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Feasibility Study of a Randomized Controlled Trial of a Telephone-Delivered Problem Solving-Occupational Therapy Intervention to Reduce Participation Restrictions in Rural Breast Cancer Survivors Undergoing Chemotherapy

Mark T. Hegel[1,*], **Kathleen D. Lyons**[1], **Jay G. Hull**[2], **Peter Kaufman**[3], **Laura Urquhart**[3], **Zhongze Li**[4], and **Tim A. Ahles**[5]

[1]Department of Psychiatry, Dartmouth Medical School, Hanover, NH, USA

[2]Department of Psychological and Brain Sciences, Dartmouth College, Hanover, NH, USA

[3]Department of Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA

[4]Norris Cotton Cancer Center, Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA

[5]Memorial Sloan Kettering Cancer Center, New York, NY, USA

Abstract

Objective—Breast cancer patients receiving adjuvant chemotherapy often experience functional effects of treatment that limit participation in life activities. The purpose of this study was to examine the feasibility of conducting a randomized controlled trial (RCT) of a novel intervention for these restrictions, determine acceptability of the intervention, and preliminarily assess its effects.

Methods—A pilot RCT of a telephone-delivered Problem Solving and Occupational Therapy intervention (PST-OT) to improve participation restrictions in rural breast cancer patients undergoing chemotherapy. Thirty-one participants with Stages 1-3 breast cancer were randomized to 6 weekly sessions of PST-OT (n=15) and Usual Care (n=16). The primary study outcome was the feasibility of conducting the trial. Secondary outcomes were functional, quality of life and emotional status as assessed at baseline, 6 weeks and 12 weeks.

Results—Of 46 patients referred 31 were enrolled (67% recruitment rate), of which 6 participants withdrew (81% retention rate). Twenty-four participants completed all study-related assessments (77%). Ninety-two percent of PST-OT participants were highly satisfied with the intervention, and 92% reported PST-OT to be helpful/very helpful for overcoming participation restrictions. Ninety-seven percent of planned PST-OT treatment sessions were completed. Completion rates for PST-OT homework tasks were high. Measures of functioning, quality of life and emotional state favored the PST-OT condition.

Conclusion—This pilot study suggests that an RCT of the PST-OT intervention is feasible to conduct with rural breast cancer patients undergoing adjuvant chemotherapy and that PST-OT may have positive effects on function, quality of life, and emotional state.

Keywords

breast cancer; oncology; rehabilitation; problem solving; chemotherapy; telehealth

[*]Correspondence to: Department of Psychiatry, Dartmouth-Hitchcock Medical Center, One Medical Center Drive, Lebanon, NH 03756, USA Mark.T.Hegel@Dartmouth.EDU.

Introduction

Most breast cancer patients experience functional limitations while undergoing cancer treatment[1-4]. These limitations interfere with roles which they value in their daily lives, known as “participation restrictions” (i.e., instrumental activities of daily living, social, work and leisure activities)[5]. Participation restrictions during treatment not only affect quality of life but may also lead to enduring restrictions long after cancer treatment has ended[6]. For example, most breast cancer survivors experience a reduction in physical activity levels by as much as two hours per week from pre-diagnosis to one year post-diagnosis, particularly for vigorous activities[6,7]. When participation restrictions are added to negative mood states such as anxiety and depression, a downward spiral of worsening mood and participation restrictions can result[8]. Programs of aerobic exercise and physical therapy may help underlying impairments such as fatigue and lymphedema, which contribute to participation restrictions, [9-12], but adherence to exercise and home-based physical therapy programs is typically poor[9,13-18].

Overcoming participation restrictions and adhering to self-directed rehabilitation programs therefore may not be possible without addressing environmental and practical barriers. Addressing such barriers falls within the realms of problem solving therapies [19]and occupational therapy interventions[20], however such interventions have not been tested for this purpose in breast cancer survivors undergoing chemotherapy. Furthermore, for populations who have difficulty accessing the services of a cancer center, such as rural patients, interventions which are feasible to implement are required. Developing such interventions is a key area of research necessary for reducing cancer health disparities.

To address these issues we designed a telephone-delivered problem solving and occupational therapy intervention (PST-OT) to assist rural breast cancer patients undergoing adjuvant therapy to reduce participation restrictions in valued areas (e.g., self care, work, social, and leisure activities), and promote adherence to activities that support this task (i.e., aerobic exercise, upper extremity physical therapy and stress management). Theoretically, the PST-OT intervention is derived from a self-regulation perspective of disability and adaptation [21]. Disability represents a discrepancy between the person's intrinsic capabilities and demands of the environment[22]. Adaptation involves reducing this discrepancy[23].

PST-OT was partially adapted from our earlier research to prevent depression in medical populations. In these prevention studies the problem solving treatment focused on reducing participation restrictions caused by the medical problem (e.g., macular degeneration and stroke)[24,25]. Problem solving interventions address two main aspects of problem solving: problem orientation and problem-solving style[19]. A positive problem orientation frames situations as challenges rather than as threats and accepts negative emotions that accompany those challenges rather than avoiding them. A problem solving style focuses on rational problem solving strategies using a set of adaptive skills, such as generating alternative solutions (i.e., brainstorming) and considering their consequences rather than acting impulsively or avoiding problems.

A key modification for the new PST-OT intervention was the integration of the Person, Environment, Occupation Model (PEO) of occupational therapy into the brainstorming stage of problem solving[26]. In the PEO model the term “occupation” refers to “valued activities,” which are the meaningful and purposeful activities that occupy one's time, contribute to one's identity and community, and reflect one's culture. The PEO model suggests three potentially complementary courses of action in response to impaired function. When faced with a participation restriction the individual can: (1) change something about

their personal skills and capabilities such as through exercise, physical therapy and stress management, (2) change the environment in which the activity is performed, or (3) change the nature of the activity itself. Thus, the OT component of PST-OT was to educate regarding environmental and activity adaptation. Because the intervention was conducted entirely by phone no “hands on” OT modalities were administered as part of the intervention.

Prior to testing the efficacy of a novel intervention it is necessary to demonstrate the feasibility of delivering the intervention and test the study methods with the population of interest. This step is perhaps particularly important when the patient population is ill, as is the case for women undergoing chemotherapy for breast cancer. The primary aim of the Living Well with Breast Cancer pilot study was to evaluate 1) the feasibility of recruiting and retaining the study sample and 2) the acceptability of the PST-OT intervention. A secondary aim was an exploratory evaluation of possible intervention effects on measures of function, quality of life and emotional state.

Methods

Design Overview

The Living Well trial was a randomized controlled study in which female breast cancer patients (Stages 1-3) undergoing rigorous chemotherapy regimens were administered a telephone-delivered 6 week, 6 session PST-OT intervention or usual care (UC). Participants were assigned to PST-OT (n=15) and UC (n=16) in a blocked-random fashion and stratified by stage (Stage 1 vs Stages 2 and 3) to promote balance in case complexity. Participants were assessed at baseline, at 6 weeks for acute outcomes, and at 12 weeks for maintenance effects. This research was approved by the Institutional Review Board (Committee for Protection of Human Subjects) of Dartmouth College.

Enrollment of the Study Sample

Participants were recruited from the breast oncology clinic of the Norris Cotton Cancer Center at the Dartmouth-Hitchcock Medical Center, Lebanon, NH. Women were eligible if they were at least 18 years of age, were diagnosed with stage 1-3 breast cancer, were beginning their second cycle of chemotherapy with doxorubicin or docetaxel/ cyclophosphamide every three weeks or dose dense doxorubicin/cyclophosphamide every two weeks or doxorubicin/paclitaxel/trastuzumab, were cognitively intact, had no history of a severe mental illness (schizophrenia or bipolar disorder), and had no concurrent cancer diagnosis other than non-melanotic skin cancer. The oncology nurse practitioner described the study to patients arriving consecutively for their initial chemotherapy consultation visit and provided their name to the study research assistant. The research assistant then completed the eligibility determination and informed consent process.

Procedure

A baseline assessment packet and a pre-stamped envelope were provided to the participant. Upon receiving the returned baseline assessment the research assistant determined their randomized treatment assignment. If assigned to the PST-OT intervention the research assistant mailed the participant the PST-OT patient manual. Follow-up assessments at 6 and 12 weeks were collected from both groups by mail with occasional phone reminders as necessary. In addition to the outcome measures, the baseline assessment packet also included an investigator-designed 22-item survey of potential participation restrictions in various daily activities (e.g., family, work, social, leisure) that would be used during PST-OT sessions if so assigned.

Interventions

PST-OT Intervention—The first telephone-delivered PST-OT session was conducted within one week of the baseline assessment and subsequent sessions were provided on a weekly basis for six weeks. A licensed occupational therapist (OT) conducted all treatment sessions (KL). The OT was trained by the principal investigator, which included reviewing the treatment manual adapted from our previous research[27], and role play sessions with experienced oncology nurses. The first author supervised the OT throughout the course of the study via review of session audiotapes using a standardized treatment fidelity scale[28] and weekly meetings. The PST-OT patient manual contained a lay description of the problem solving process, worksheets to be used during PSTOT treatment sessions, guidelines for energy conservation to address fatigue, and a compact disc with a progressive muscle relaxation (PMR) exercise personally recorded by the OT.

The participant was instructed to follow along in their manual which included helpful diagrams and bulleted major points (i.e., adopting a positive problem orientation, the steps of problem solving, the PEO model, and fatigue management through activity and adaptation). At the beginning of session 1 the rationale for testing PST-OT for reducing participation restrictions during chemotherapy was explained. The OT then reviewed the participation restriction survey with the participant to identify activities that were rated as at least moderately important and that had at least a moderate level of difficulty. These activities became the targeted problem areas for PST-OT sessions.

The OT used a structured worksheet to lead the participant through a PST-OT treatment session which followed seven steps: 1) Exploration, clarification and definition of the participation restriction; 2) Setting a goal that was objective, behavioral and achievable; 3) Brainstorming alternative solutions, guided by the PEO model, without judgment of the solutions; 4) Decision analysis of each solution to evaluate their feasibility (i.e., the amount of effort, time, cost, emotional impact on self or others, and the need to involve other people in the solution); 5) Choosing a solution that was feasible and that carried limited negative impact on the participant or others; and 6) Implementing the solution (or Action Plan) by identifying the specific steps to be completed (e.g., where, when, how, with whom). In PST-OT, the goal, solutions and action plans came from the participant as the best judge of their own situation. The OT's primary role was to teach and facilitate the PST-OT process, using the participation restrictions as the context for this process. The participant's role was to use the one page worksheet to formulate and elaborate the above steps and to record her progress during the week.

The last task of the first and each subsequent session was for the OT to remind the participant to engage in aerobic exercise, stress management using the PMR CD, and upper extremity exercises if indicated (all breast cancer patients received a physical therapy evaluation and recommendations for home-based therapy as part of their routine care). If the participant was experiencing difficulties with these programs they were targeted in PST-OT sessions.

Sessions 2-6 began by completing the seventh step of problem solving; evaluating the outcome of the action plan. Depending on the outcome the OT then asked the participant if they wished to continue working on the previous participation restriction or to address a different restriction. During each session the entire seven-step problem solving procedure was applied for at least one participation restriction or healthy behavior. In later sessions, if most of the obstacles to the targeted participation restrictions had already been addressed, sessions occasionally consisted primarily of refining goals and action plans rather than completing each step of PST-OT.

Usual Care—Participants assigned to UC were observed under naturalistic conditions. Participants and their clinicians were allowed to use all oncologic and other medical center services without restrictions (e.g., care management, rehabilitation, palliative care), as well as pursue like services in their communities.

Measures

Eligibility Measure

A chart review was conducted for cancer-related medical information (e.g., treatments received) and questions were asked about lifetime diagnoses of schizophrenia or bipolar illness. A score of 3 or less on the Callahan Six Item Cognitive Screen was used to exclude patients with significant cognitive impairment[29]. A score in this range has a sensitivity and specificity for a diagnosis of dementia of 88.7 and 88.0, respectively.

Medical Services Use

Cornell Services Index- Modified (CSI-M). The CSI is a health service use questionnaire. We used an abbreviated version of the CSI (CSI-M)[30] via chart review to assess health service utilization during the 12 weeks of study participation. The CSI-M documents the type of services used, such as physician, rehabilitation, emergency department, and mental health visits.

Primary Outcomes

Recruitment/Retention

Study recruitment and retention data included the number of patients referred for potential participation, patients meeting eligibility criteria, participants enrolled, participants completing treatment, and participants completing the 6-week and 12-week assessments.

Participant Satisfaction

At 12 weeks a satisfaction survey asked two questions to all participants regarding their satisfaction with a) participation in the study, and b) the general quality of care they received for their cancer-related needs. Two additional questions were asked to PST-OT participants regarding a) their satisfaction with the PST-OT intervention, and b) the helpfulness of PST-OT for addressing their participation restrictions.

Secondary Outcomes

At baseline, 6 weeks and 12 weeks participants completed measures of function, quality of life, emotional status, and adherence to aerobic exercise, self-directed physical therapy, and relaxation programs.

Health-Related Function

Medical Outcomes Short Form-36 (SF-36). The SF-36 is a multidimensional measure of health-related function. The SF-36 consists of eight scales (physical functioning, role limitations -physical, role limitations - emotional, energy-fatigue, well being, social functioning, bodily pain, and general health) and two standardized component summary scores (physical and mental)[31]. The scores, derived from factor analysis, are transformed to T scores with a mean of 50 and standard deviation of 10.

Quality of Life

Functional Assessment of Cancer Therapy-Breast Cancer Version (FACT-B). The FACT-B is a health-related quality of life measure specifically designed for breast cancer patients[32,33]. The FACT-B assesses perceived well being in physical, social, emotional, and functional domains, as well as topics specific to breast cancer patients (e.g., self-image and sexuality). Subscale scores are derived in each domain as well as a total score. Internal consistency for the total score and subscale scores are high (alphas ranging .63-.90). Test-retest correlations are high, ranging from .85 to .89. The FACT-B demonstrates adequate convergent and divergent validity[33].

Emotional State

Hospital Anxiety and Depression Scale (HADS). The HADS is a 14-item self-report measure of depressive and anxiety symptoms which contains only the cognitive symptoms of depression and anxiety, thus eliminating the somatic symptoms that are poor indicators of psychiatric distress in the medically ill[34]. Internal consistency alphas range from .41 to . 91[35]. Concurrent validity with other depression and anxiety measures is strong ($r>0.70$). Scores are sensitive to change with treatment[36,37].

Healthy Activities

Adherence to aerobic exercise, self-directed physical therapy, and stress management programs was assessed by individual items asking the frequency of engaging in these activities during the past week.

Analyses

Descriptive statistics were calculated for feasibility and acceptability of PST-OT (i.e., recruitment, retention, and participant satisfaction). We conducted bivariate analyses, using t-tests for continuous variables and Fisher's exact test for categorical variables, to compare demographic, clinical characteristics and outcome measures at baseline. We tested the difference in outcome in both groups at each follow-up time from baseline using analysis of variance with baseline included as a covariate. We also calculated effect sizes using η^2. SAS 9.2 (SAS Institute, Cary, NC) was used for all analyses.

Results

Sample Characteristics

Fifteen participants were assigned to the PST-OT condition and 16 were assigned to the UC condition, with even distributions on the stratification variable of disease stage (80% Stage 2-3 in PST-OT and 75% Stage 2-3 in UC). The study sample averaged 52.6 (SD=9.4) years of age, was 100% Caucasian (reflecting the racial makeup of rural Northern New England at 96% Caucasian) and was married (76%) or divorced (24%). The majority of the sample was employed (48% full time; 14% part time; remainder retired, unemployed, or homemaker) and had at least some college education (66% at least bachelors; 24% some college). The annual household income of most participants (72%) exceeded $40,000 per year. At baseline there were no significant differences between groups on any of the demographic or clinical characteristics.

Primary Outcomes

Recruitment and Retention

Forty-six patients were referred for the study. Eleven declined participation and four were unable to be contacted. The 11 that declined did so for various reasons: six stated they were

"not interested;" two stated they were too "overwhelmed;" one stated she "hate(s)" talking on the phone; one did not want to be "reminded" of her cancer; and one stated she did not have any function-related problems to address. No potential participants were excluded on the basis of psychiatric or cognitive disability. Of the remaining 31 patients, all were found eligible and all were enrolled, for a 67% recruitment rate. Of these 31, six participants withdrew; five from PST-OT and one from UC, for an 81% overall retention rate. One withdrawal from PST-OT and the one withdrawal from UC occurred prior to the baseline assessment. One participant withdrew from the PST-OT condition following baseline and prior to her first PST-OT treatment session. One withdrew after one PST-OT session without explanation. One participant withdrew after one session and one withdrew after the second session, both stating that they did not need help addressing function problems. In total, 29 participants completed the baseline assessment (PST-OT=14; UC=15), 23 completed follow-up 1 (PST-OT=9; UC=14), and 24 completed follow-up 2 (PST-OT=9; UC=15) (77% of the original sample).

Participant Satisfaction

Regarding the quality of overall cancer-related care received, 85% of PST-OT and 86% of UC participants stated their care was very good/excellent (chi square=.10, df=1, p=.75). Regarding their level of satisfaction with participation in the study, 93% of the PST-OT group and 86% of UC participants stated they were satisfied/very satisfied (chi square=.10, df=1, p=.75).

Regarding the acceptability of the PST-OT intervention, the majority of PST-OT participants rated themselves as being satisfied or very satisfied with the intervention (92%). In addition, the majority rated the PST-OT intervention as being either helpful or very helpful for overcoming their participation restrictions (92%).

PST-OT Treatment Characteristics

The mean length of the first session, which included providing the treatment rationale, discussing the range of participation restrictions, and conducting a full PST-OT session, was 71 minutes (sd=16 minute). The mean length of the follow-up sessions (sessions 2-6) which included only a PST-OT session was 35 minutes (sd=13 minute).

The most common problems addressed in PST-OT sessions were initiating and/or maintaining an aerobic exercise program (29% of sessions), followed by instrumental activities of daily living (e.g., cleaning the house, shopping, child care) (15%), work (13%), stress management (12%), maintaining adequate nutrition (9%), and other issues such as sleep problems, leisure activities, upper extremity exercises, and habit change (22%). Participants addressed an average of 2.6 separate problems (sd=1.5, Range=1-5) over the course of the six session treatment.

At the end of each PST-OT session the OT used a 0-10 scale to rate the participant on their efforts to attempt their action plan, the degree to which they completed the action plan, the extent to which the action plan led to resolution of the participation restriction, and the degree to which they understood and independently applied the PST-OT strategy (0=none, 10=completely). The mean scores for attempting the action plan, success with the action plan, and resolution of the participation restriction were 8.0 (sd=3.0), 8.8 (sd=2.6) and 6.8 (sd=2.1), respectively. The mean score for understanding and applying the principles of PST-OT was 7.4 (sd=3.1).

Feasibility of Conducting the PST-OT Intervention

Of 68 planned PST-OT sessions (including those with three former UC participants who requested and received PST-OT after their study participation ended) 65 were completed, for a 97% treatment completion rate. Of the 10 PST-OT participants remaining after the early withdrawals, 62% completed their treatment within the 6-week window targeted in the protocol (i.e., six weekly sessions). The remainder (38%) completed all sessions in seven weeks.

Secondary Outcomes

Of the 31 participants enrolled in the study 29 completed at least one assessment (PST-OT n=14; UC n=15). Unadjusted means for secondary measures at baseline and both follow-ups are reported in the Table (columns labeled Arithmetic Means). In addition, follow-up means adjusted for baseline using ANCOVA are reported together with significance level, effect size, and observed power for PST-OT versus Usual Care comparisons (columns labeled Follow-up 1 and Follow-up 2).

At baseline the PST-OT participants were exercising less (“fitness,” p=.001), and had lower scores on the Emotional Well-Being subscale of the FACT-B (p=.011) and higher anxiety levels on the Anxiety subscale of the HADS (p=.006). These baseline differences were controlled in subsequent analyses.

For baseline adjusted means, several analyses at Follow-up 1 and Follow-up 2 suggested better outcomes for the Intervention group relative to the Usual Care group. Regarding quality of life outcomes as measured by the FACT-B, compared to the UC group at six weeks the PST-OT group scored better on the Social Well-Being subscale, Emotional Well-Being subscale, and Functional Well-being subscale as well as the overall FACT-B scale after adjusting for their respective baselines. Regarding emotional state outcomes, after adjusting for baseline, at both six and twelve weeks the PST-OT group scored better on the HADS anxiety subscale compared to the UC group. . At 12 weeks the PST-OT group also scored better on the Role Emotional subscale of the SF-36 than the UC group. Finally, there were no differences between groups in the frequency of engaging in healthy activities (i.e., upper extremity range of motion exercises, aerobic exercise, stress management activities) (See Table).

Although not included in the table, we also examined utilization of medical services. Of the eight possible categories of visits (e.g., medical, mental health, social work, rehabilitation) only visits for physical therapy showed a trend for differences between groups. Six participants in the UC group had visits for physical therapy versus only one participant in the PST-OT group (p<.06).

Discussion

In this pilot study we tested the feasibility of conducting a randomized controlled trial of a telephone-delivered problem solving occupational therapy intervention (PST-OT) for participation restrictions in rural women with breast cancer who were undergoing chemotherapy. Recruitment and retention of the study sample were relatively strong despite enrolling only participants undergoing the most rigorous chemotherapy regimens. Both PST-OT and UC participants were highly satisfied with their participation in the study and the PST-OT participants were highly satisfied with the PST-OT intervention. A diverse set of participation restrictions were addressed in PST-OT sessions with an average of 2.6 different restrictions being addressed over the course of the 6 PST-OT sessions. The vast majority (97%) of the planned phone-based PST-OT sessions were completed. Rates for attempting

and completing PST-OT homework tasks were moderate to high, and participants were largely successful in resolving their function-related problems.

Observed treatment effects all favored the PST-OT condition across the realms of function, emotional status, and quality of life scales. The UC group was more likely than the PST-OT group to require physical therapy. We hypothesize that the PST-OT intervention, which always encouraged adherence to self-directed physical therapy programs (and specifically problem solved means to this end with two participants), may have circumvented the need for formal physical therapy services.

This study carries limitations common to small scale randomized controlled trials. Due to the small sample size and multiple comparisons, the findings for the secondary aims are subject to an inflated Type I error rate. However, the study was not powered to show treatment effects, and in addition the sample was not chosen on the basis of already existing participation restrictions. On the participation restriction survey administered at baseline participants reported only slight to moderate difficulty with most activities. Some of the participants in both conditions may not have needed a formal intervention.

Also, more participants withdrew from PST-OT (n=5) than UC (n=1). One withdrew from PST-OT prior to baseline assessment, one prior to beginning treatment, two following Session 1 and one following Session 2. It is possible that the “early withdrawals” were due to inadequate randomization in a small scale study rather than a rejection of the treatment. However, three participants withdrew from PST-OT after having sampled a treatment session or two, with two of them stating that they did not need the intervention. Therefore, we may have seen greater treatment effects, as well as fewer withdrawals, had the sample been selected based on the report of participation restrictions. Finally, beneficial effects of PST-OT relative to Usual Care were only observed after covarying baseline values. Given that the PST-OT group evidenced poorer functioning at baseline, these tests could be affected by regression to the mean artifacts.

How do these findings inform future research? First, the modest levels of adherence to the aerobic exercise and stress management programs suggest that these areas should be proactively targeted, along with other participation restrictions, by the PST-OT intervention. Second, only two of the seven significant treatment effects were apparent at the 12 week follow-up; a time when many of the women were still undergoing chemotherapy. The PST-OT intervention ended after six weeks suggesting that some form of intervention may be necessary throughout the entire course of chemotherapy and perhaps even beyond. Finally, future studies should enroll a more racially, socio-economically and ethnically diverse sample.

In conclusion, the findings from this feasibility study support moving forward with larger scale studies of the PST-OT intervention to reduce participation restrictions in female breast cancer patients undergoing chemotherapy.

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