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RCT of a Psychological Intervention for Patients With Cancer: I. Mechanisms of Change

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Abstract

Little is known about the therapeutic processes contributing to efficacy of psychological interventions for patients with cancer. Data from a randomized clinical trial yielding robust biobehavioral and health effects (B. L. Andersen et al., 2004, 2007) were used to examine associations between process variables, treatment utilization, and outcomes. Novel findings emerged. Patients were highly satisfied with the treatment, but their higher levels of felt support (group cohesion) covaried with lower distress and fewer symptoms. Also, specific. treatment strategies were associated with specific outcomes, including lower distress, improved dietary habits, reduced symptomatology, and higher chemotherapy dose intensity. These data provide a comprehensive test of multiple therapeutic processes and mechanisms for biobehavioral change with an intervention including both intensive and maintenance phases.

Keywords

process; therapy; cancer; compliance; dose intensity

Psychological interventions for patients with cancer are largely effective in reducing the many burdens and sequelae of the disease and treatment. Interventions can improve emotional adjustment and quality of life, with selected demonstrations of positive health and immune outcomes (Andersen, 2002; Meyer & Mark, 1995). Despite this, little is known about the therapeutic events or processes that lead to or are responsible for therapeutic change and the durability of such change. Kazdin (2006) noted that evaluating mechanisms is important for many reasons. Data on mechanisms can bring order to the variety of treatments available, provide explanations of the broad effects of therapy, enhance translation of treatments to clinical practice, assist in the identification of treatment moderators, and facilitate understanding of therapeutic change. We discuss the influence of process variables–satisfaction with the treatment and feelings of cohesion–and the relationship between utilization of intervention techniques and treatment outcomes. Necessarily, we also draw on the psychotherapy outcome research literature.

Patient satisfaction with treatment is a singularly important goal, but it may also be important because it is influential to patients' involvement intreatment (Dearing, Barrick, Dermen, &

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Walitzer, 2005) and, in turn, treatment efficacy. For group psychotherapy patients, treatment satisfaction has been associated with willingness to participate (Perrone & Sedlacek, 2000). It is important to note that studies with both psychotherapy and primary care outpatients have identified associations between satisfaction and adherence, including appointment keeping (Dearing et al., 2005), compliance with treatment recommendations (Hirsh et al., 2005), and medication use (Barfod et al., 2005). When asked, patients with cancer are typically satisfied with what psychological interventions have to offer (Petersson, Berglund, Brodin, Glimelius, & Sjoden, 2000; Manne et al., 2007). More specific questions have found that, among interventions that included relaxation, it was the component rated as most helpful; also highly rated has been provision of information about cancer, treatments, and side effects (Berglund, Petersson, Eriksson, & Haggman, 2003; Petersson et al., 2000).

According to Yalom (1995), the single most important component of effective group therapy is cohesion–the bonding, collaborative, working alliance among members (Burlingame, Fuhrimarn, & Johnson, 2002). In psychotherapy, the effects of cohesion are robust, and it is positively associated with attendance and involvement (Marmarosh, Holtz, & Schottenbauer, 2005; McCallum, Piper, Ogrodniczuk, & Joyce, 2002). Moreover, the association of cohesion with short-term outcomes is clear and has been found for a wide range of patients (e.g., Van Andel, Erdman, Karsdorp, Appels, & Trijsburg, 2003), psychiatric disorders (e.g., Marziali, Munroe-Blum, & McClearly, 1997), and clinical problems (e.g., Taft, Murphy, King, Musser, & DeDeyn, 2003). In addition, some data suggest that cohesion can predict outcomes after groups have ended (Taft et al., 2003). While it has been discussed (Midtgaard, Rorth, Stelter, & Adamsen, 2006), cohesion has not been studied in cancer interventions.

Regarding use of treatment techniques, it is logical (and usually assumed) that patients who use intervention strategies have better outcomes, and in many forms of psychotherapy they do (Taft et al., 2003). Cancer intervention studies have not examined this relationship, but some have taken the first step and assessed utilization (e.g., Larsson & Starrin, 1992). It is not known whether differential levels of utilization impact outcomes, either at treatment's end or thereafter.

In summary, review of the literature suggests that examining the factors associated with positive treatment outcomes can advance cancer intervention research. In this article, we provide one such study. An ongoing randomized clinical trial, the Stress and Immunity Breast Cancer Project (SIBCP), tests the hypothesis that a psychological intervention can impact disease endpoints, with intermediate outcomes including psychological, behavioral, biologic, and health status measures (see Andersen, Kiecolt-Glaser, & Glaser, 1994). Patients with breast cancer were randomized to intervention and assessment or assessment-only conditions. An atypical research design feature was that the intervention was conducted in two phases. As with other trials, there was a phase of weekly sessions (intensive phase). However, this was followed by monthly sessions (maintenance phase) that were designed to promote patients' sustained use of the intervention components and continue change. Outcome data show that the intervention arm patients had significant gains at the end of both the intensive (Andersen et al., 2004) and the maintenance phases (Andersen et al., 2007). In particular, reductions in emotional distress, increases in social support from family members, improved dietary behaviors, reduced variability in chemotherapy dose, improved immunity, fewer symptoms and signs, and higher functional status were achieved. With robust effects, the trial provides an opportunity to study mechanisms of change. Consistent with recommendations for process research (Kazdin, 2006), the trial includes multiple process assessments, conducts process assessments prior to outcomes, tests more than one mechanism for each outcome, tests for a gradient of change, and, finally, includes a conceptualization for the selection of mechanisms. In addition, the repeated posttreatment assessments provide for an examination of the impact of process and treatment utilization variables across time, and in this case, time corresponded to the different phases of the intervention.

Method

Participants

Descriptions of accrual are available (Andersen et al., 2004, 2007). The study was in compliance with the Ohio State University and Comprehensive Cancer Center institutional review boards. Following informed consent, an initial assessment included psychological and behavioral data, a research nurse evaluated physical functioning, and a 60-mL blood sample was drawn. Patients (N = 227) had Stage II (90%) or Stage III (10%) breast cancer treated with segmental (57%) or modified radical mastectomy (43%). Participants ranged in age from 28 to 84 years (M = 50.82, SD = 10.76), and the majority (74%) had a spouse or partner. The sample was predominantly Caucasian (90%; African American = 9%, Hispanic = 1%). The distribution for education was 28% with at least some high school, 47% with some college or a college degree, and 25% with some postgraduate education. Most participants (67%) were employed at least part time; annual household incomes were as follows: less than $15,000 1= 0%, $15,000−29,000 = 16%, $30,000−49,000 = 22%, $50,000−79,000 = 23%, and $80,000 or more = 29%.

Patients were randomized to assessment-only (n = 113) or intervention plus assessment (n = 114) study arms (for the CONSORT flowchart, see Figure 1). There were no significant differences between arms in sociodemographic, disease, or prognostic factors; type of surgery received; or adjuvant treatments planned (all ps > .23). As only data from the intervention arm are examined in this article, the assessment-only group is not discussed further. In addition to the psychological intervention, adjuvant therapy followed randomization. From the initial assessment to 4 months, 83% of participants received chemotherapy, and 43% received radiotherapy. From 4 to 8 months, the rates were 17% and 22%, respectively. From 8 to 12 months, the rates were 0% and 4%, respectively.

Intervention

A biobehavioral conceptualization (Andersen et al., 1994) guided selection of intervention targets. For each, specific intervention components (strategies and techniques) were used, and corresponding utilization and outcome measures were selected (see Table 1), providing the specification for the analyses below. (Note that immunity was included in the model as. a potential mechanism for health and disease effects but was notan intervention target per se.)

As previously described, the intervention was provided in small (8 to 12 patients) cohorts or groups (n = 13) led by two of three clinical psychologists (two with a doctorate and one with a master's degree) who had 20, 10, and 2 years of experience, respectively. Sessions were 1.5 hr, with an intensive phase of, 18 weekly sessions during the first 4 months and then a maintenance phase of 8 monthly sessions, for a total of 26 sessions (39 therapy hours) over 12 months. A procedure was used to reduce variability in treatment dose across patients. If a patient was absent, the lead therapist called her within 3 days to discuss the- week's topic, assign any homework, and provide support; handouts were mailed or faxed. Attendance was recorded as 0 = absent or 1 = present or completing phone session. Cohorts did not differ in attendance (p > .20). To reduce variability between cohorts and ensure treatment fidelity, therapists followed a session-by-session manual, and patients received a companion manual. Therapists met prior to the sessions to review the day's topics. Equivalence of content was monitored with videotapes and evaluated with patient ratings. Patient ratings of satisfaction and cohesion were completed at the end of the intensive phase: (4 months). Treatment utilization measures were completed at 4, 8, and 12 months.

Table 1 lists the intervention components and corresponding session numbers for their coverage. It was during the intensive period that the needs of patients were greatest and their

physical status the poorest, as the majority (83%) were receiving adjuvant cancer treatment. For the maintenance phase, components were reviewed, patients set goals for use of intervention strategies, behavior change was evaluated, and new goals for the coming month were made. By 8 months only 22% of the patients continued cancer treatments, and by 12 months therapies for virtually all (96%) were completed. Thus, during the maintenance phase patients were completing cancer treatments, beginning recovery, and resuming activities.

Measures

Process

Satisfaction—Participants rated each intervention component using a 4-point Likert scale ranging from 1 = *not at all helpful* to 4 = *very helpful*. We conducted an exploratory factor analysis to determine whether a total score could be used. Examination of the scree plot, stability of factor loadings, and coefficient alphas suggested a single factor solution (root-mean-square error of approximation = .076). Thus, items were combined and averaged for a total score as well as examined individually. Coefficient alpha reliability was 76.

Group cohesion—Survey of the literature suggested two items: “How involved did yo' become in this group experience?” and “How supported by this group did you feel?” Participants rated each using an 11-point Likert scale ranging from 0 = *not at all* to 10 = *extremely*. The correlation between the two items was 61; they were averaged for a total score.

Utilization of Intervention Techniques—Intervention components were paired with at least one utilization measure, and utilization measures were.paired with at least one outcome (see Table 1). Pairings corresponded directly (e.g., relaxation training paired with frequency of relaxation) or were empirically based (e.g., strategies for increasing activity and symptoms or signs). For each, utilization during the last month (e.g., “How often have you done relaxation training?”) was rated on a 9-point scale ranging from 0 = *not at all* to 8 = *two or more times a day/all the time*.

Outcomes—Measures have been previously detailed with supporting reliability/validity data.

Emotional distress—The Profile of Mood States (POMS; Mc-Nair, Lorr, & Droppleman, 1971) assesses negative mood. A Total Mood Disturbance (TMD) score was used.

Social adjustment—The Perceived Social Support Scale for Family (PSS Family; Procidano & Heller, 1983) assesses need for and perception of receiving support.

Dietary patterns—The Food Habits Questionnaire (Kristal, Shattuck, Henry, & Fowler, 1990) assesses dietary choices and eating patterns. A total score is used.

Physical activity—A 7-day report of physical activity (Blair et al., 1985) indexed energy expenditure.

Physical functioning—A clinical nurse specialist assessed the patient and completed two measures. First, The Karnofsky Performance Status Scale (KPS; Karnofsky & Burchenal, 1949) evaluates patients' functional status using an 11-point scale ranging from 100 (*normal, no complaints, no evidence of disease*) to 0 (*dead*). Second, items for symptoms, signs, illnesses, lab values, exam findings, and so on (Sym/S) came from the same measure used by the Southwest Oncology Collaborative Group in their clinical trials (1994 version; detailed in Andersen et al., 2007). Items are grouped within 22 body categories, with four to six items in

each category, all rated on a 4-point-toxicity severity scale. Items were averaged for a total score.

Chemotherapy dose intensity—Relative dose intensity for each chemotherapy drug that a patient was receiving was calculated on the basis of pharmacy records (see Hryniuk, 1988, for procedures). The primary agents were doxorubicin (Adriamycin), cyclophosphamide (Cytoxan), and the taxanes (Taxol, Paclitaxel, Taxotere).

Results

Retention was 93% (106 of 114) at 12 months; 4 patients recurred or died, and 4 dropped out of the trial. Of the 106, 14 patients (12%) were intervention dropouts (most attended only one or two sessions, so process data were not available), but they remained in the trial and continued assessments. The 92 (81% of 114) patients receiving the intervention participated in an average of 22 of 26 sessions (85%), 14 (*SD* = 6) of the 18 intensive sessions and 6 (*SD* = 3) of the 8 maintenance sessions. Five participants did.not have utilization data because of delay in implementing the process measures and had to be excluded, which resulted in analyses with 87 patients. Preliminary analyses indicated there were no significant differences between cohorts of the intervention on any of the process, utilization,. or outcome measures described above (all *ps* > .40). Nevertheless, cohort was included as a control.

Descriptive Data and Analyses Testing Processes and Outcomes

In general, patients were very satisfied with the intervention content (*M* = 3.52, with 4 being highest, *SD* = 0.36; see Table 2). The topics receiving the highest ratings (data not shown) were dietary information (*M* 3.90, *SD* = 0.36), relaxation (*M* = 3.70, *SD* = 0.58), and the stress conceptualization (*M* = 3.7, *SD* = 0;60). Even the topic with the lowest rating (communication with medical providers; *M* = 3.3, *SD* = 0.57) had a *moderately satisfied* rating. As evidenced by the Cohesion score (*M* = 7.8, with 10 being highest), women reported high involvement and reciprocated feelings of support. Patients' overall satisfaction with the intervention was significantly associated (*r* = .45), but did not overlap, with feelings of group cohesion.

As robust effects of both satisfaction and cohesion on outcomes have been reported in the psychotherapy literature, all were tested. Longitudinal hierarchical linear modeling (HLM; Raudenbush & Bryk, 2002) was used. HLM involves two levels. At the within-subject level, the outcome varies within participants over time as a function of a person-specific growth curve. At the between-subjects level, the person-specific change parameters vary randomly across participants as a function of the process variable (cohesion or satisfaction). HLM models considered outcomes at 4, 8, and 12-months. As process variables were assessed at 4 months only, data from the initial assessment were not included. The three assessment points representing time were coded such that the intercept reflected the level of the outcome variable at 4 months. Each model estimated time, process, and Process × Time effects. The time effect tested whether the outcome changed across the 4-, 8-, and 12-month assessments. The process effect tested whether the process variable covaried with the intercept (4-month outcome score). The Process × Time effect, if significant ($p \leq .05$), indicated that the process variable covaried with the rate of change in the outcome. For interpretability, process variables were centered at the mean. We computed partial correlation coefficients using *t* values and degrees of freedom to estimate effect size (Rosenthal, 1994).

In the analyses, satisfaction was not associated with outcomes at 4 months (i.e., the intercept; all *ps* >.07) or the rate of change (i.e., the Satisfaction × Time interaction; *ps* >.06). In contrast, the relationship between cohesion and therapy outcome was robust. Table 3 displays the fixed effects for time, cohesion, and the Cohesion × Time interaction for outcomes after cohort effects were controlled for. Time effects were significant for POMS TMD, KPS, and symptoms

and signs (all *ps* ≤ .05). Cohesion was not associated with any of the outcomes at 4 months (i.e., the end of the intensive phase; all *ps* ≥.05), indicating that scores at 4 months did not covary with cohesion. However, significant Cohesion × Time effects were found for POMS TMD ($p = .04$), physical activity ($p = .02$), and performance status (KPS; $p = .04$) measures. The Cohesion × Time effect indicates that patients reporting greater personal involvement with and felt support from the group from the intensive phase also reported greater improvement (lower distress, more physical activity) and higher functional performance status into the maintenance phase (see Figure 2 for an example).

On the basis of the interaction findings, we conducted follow-up analyses to examine whether the associations between cohesion and positive outcomes could be related to (or a by-product of) an association between cohesion and more frequent use of the intervention techniques for these outcomes. We used the same HLM analytic model, and technique utilization at 4, 8, and 12 months was the outcome. Each model estimated time, cohesion, and Cohesion × Time effects while controlling for cohort. For all techniques, neither cohesion (all *ps* > .30) nor the interaction of cohesion and time (all *ps* > .14) was significant. In combination, this suggests that the cohesion interaction effects described above for the POMS, physical activity, and KPS outcomes were due to factors other than patients' differential use of the respective intervention strategies.

Analyses Testing Utilization of Intervention Techniques and Outcomes

Hierarchical linear models were used for utilization measures and their corresponding outcomes. Each model included the initial (baseline) value and 4-, 8-, and 12-month outcomes. For these analyses, the intercept reflected the level of the outcome variable at the initial assessment. The corresponding utilization variable, assessed at 4, 8, and 12 months, was included as a time-varying predictor; utilization at initial assessment was fixed to zero on the basis of the assumption that there was no technique use at that time and usage began with the intervention. This strategy allowed for the examination of discontinuous trajectories during the intensive (initial to 4 months) and maintenance phases (4 to 12 months). Cohort assignment was again controlled. Each model estimated time, utilization, and Utilization × Time effects. We computed partial correlation coefficients using t values and degrees of freedom to estimate effect size (Rosenthal, 1994).

As recommended (Raudenbush & Bryk, 2002), we first determined the general form of change that best fit the data. With four data points, linear and, potentially, quadratic models could be fit. According to a likelihood ratio test, if the fit of the quadratic model was not significantly better ($\alpha = .05$), the linear .model was retained. If the Utilization × Quadratic Time interaction was not significant, it was dropped for parsimony (Cnaan, Laird, & Slasor, 1997). Table 4 displays the fixed effects for time, utilization, and the Utilization × Time interaction for each outcome.

We first tested the association between utilization of the three strategies (stress conceptualization, relaxation, and problem solving) for stress–distress management and the POMS outcome. In each model, there was a significant time effect (*ps* < .05), indicating that POMS scores decreased over time, The stress conceptualization effect and the Stress Conceptualization × Time interaction effect were not significant. There was a significant effect for relaxation ($p = .02$), indicating that more frequent relaxation use was associated with a lower level of distress. The Relaxation × Time effect was not significant ($p = .12$). The problem solving effect was not significant ($p = .19$), but there was a significant Problem Solving × Time interaction ($p = .02$). POMS scores declined regardless of the level of problem solving use during the intensive phase. During maintenance, however, usage was associated with less improvement in POMS.

For the PSS Family outcome, the effects of time, social strategies use (both identifying and using social support and assertive communication) and the interaction were not significant. For the Food Habits Questionnaire outcome, time was not significant ($p = .08$), but both dietary strategies use (reducing fat and increasing fiber; $p = .04$) and the interaction ($p = .02$) were significant. The interaction was graphed according to the strategies recommended by Preacher, Curran, and Bauer (2006). Three levels of utilization (monthly, weekly, and daily) were chosen for graphical representation (see Figure 3). The figure shows that more frequent dietary strategies use was associated with greater positive change in food habits, an effect most pronounced during the intensive phase but still evident during maintenance.

As previously reported, the intervention did not result in a significant increase in exercise for the intervention group ($p = .08$ for the Group × Time interaction; Andersen et al., 2004). For the readers' information, however, we examined these data. The effects for time, use of energy expenditure techniques, and the Energy Expenditure × Time interaction were not significant for activity level outcome.

We tested the associations of physical functioning outcomes with four strategies–the stress conceptualization, relaxation, communication with medical providers, and energy expenditure. Time effects were observed for the KPS ($ps < .03$), indicating that patients' functional status improved with time. Effects were not observed for any of the strategies nor their interactions for the KPS outcome. In contrast, strategy use and interaction effects were observed across strategies on symptoms and signs. For this outcome, the quadratic form of change best fit the data. Stress conceptualization ($p =$. .001), relaxation ($p = .004$), medical provider ($p = .002$), and strategies for increasing physical activity ($p = .004$) were all associated with a reduction in symptoms and signs. Interaction effects of a similar form were observed with patients' use of the stress conceptualization ($p = .02$) and frequency of relaxation ($p = .05$; see Figure 4). In both cases, as chemotherapy began during the intensive phase, more frequent use of the conceptualization for understanding stress and more frequent relaxation practice were reported by those found to have the highest levels of signs and symptoms. However, during the maintenance phase, as cancer treatments ended, the level of strategy usage was related to the level of decline in symptoms and signs.

The pattern of interaction effects for medical provider communication ($p = .002$) and increasing physical activity ($p = .004$) were of similar form. For illustration, Figure 5 displays the relationship between patients' reports of strategies to increase physical activity and nurses' evaluations of the patients' symptoms. As can be seen, the quadratic pattern of symptom change was manifested by the increase in symptoms as adjuvant cancer therapies began, and then symptoms declined as therapies ended and patients recovered. As symptoms increased, however, so too did patients' efforts to cope with them by increasing their activity level and communicating more frequently with their medical providers. As treatments ended, those patients who maintained their high level of activity (and provider communication) were evaluated as having the greatest reductions in symptomatology.

Finally, relevant to the above symptom effects are the analyses for dose intensity. Hierarchical linear models could not be used, as there was only one data point per drug per person (it was calculated once, when the regimen was completed), and the data were not normally distributed (the goal was for every patient to receive 100% of every drug). StatXact (Cytel Software Corp., 2004) was used to compute permutation one-way analyses of variance (ANOVAs) with general scores (Gibbons, 1985). This analysis uses exact permutational distributions rather than F distributions and does not depend on assumptions of normality. Three utilization variables were hypothesized as relevant (see Table 1). For each, the mean of the 4- and 8-month utilization scores (the period when chemotherapy was administered) was calculated. Via a median split, patients were classified as low (coded as 0) versus high (coded as 1) users of a

strategy. We tested the null hypothesis that the low- and high-utilization groups would have identical dose distributions. Exact significance values were estimated via Monte Carlo sampling (1,000 tables sampled for each significance value). For analyses with significance values less than .05, post hoc analyses were conducted to identify the minimum level of technique use associated with improvements in dose intensity.

There was a significant association between dose intensity for the taxanes and exercise (T = 6.10, p = .003). Women who reported more frequent use of strategies to increase energy expenditure received a significantly higher proportion of taxanes compared to women who exercised less (or not at all). The actual dosage differences were substantial, with a 99% (*SD* = 3%) average dose intensity for women who reported a higher activity level, compared to 88% (*SD* = 11%) for those patients who reported lower activity levels. Post hoc analyses revealed that using strategies to increase energy expenditure four times per week was the minimum amount of use associated with increased dose intensity.

Discussion

This study provides a comprehensive evaluation of treatment processes, utilization, and outcomes. Novel findings emerged. First, it was important for patients to be satisfied with the intervention, but their feelings of connection to and support from group members, in particular, were related to better outcomes. Second, offering patients a conceptualization of how stress impacted their life negatively and how multiple strategies could interact to help them in positive ways was related to better health. Third, of the significant relationships between treatment utilization and outcomes, we highlight three that related to both psychological and health- and cancer-relevant outcomes. Relaxation traiinig was associated not only with distress reduction but also with symptom lowering. Training in and encouragement of the use of communication strategies with health care providers were associated with better outcomes. In addition, few psychological intervention trials have targeted chemotherapy compliance (see Richardson et al., 1987, for an exception), health behaviors, and physical functioning, and these data identify intervention strategies associated with higher chemotherapy dose intensity and fewer signs and symptoms.

Therapeutic Processes and Outcomes

In their volume *Principles of Therapeutic Change That Work*, Castonguay and Beufler (2006) identified nine common principles of change relevant to the therapeutic relationship. The first principle is developing and maintaining a positive working alliance when conducting individual therapy. The second is a parallel principle for group therapy: Change is enhanced when the therapist successfully fosters a strong level of cohesiveness within the group. The cohesion findings are novel for the cancer literature and compelling. Cohesion covaried with change across psychological, behavioral, and health domains. Further, the cohesion effect was manifested across time; high levels of cohesion covaried with change extending to 12 months. Finally, cohesion exerted its effect through mechanisms other than treatment technique utilization.

These powerful effects are juxtaposed with the dearth of effects with treatment satisfaction ratings. As it is typical for patients to report high overall levels of satisfaction (Petersson et al., 2000), we were hopeful that ratings for the specific intervention topics would be more informative. They were not. In short, individuals viewed intervention components as helpful, but these perceptions did not translate into a higher frequency of use or greater efficacy. For example, assertive communication training and strategies for communicating with medical providers received relatively lower satisfaction ratings, yet their reported use with providers was associated with increased chemotherapy dose intensity and a rapid reduction in symptoms following chemotherapy–two important outcomes.

Treatment Utilization and Outcome

Our findings suggest, to no surprise, that relaxation practice has distress reduction properties; it is more notable that relaxation related to a greater reduction in symptoms and signs following adjuvant treatment. Despite the commonality of its use for physical disorders, there have been relatively few tests of relaxation usage and outcomes (Walker et al., 1999). Antoni et al. (2006) reported effects not with relaxation frequency but with patients' reported confidence in their ability to use relaxation. The symptomatology effects shown here are consistent with relaxation in the management of chemotherapy side effects and cancer-related pain (e.g., Syrjala, Donaldson, Davis, Kippes, & Carr, 1995).

The cohesion effects notwithstanding, the SIBCP intervention was not conceptualized as a social support group. Instead, the social component sought to teach patients strategic use of their existing support networks and improvement of their social environment via cnanging their own communications. Patients identified salient individuals in their network, evaluated the capacities of these individuals to provide tangible and/or emotional support, identified their specific tangible or emotional needs, and “matched” their needs to individuals capable of meeting them. Assertive communication training (i.e., making clear, specific statements; speaking directly; “owning” one's message; and asking for feedback; Jakubowski & Lange, 1978) was offered for women to identify, express, and get their needs met–be it at home or in the doctor's office. Patients with cancer have acknowledged the importance of communicating their needs (Kilpatrick, Kristjanson, Tataryn, & Fraser, 1998), but have reported that this dialogue is often infrequent (Fried, Bradley, O'Leary, & Byers, 2005). We too sensed these were difficult exchanges for patients, and the relatively lower satisfaction ratings for assertive communication provide empirical confirmation. Nevertheless, use of these strategies with health care providers covaried with a quicker recovery.

The SIBCP intervention differs from others (Andersen, 2002) in the inclusion of the health behavior and compliance components, as both were hypothesized as relevant to disease course (Andersen et al., 1994). Currently, the effect of dietary interventions remains unknown (Davies et al., 2006), as it did when the trial began. Regardless, improved health behaviors can positively impact other. health conditions and quality of life (Herrero et al., 2006).

Doxorubicin (Adriamycin) and cyclophosphamide (Cytoxan) were and continue to be efficacious agents in the treatment of breast cancer. The taxanes, however, were introduced in the middle of the trial and regarded with early enthusiasm. In the early trials, taxanes were added (usually four cycles) to the end of the standard, four-cycle, doxorubicin-based regimens. The efficacy of the taxanes has been confirmed only recently (Marmounas et al., 2005). Significant advantages have been found in the lymph-node-positive patients (as studied here) in both disease-free rates (risk ratio of .84) and overall survival rates (risk ratio of .84), which translates to an absolute benefit of 2.0% to 2.8%, respectively (Bria et al., 2006). Moreover, data suggest a dose-response relationship to disease endpoints in the treatment of breast cancer (Nabholtz et al., 1996).

Intervention components were designed to help patients prevent or control treatment toxicities, stay on schedule and remain in treatment, and then return for medical follow up. For this trial, dose intensity was an important, cancer-relevant outcome. One strategy, assertive communication skill training, was brought to this context because we reasoned that patients skilled in this manner of communicating might be better served in today's busy medical care environment. Patients might receive more information about toxicities, have better physician management of these toxicities, or have greater tolerance, for example. Prior correlational studies had suggested that treatment side effects (Demissie, Silliman, & Lash, 2001) and emotional distress (McDonough, Boyd, Varvares, & Maves, 1996) were related to compliance with chemotherapy, and dosage reductions compromise survival (e.g., Budman et al., 1998).

For the individual, taxanes come with multiple side effects similar to those of doxorubicin-based drugs (i.e., nausea and vomiting; loss of appetite; diarrhea; difficulty swallowing; thinned or brittle hair; and swelling, pain, redness, or peeling of the skin), but this group of drugs adds the myalgias, arthralgias, and paresthesias that are debilitating and difficult to manage medically (Spratto & Woods, 2005). We do not know, but the dose intensity findings for the taxanes may be linked to the strategies used for symptom management. As in data from MacVicar, Winningham, and Nickel (1989), exercise might have reduced nausea and other symptoms, lowering toxicities (or making them more tolerable) such that patients could stay on schedule with no lengthening of days between chemotherapy cycles. Patients who were experiencing more symptoms were also more apt to contact their physicians; it is possible that those communications resulted in better medical management of symptoms. Also, relaxation frequency did covary with symptom lowering and distress reduction, which might have achieved the same indirect positive effects.

Maintenance of Treatment Effects

The evaluation of the efficacy of psychological interventions for patients with cancer comes primarily from analyses of posttreatment outcomes, with fewer data on the durability of treatment effects. This circumstance is not unique. For example, Karoly and Anderson (2000) overviewed the psychotherapy literature, sampling over 50,000 studies published from 1989 to 1998. Across seven types of therapy (e.g., cognitive-behavioral, interpersonal, psychoanalytic), the percentage of studies addressing maintenance, follow-up, generalization, and/or relapse prevention ranged from 0% to 10%. One strategy to achieve longer lasting effects is to simply offer more treatment. Indeed, within the psychotherapy outcome literature there is a reliable dose–response effect for improvement (Hansen, Lambert, & Forman, 2002). Rehse and Pukrop's (2003) meta-analysis of cancer intervention studies found the number of sessions to be a moderator of effect size and more powerful than gender and other characteristics of the patients, intervention methods, or type of outcome measures used.

Alternatively, another strategy to achieve maintenance is to “build it in,” as was done here. The data suggest this was an effective tactic for achieving durable gains. The findings require replication, but consider what might have been observed if the intervention had ended with the intensive phase and patients' frequency of technique use, in turn, declined, as is typically the case. Figure 3 can be used for illustration. Patients who used the dietary strategies on a daily basis during the intensive phase might, without maintenance, subsequently become weekly or monthly users. If so, their trajectories from 4 to 12 months would be stable or declining rather than continuing to improve. Figure 5 provides another example. In this figure, the data also show that oftentimes the most vigorous users of the intervention components during the intensive phase were also those most in need of doing so, as they had the highest levels of symptoms. Then, as they recovered during the period of maintenance, if they continued to be vigorous users of a component, they then had the greatest rate of improvement. In some cases, they achieved the lowest level of symptoms by 12 months, even compared to patients who started with fewer symptoms but who used techniques less frequently. Taken together, these data suggest that a maintenance phase provides important benefits in continuing, if not accelerating, a trajectory of positive change.

Findings in Context

Characteristics of the trial offered advantages to the study of process and outcome. First, the sample was large and homogeneous, thereby increasing statistical power. Second, attrition from the trial, as well as intervention dropout, was low. Third, according to recommendations (Perepletchikova & Kazdin, 2005), treatment integrity was high. Group leaders had similar theoretical backgrounds, were trained, followed a manual, and were monitored; the intervention was delivered reliably across cohorts; and, the data show significant relationships

between treatment utilization and outcomes. Fourth, the design of the trial matched intervention targets to components, components to utilization variables, and utilization to outcome variables–providing an a priori clarity for testing process and outcome relationships.

We also note limiting characteristics of the study and this report. In some respects the sample was too homogeneous, having minimal racial diversity. There were few treatment evaluation measures in the literature, and those used only assessed positive experiences. Including negative valence items might provide an understanding of the contributors to early dropout, low attendance, or poor outcomes. Finally, while there are many standardized outcome measures, there are no parallel measures for assessing mechanisms of therapy (Kazdin, 2006). The utilization reports used here were straightforward, paper-and-pencil reports rather than written or electronic diaries.

Implications and Future Directions

> "What treatment, by whom, is most effective for this individual with that specific problem, under which set of circumstances, and how does it come about?" (Paul, 1969, p. 44)

As Gordon Paul (1969) observed, no single study would ever be able to answer this "ultimate question." This effort addresses only some of the issues. These "individuals" were patients with breast cancer studied early in their cancer trajectory. In the future we will examine individual differences among patients in relationship to intervention outcomes. These data are limited by the "set of circumstances" of the trial: group treatment led by female psychologist-therapists.

Prior reports provided efficacy for the intervention as a whole. These data, however, clarify the "how does it come about" of specific treatment effects. For example, the 12-month outcome data showed improved health outcomes for the intervention arm compared to the assessment-only arm, and, further, support was found for an indirect effect of distress reduction (Andersen et al., 2007). That is, when intervention patients' distress was specifically lowered at 4 months, their health was improved at 12 months ($p < .05$). The data in this article clarify that finding in showing that, of the relevant components, it was patients' practice of relaxation training (rather than their use of problem solving, e.g.) and their feelings of involvement in and support from the intervention group that likely led to declines in their distress.

As with many interventions for patients with cancer, the treatment was multicomponent, and the design did not yield experimental data on the efficacy of individual components, as does a dismantling study. The pairing of intervention utilization with outcomes is, however, a valuable way to provide related, correlational data. These data could be used, for example, as evidence in choosing among components for a second generation of intervention trials. They may also assist in the development of more complex process measures. If we can choose the strategies most responsible for change, it will increase efficiency, intervention effect sizes, and maintenance of intervention effects for our patients. We encourage examination of therapeutic processes, as it is a complementary effort to determine the most efficacious psychological treatments for patients with cancer.

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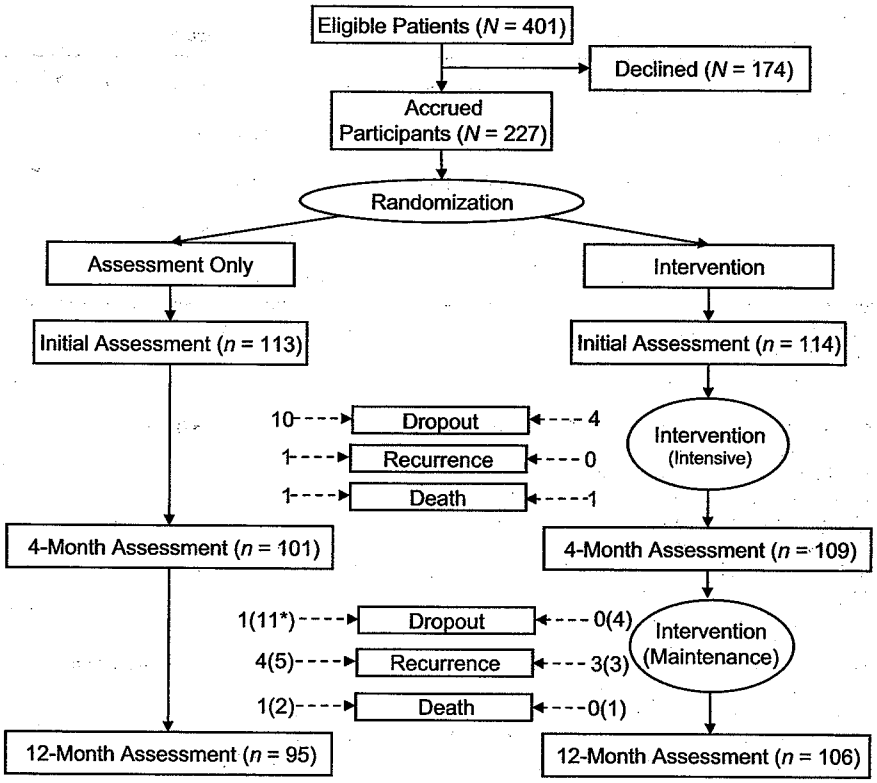

Figure 1.
CONSORT flowchart. *Cumulative values across therapy phases.

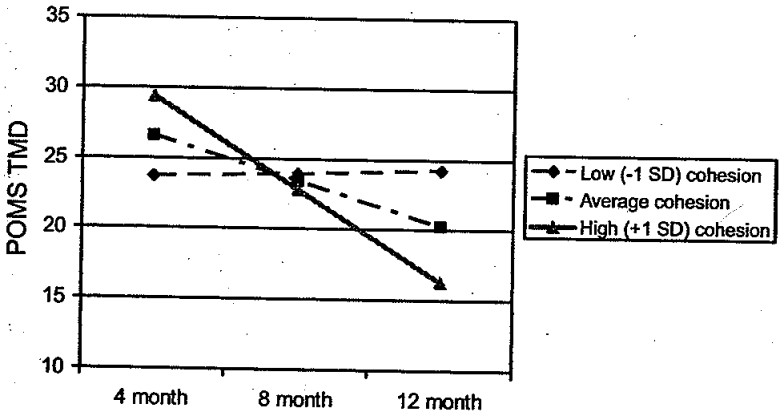

Figure 2.
Estimated trajectories of change in the patients' Profile of Mood States Total Mood Disturbance (POMS TMD) scores by level of cohesion. Whereas patients feeling less support from the group showed no change in the level of their emotional distress, those reporting high levels of cohesion from the intensive phase experienced mood improvement through the shift to maintenance sessions.

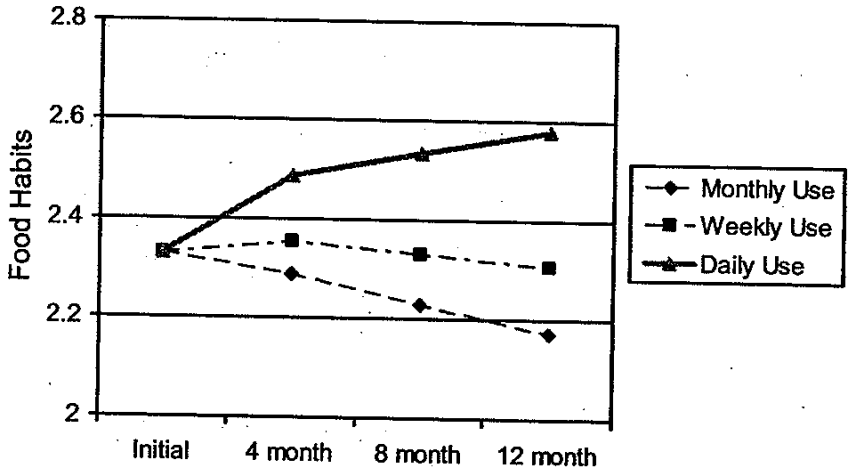

Figure 3.
Estimated trajectories of change in the patients' Food Habits. Questionnaire scores by level of dietary strategies use. The findings suggest that more frequent dietary strategies use was associated with greater positive change in food habits, an effect most pronounced during the intensive phase but still evident during maintenance.

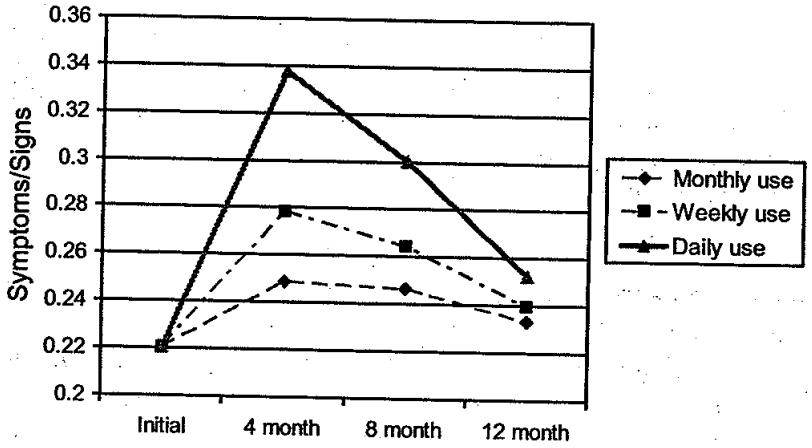

Figure 4.
Estimated trajectories of change in the patients' reported frequency of their relaxation practice and the nurses' ratings of the patients' symptoms and signs. The findings suggest more frequent relaxation use by those with the highest levels of symptoms, who then achieved the greatest decline in symptoms.

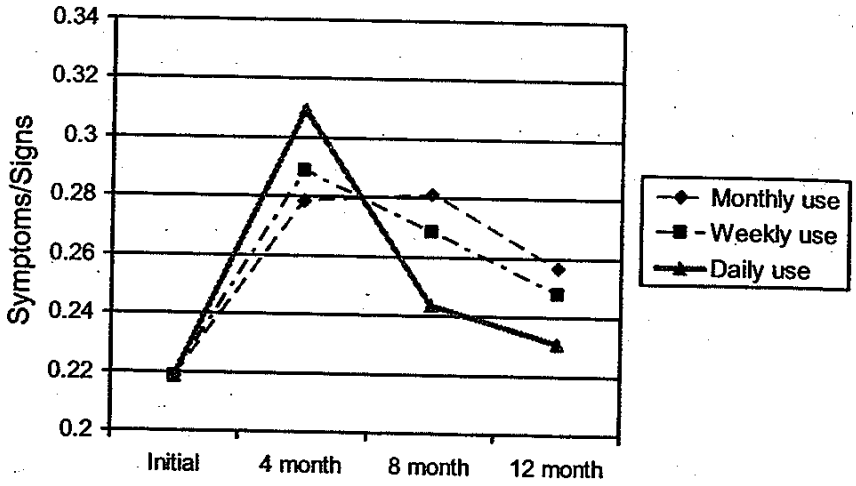

Figure 5.
Estimated trajectories over time in the patients' reports of physical activity and the nurses' ratings of the patients' symptoms and signs. The findings suggest that the patients who made the most use of exercise strategies were those with the highest levels of symptoms, who then achieved a rapid, steep decline in symptoms exceeding that of all others who exercised less.

Table 1

Intervention Target and Components and Correspondence to Utilization and Outcome Measures

Intervention target	Intervention component	Session no.[a]	Utilization measure	Outcome measure
Stress	Conceptual model (i.e., understanding stress and responses to it)	1, 18, 26	Stress conceptualization	POMS TMD
	Problem solving	10−12, 19−25	Problem solving	POMS TMD
Quality of life				
Emotional distress	Relaxation training	1−26	Relaxation training	POMS TMD
	Problem solving, positive coping	10−12, 19−25	Problem solving	POMS TMD
Social adjustment	Social support (i.e., identify social network, support needs, and contacts) and assertive communication training	4−9, 21−23	Use of support resources and assertive communication skills	PSS Family
Health behaviors				
Diet	Strategies for low-fat/high-fiber food consumption, food intake diary (two times a day for 3 days), and energy balance information	14−17, 24	Use of dietary strategies	Food Habits Questionnaire
Exercise	Walking protocol and strategies to increase daily activity level	13, 17, 25	Use of strategies for increasing activity	Seven-day exercise recall
Physical function	Strategies for physical (e.g., nausea, fatigue, hot flashes) and stress-related (e.g., sleep problems, headaches) symptom management	3	Stress conceptualization	Symptoms/signs
			Relaxation training	Karnofsky performance status (KPS)
	Assertive communication skills with physician		Medical provider communication	
	Increasing daily activity level		Exercise	
Dose intensity	Assertive communication skills with physician, disease/treatment information, strategies for managing symptoms, planning appointments, goal setting	2, 3, 10, 20, 22	Medical provider communication	Dose intensity
			Relaxation training Exercise	Doxorubicin Cyclophosphamide Taxanes

Note. POMS = Profile of Mood States; TMD = Total Mood Disturbance; PSS Family = Perceived Social Support Scale for Family.

[a]The intensive intervention phase corresponds to Sessions 1−18, and the maintenance phase corresponds to Sessions 19−26.

Table 2

Descriptive Statistics for Process, Utilization, and Outcome Measures

Measure	Initial	4 months	8 months	12 months
	M (*SD*)	*M* (*SD*)	*M* (*SD*)	*M* (*SD*)
Process				
Satisfaction		3.52 (0.36)		
Group cohesion		7.85 (1.03)		
Utilization				
Stress conceptualization		5.63 (1.90)	5.37 (1.94)	5.32 (2.05)
Relaxation practice		3.52 (1.84)	3.16 (2.12)	3.07 (2.27)
Medical provider communication		4.27 (2.86)	4.43 (2.99)	4.53 (3.08)
Social strategies		4.66 (1.88)	3.97 (1.69)	4.20 (1.88)
Problem solving		4.05 (2.13)	4.02 (2.09)	4.23 (2.42)
Dietary strategies		6.73 (1.37)	6.52 (1.56)	6.42 (1.68)
Energy expenditure strategies		4.11 (1.97)	4.53 (2.03)	4.59 (1.95)
Outcome				
POMS TMD	41.45 (35.64)	28.54 (37.47)	25.61 (33.98)	23.64 (34.13)
PSS Family	16.26 (4.34)	16.67 (4.09)	16.81 (4.25)	16.33 (4.33)
Food Habits Questionnaire	2.28 (0.48)	2.45 (0.49)	2.47 (0.49)	2.53 (0.48)
7-day exercise recall	14.62 (24.28)	25.09 (42.14)	28.92 (55.03)	31.57 (50.12)
Karnofsky Performance Status	83.68 (8.65)	84.72 (7.95)	87.48 (7.63)	88.59 (7.42)
Symptoms/signs	0.21 (0.11)	0.29 (0.13)	0.25 (0.11)	0.24 (0.10)

Note. POMS = Profile of Mood States; TMD = Total Mood Disturbance; PSS Family = Perceived Social Support Scale for Family.

Table 3

Fixed Effects for Hierarchical Linear Models Examining the Association Between Cohesion and Treatment Outcomes

Outcome	Fixed effects	*B*	*SE*	*T*	*p*	95% CI	p*r*
POMS TMD	Time	−0.76	0.38	−2.02	.05	−1.51, −0.02	−.22
	Cohesion	2.75	3.46	0.79	.43	−4.11, 9.61	.09
	Cohesion × Time	−0.82	0.40	−2.05	.04	−1.61, −0.03	−.22
PSS Family	Time	0.004	0.04	0.09	.93	−0.08, 0.08	.01
	Cohesion	0.27	0.39	0.70	.49	−0.50, 1.04	.08
	Cohesion × Time	−0.002	0.04	−0.04	.97	−0.09, 0.08	.00
Food habits	Time	0.001	0.004	1.30	.20	−0.003, 0.01	.14
	Cohesion	0.05	0.05	1.10	.27	−0.04, 0.14	.12
	Cohesion × Time	0.01	0.004	1.86	.06	−0.0005, 0.02	.20
Physical activity	Time	1.01	1.02	0.99	.32	−1.01, 3.03	.12
	Cohesion	−6.91	4.89	−1.41	.16	−16.57, 2.75	−.17
	Cohesion × Time	2.27	0.97	2.34	.02	0.35, 4.19	−.27
KPS	Time	0.51	0.13	3.97	.001	0.26, 0.77	.40
	Cohesion	−1.49	0.76	−1.97	.05	−2.98, 0.004	−.21
	Cohesion × Time	0.28	0.13	2.12	.04	0.02, 0.54	.23
Symptoms/signs	Time	−0.006	0.002	−3.76	.001	−0.01, −0.002	−.39
	Cohesion	0.009	0.01	0.82	.42	−0.01, 0.03	.09
	Cohesion × Time	−0.003	0.002	−1.89	.06	−0.01, 0.0001	−.21

Note. CI = confidence interval; p*r* = partial correlation; POMS = Profile of Mood States; TMD = Total Mood Disturbance; PSS Family = Perceived Social Support Scale for Family; KPS = Karnofsky Performance Status Scale.

Table 4

Fixed Effects for Hierarchical Linear Models Examining the Association Between Utilization of Intervention Techniques and Treatment Outcomes

Outcome	Intervention technique	Fixed effects	*B*	*SE*	*T*	*p*	95% CI	p*r*
POMS TMD	Stress conceptualization	Time	−1.43	0.68	−2.09	.04	−2.77, −0.08	−.22
		Stress concept use	−1.40	0.92	−1.52	.13	−3.21, 0.42	−.16
		Stress Concept Use × Time	0.16	0.15	1.08	.28	−0.13, 0.44	.11
	Relaxation	Time	−1.19	0.45	−2.64	.01	−2.08, −0.30	−.27
		Relaxation use	−3.25	1.35	−2.41	.02	−5.90, −0.59	−.25
		Relaxation Use × Time	0.26	0.17	1.55	.12	−0.07, 0.59	.16
	Problem solving	Time	−2.31	0.53	−4.33	.001	−3.36, −1.26	−.43
		Problem solving use	−1.54	1.17	−1.32	.19	−3.84, 0.76	−.15
		Problem Solving Use × Time	0.37	0.15	2.44	.02	0.07, 0.66	.26
PSS Family	Social support	Time	−0.01	0.07	−0.07	.95	−0.15, 0.14	−.01
		Social support use	0.14	0.13	1.11	.27	−0.11, 0.40	.12
		Social Support Use × Time	−0.007	0.02	−0.35	.73	−0.05, 0.03	−.04
Food habits	Dietary strategies	Time	−0.02	0.01	−1.76	.08	−0.04, 0.002	−.19
		Dietary strategies use	0.02	0.008	2.06	.04	0.001, .03	.22
		Dietary Strategies Use × Time	0.004	0.002	2.43	.02	0.001, .01	.25
Physical activity	Energy expenditure strategies	Time	−0.28	0.93	−0.30	.77	−2.12, 1.57	−.03
		Energy expenditure use	0.29	1.89	0.15	.88	−3.45, 4.04	.02
		Energy Expenditure × Time	0.31	0.27	1.15	.25	−0.22, 0.84	.13
KPS	Stress conceptualization	Time	0.39	0.17	2.32	.02	0.06, 0.72	.24
		Stress concept use	−0.14	0.23	−0.58	.56	−0.59, 0.32	−.06
		Stress Concept Use × Time	0.12	0.04	0.32	.75	−0.06, 0.08	.03
	Relaxation	Time	0.42	0.11	3.73	.001	0.20, 0.64	.37
		Relaxation use	−0.12	0.34	−0.34	.74	−0.79, 0.56	−.04
		Relaxation Use × Time	0.001	0.04	0.03	.97	−0.08, 0.08	.01
	Medical provider comm.	Time	0.41	0.11	3.60	.001	0.19, 0.63	.36
		Med comm. use	−0.35	0.26	−1.34	.18	−0.86, 0.16	−.14
		Med Comm. Use × Time	0.02	0.03	0.80	.42	−0.04, 0.08	.08
	Energy expenditure strategies	Time	0.33	0.15	2.17	.03	0.03, 0.63	.23
		Energy expenditure use	0.24	0.29	0.81	.42	−0.34, 0.82	.09
		Energy Expenditure × Time	−0.001	0.04	−0.14	.89	−0.08, 0.07	−.01
Symptoms/signs	Stress conceptualization	Time	−0.003	0.01	−0.43	.67	−0.02, 0.01	−.05
		$Time^2$ (quadratic term)	0.0004	0.001	0.65	.51	−0.001, 0.002	.07
		Stress concept use	0.02	0.006	3.30	.001	0.01, 0.03	.33
		Stress Concept Use × Time	−0.002	0.001	−2.28	.02	−0.003, 0.0002	−.24
	Relaxation	Time	0.003	0.006	0.44	.66	−0.01, 0.01	.05
		$Time^2$ (quadratic term)	−0.0001	0.001	−0.26	.80	−0.001, 0.001	−.03
		Relaxation use	0.02	0.007	2.90	.004	0.01, 0.04	.30
		Relaxation Use × Time	−0.002	0.0008	−1.97	.05	−0.003, −0.001	−.21
	Medical provider comm.	Time	0.02	0.01	3.46	.001	0.01, 0.03	.35
		$Time^2$ (quadratic term)	−0.002	0.001	−3.16	.001	−0.003, −0.001	−.32
		Medical comm. use	0.03	0.01	3.23	.002	0.01, 0.05	.33
		Medical Comm. Use × Time	−0.01	0.003	−3.34	.001	−0.01, −0.004	−.34
		Medical Comm. Use × $Time^2$	0.001	0.0002	3.20	.002	0.0002, 0.001	.32
	Energy expenditure strategies	Time	0.02	0.01	2.29	.02	0.003, 0.03	.24
		$Time^2$ (quadratic term)	−0.001	0.001	−1.69	.09	−0.003, 0.0002	−.18
		Energy expenditure use	0.03	0.01	2.89	.004	0.01, 0.05	.29
		Energy Expenditure × Time	−0.01	0.003	−2.67	.01	−0.01, −0.002	−.27
		Energy Expenditure × $Time^2$	0.0004	0.0002	2.07	.04	0.0001, 0.001	.22

Note. CI = confidence interval; p*r* = partial correlation; POMS TMD = Profile of Mood States Total Mood Disturbance; PSS Family = Perceived Social Support Scale for Family; KPS = Karnofsky Performance Status Scale; comm. = communication.