations medical interventions such as selective enrollment, lack of engagement in treatment, and drop out and loss to follow-up, however some challenges are unique to trials of behavioral interventions, such as the inability to blind participants and treatment providers to treatment, the more prominent influence of treatment provider-participant relationship factors, and the challenge of designing credible control conditions⁶⁸. These aspects mean that researchers in this area need to be particularly creative, thoughtful, and resourceful; below we discuss some potential ways to address these challenges.

Potential Remedies

Some preliminary work has begun to try to increase the awareness of research trials in cancer patients and decrease misconceptions about them. These efforts have taken the form of sending a letter to all patients letting them know that offering a clinical trial was the norm and that standard care was always available⁶⁹ and a series of media products that conveyed a message of hope and put a human face on clinical research⁷⁰. Monetary incentives are another potential means of addressing reluctance to participate in psychosocial intervention research, as well as improving adherence⁷¹. In this area of investigation providing incentives for participation is a strategy that has not been commonly used in the past, prompting some researchers, who have had difficulty recruiting participants, to suggest that they are something that researchers conducting psychosocial intervention research with cancer patients should consider²³. One study of a psychoeducational group intervention for African American breast cancer patients offered financial compensation for attending group meetings (with control participants receiving the same amount of money as those who attended all meetings), for completing assessments, and to cover the cost of transportation. The study had a good recruitment rate (63%) and an 86% follow-up rate with the assessment 12-months following the intervention⁷². Financial incentives are common in other areas of research, potential participants (e.g., in genetic research) report that they are motivating⁷³, and even fairly large incentives have been shown to effectively increase the representativeness of follow-up data while not inducing participant perceptions of coercion⁷⁴. Future research should directly investigate the role that incentives might play in recruitment and retention in trials of psychosocial interventions for cancer.

Because preferences for one type of treatment versus another appear to have important effects, it may be important to include assessments of such preferences and their potential effects on trial outcomes. As an example, one study of two types of exercise versus usual care found that although 23% of their sample had no preference, 41% preferred the resistance exercise training whereas 36% preferred the aerobic exercise training⁷⁵. Participants who preferred resistance exercise training had improved quality of life when they were assigned to that treatment rather than to usual care or aerobic exercise training and those who had no preference had improved quality of life when they were assigned to aerobic exercise training compared with resistance exercise. In behavioral weight-loss trials, for instance, extensive orientation using motivational interviewing techniques prior to randomization have been successful in helping potential participants understand the reasons for alternative trial conditions and reducing attrition⁷⁶. Alternatively, research designs that take preferences into account when assigning participants to groups, and appropriate methods to analyze them, have also been developed^{77–81}.

Competition from off-study resources, which can affect study recruitment and contamination, speaks to the notion that cancer patients are motivated to seek out resources that may be helpful to them. Potential participants may not be aware of the differences in the type of interventions offered by cancer support organizations and research studies. Thus it may be valuable for investigators, where possible, to note to potential participants how the interventions being evaluated in their trials may be distinct from those offered by cancer support organizations. At the same time, because cancer support organizations provide numerous valuable services to cancer patients,⁸² and often are familiar to and respected by the public, partnering with them may be a valuable strategy for researchers. The California Breast Cancer Research Program Community Research Collaboration award, which supports scientific research of community-based ideas in the area of breast cancer⁸³, and The National Center on Minority Health and Health Disparities Community-Based Participatory Research Initiative⁸⁴ are some examples of funding mechanisms that create synergy between academic expertise and community experience. Similarly, shifting the focus to implementing interventions that have already been shown to be effective rather than re-evaluating them would be valuable.

In an example of an intervention funded by one of these awards, a community-initiated, theoretically-based workbook-journal was designed as an alternative to a face-to-face support group for isolated rural women with breast cancer⁵⁵. It was created and evaluated by a partnership of researchers, a group of rural women with breast cancer, and medical and social work professionals. The input of the community partners revealed that the required language for the consent form outlining risks and benefits would be off-putting to potential participants and led to ways to make the consent forms more appealing (changing font, using color, using the term “participant” instead of “subject”). This type of collaboration will likely be fruitful in developing study procedures that are sensitive to participants’ point of view.

Similarly, more input from cancer patients and potential research participants is essential. Research participants in general are seldom asked about their experience of participation⁸⁵. Thus, focus groups or research querying patients themselves about the types, formats, structure, timing, and ingredients of interventions and trials could be extremely valuable, especially prior to embarking on a proposed trial. For instance, in one survey of a large group of patients with various cancer types, participants noted that they preferred to be involved in an intervention immediately after diagnosis, that obtaining medical information was an important goal, that a drop-in format was desirable, compared to the closed membership format with a predetermined duration typically provided in intervention studies, and the inclusion of spiritual components, not often included in interventions designed by

researchers, was welcomed⁸⁶. A focus on patients' perspectives is related to the suggestion to borrow insights from the field of marketing, such as better understanding what people in a market segment value and conveying persuasively the value proposition to them, in the development and conduct of clinical trials⁸⁷. Such feedback will help ensure that researchers are developing useful and appropriate psychosocial interventions for cancer patients and delivering them in the most acceptable way.

Some researchers have begun to try to predict contamination, with an eye toward developing strategies to avoid it. For instance, one study examined which participants are more likely to engage in physical activity when assigned to the control condition of an exercise trial. Past exercise, being male, and exercise intentions assessed before learning group assignment predicted level of exercise engaged in during the trial⁴¹. This finding led to the simple recommendation to minimize potential contamination by screening out regular exercisers from such trials. Some investigators have attempted to reduce contamination by downplaying the potential benefits of the intervention; this may not be feasible or realistic in all studies. One study that examined the therapeutic effects of a structured interview designed to enhance coping, optimism, and health-related quality of life wished to avoid control group participants perceiving the intervention as desirable and trying to reproduce it on their own⁸⁸. Thus, the investigators simply presented the interview as a means to investigate the experiences of women with breast cancer during and after chemotherapy, rather than as an intervention.

Wait-list procedures, whereby participants assigned to control conditions are given access to the active treatment at a later point, may mitigate problems with disappointment with being assigned to a control condition. Participants seem to welcome the opportunity to have access to the treatment later. One study of an intervention designed to improve patient recall of diagnostic information audiotaped cancer patients' initial consultations with their oncologist and provided the tapes only to those in the experimental condition initially⁸⁹. The authors noted that, even 3 months later, 77% of those in the control condition were interested in receiving the audiotape. Similarly, 89% of patients in the control condition of a study of a preparatory booklet for radiation therapy wished to receive a copy when they were later offered it⁹⁰. However, in trials of exercise programs for cancer patients where control participants are instructed not to embark on a structured exercise program and assured that when the trial is complete they would be given a personalized exercise prescription just like the experimental condition, levels of contamination have still been moderate^{25, 41}. Also, it is important to note that wait list procedures may be inappropriate or unethical, given that cancer patients may need particular types of assistance offered by an intervention under study at particular points in their treatment trajectory (e.g., decision assistance when treatment planning is occurring), that short-term psychological adjustment predicts long-term adjustment⁹¹, and participants themselves prefer early intervention⁸⁶. Thus, it seems prudent to monitor and report this type of additional activity, particularly in cases where there may be ethical problems in restricting it, or where it may be difficult to control access to the active ingredients of treatment.

Designing appropriate control treatments for behavioral intervention trials is challenging compared to medical interventions because it is difficult to create a treatment that is considered to be inactive (or have some inactive ingredients), but is still a credible intervention to participants^{68, 92}. Some authors suggest that whether this has been successful can be monitored by assessing participant expectations of benefits, monitoring process of change variables, and documenting differential dropout rates⁶⁸.

Conclusion

Difficulties encountered in prior work provide lessons for issues to consider when designing and planning future studies investigating psychosocial interventions for cancer patients. Investigators should be aware that patients may not feel the need for psychosocial interventions and thus may not be interested in joining a study. Those who do feel the need for such interventions may be deterred from joining trials by the prospect of being randomized to a control group; those assigned to a control group may be disappointed, drop out, or engage in compensatory additional assistance. Other aspects of research may give participants pause, such as the legal language used in consent forms, or the intrusiveness of the questions being asked of them. The extent to which a sample is representative of the population to which it is intended to draw conclusions has relevance for its external validity: the degree to which results from a study are generalizable. As such, addressing reluctance of cancer patients to join and remain in intervention research is critical. Participant disappointment with their treatment group assignment, and subsequent contamination or lack of adherence, has important implications for the internal validity of this research: the degree to which the results represent the phenomenon under study, and should also be the focus of attention. Similarly, study procedures or the wording of study materials that are viewed as off-putting or intrusive by research participants should motivate investigators to develop more acceptable methods. The challenges noted here are certainly not unique to psycho-oncology, as difficulties related to recruitment, reactance, and retention may be found in any area of research⁹³. For instance, in a survey of 114 multicenter clinical trials, less than one-third recruited their target sample size within the time originally specified, and around one-third required extensions to do so⁹⁴. Potential strategies to address these challenges may include research awareness interventions, incentives, partnering with community organizations, special efforts to inform participants about the rationale of research methodology, alternative research designs, and assessing and monitoring preferences, additional assistance, and contamination. Finally, as the challenges noted here were largely not the focus of inquiry, research directed intentionally to study challenges related to recruitment, reactions to treatment assignment, treatment engagement, and retention and potential strategies to address them is encouraged to provide further insights regarding improving the rigor of this work.

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Table 1

Challenges of Conducting Psychosocial Interventions Research with Cancer Patients Related to Recruitment, Reactivity, and Retention.

Patient Reluctance to be Part of Psychosocial Intervention Research	Participant Disappointment Regarding their Study Group Assignment	Lack of Adherence to Treatment and Study Drop Out
Perceptions of the value of psychosocial interventions	Adverse psychological reactions	Burdens and demands of treatment
Perceptions of their need for psychosocial interventions	Low engagement in treatment	Engaging in additional potentially therapeutic activities
Feelings about being involved in research and reactions to research procedures	Efforts to gain access to assistance offered in comparison group elsewhere	Non-randomly missing follow-up data
Aversion to being randomly assigned to a treatment group		