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Older Adults with Cancer: A Randomized Control Trial of Occupational and Physical Therapy

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Abstract

Background/ Objective: The impact of occupational and physical therapy (OT/PT) on functional outcomes in older adults with cancer is unknown.

Design: Two-arm, single institution, randomized control trial of outpatient OT/PT.

Setting: Comprehensive Cancer Center with two off-site OT/PT clinics.

Participants: We recruited adults 65 years and older, with a recent diagnosis or recurrence of cancer within 5 years, with at least one functional limitation as identified by a geriatric assessment. Participants were randomized to OT/PT or usual care.

Intervention: Rehabilitation consisted of individualized OT and PT that addressed functional activities and strength/endurance needs.

Measurements: Primary outcome was functional status as measured by the Nottingham Extended Activities of Daily Living Scale. Secondary outcomes were: Patient-Reported Outcomes

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Study concept and design: Pergolotti, Deal, Williams, Bryant, Reeve, Nyrop, Basch & Muss. Acquisition of subjects and/or data: Pergolotti, McCarthy, Williams, Nyrop. Statistical analysis: Deal. Analysis and interpretation of data: Pergolotti, Deal, Williams, Bryant, Covington, Reeve, Basch, Muss. Preparation of Manuscript: Pergolotti, Deal, Williams, Bryant, McCarthy. Critical revision of manuscript for intellectual content: Pergolotti, Deal, Williams, Bryant, Nyrop, Covington, Reeve, Basch, Muss

DISCLOSURE OF POTENTIAL CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest related to this research.

Measurement Information System®-Global Mental and Physical Health (GMH, GPH), ability to participate in Social Roles (SR), physical function, and activity expectations and self-efficacy (Possibilities for Activity Scale [PActS]).

Results: Among those recruited (N=63), only 45 patients (71%) were evaluable due to loss of follow-up and/or non receipt of intervention. The median age was 74 years; 53% were female, and 91% were White. Thirty percent with hematologic malignancies, 30% breast cancer, and 16% colorectal cancers. Sixty-five percent were in active treatment and 49% had stage 3 or 4 disease. At follow-up, both OT/PT ($p = .02$) and usual care ($p = .03$) groups experienced a decline in functional status. PActS scores between groups ($p = 0.04$) was significantly improved in the intervention group. GMH and SR met criteria for Minimally Important Clinical Difference favoring the intervention, but not statistical significance. Several barriers were noted in implementation of intervention program: recruitment, concerns about cost, distance, scheduling, and limited treatment provided.

Conclusions: OT/PT may positively influence activity expectations and self-efficacy. Future research needs to address significant barriers to implementation to increase use of OT/PT service and access to quality care.

Keywords

cancer; aging; cancer rehabilitation; geriatric oncology; geriatric assessment

Introduction

The steady growth in America's aging population¹ and the number of cancer survivors over age 65,² provides a unique opportunity to develop care specifically designed for older adults with cancer. Compared to older adults without cancer, older adults with cancer report increased pain, lymphedema, neuropathy, chronic fatigue, and cognitive decline.³ At least 50% of older adults with cancer need help with at least one activity of daily living (ADL) and 75% need help with one or more instrumental activities of daily living (IADL), such as managing medications, preparing meals, performing household chores, traveling within the community, or using a telephone.⁴ Dependencies in IADL and ADL (i.e. functional status) may impede an older adult's ability to safely and independently participate in social, leisure and work activities,⁵ meaningful roles (e.g. mother, caretaker, brother) and/or social activities⁶, as well as reduce overall quality of life (QOL)⁷. Furthermore, limitations in IADL are associated with increased risk for chemotherapy toxicity,⁸ decreased ability to complete treatment⁹ and reduced overall survival.¹⁰

Occupational (OT) and physical therapy (PT) are services that provide targeted, individualized interventions to help patients prevent, reverse or adapt to impairment or disability. Evidence of the need for cancer rehabilitation (defined as either OT or PT or both) strongly suggests that older adults engage with rehabilitation specialists to mitigate functional decline and improve mental health and QOL outcomes.^{11–15} OT's utilize a multitude of interventions to establish skills, maintain capacities, modify contexts (the environment in which, or the way an activity takes place), and prevent performance limitations (<https://www.aota.org/About-Occupational-Therapy/Patients-Clients.aspx>)¹⁶

PT's, in turn, assess musculoskeletal, neurological, and cardiopulmonary systems to create patient-centered plans to reduce pain, improve or restore mobility and physical function, and prevent disability (<http://www.apta.org/PTCareers/RoleofaPT/>)¹⁷ The services of both OTs and PTs are generally underutilized in the care of older adults with cancer,¹⁸ even among patients with known functional limitations; in fact, less than 9–15% of older adults with cancer receive referrals to OT or PT services.¹⁹ Without skilled assessment and intervention, the myriad challenges experienced by older adults with cancer often contribute to a decreased QOL.²⁰ Potential barriers to cancer survivors receiving OT/PT include lack of awareness of rehabilitation services by the patient, and lack of awareness of OT/PT need by the treating physician.^{21, 22} There is also a gap in research regarding the efficacy of outpatient OT/PT for adults with cancer, and specifically no trials that examine the efficacy of such services.¹³

To address this gap, we developed a, randomized control trial examining the impact of an outpatient OT/PT cancer rehabilitation program developed specifically for older adults with cancer with functional needs. The primary aim of this study was to determine if cancer rehabilitation could maintain or improve functional status. Secondary aims were to compare QOL and the possibilities for activity (i.e. activity expectations and self-efficacy, or what older adults feel they should be and could be doing) between intervention and control groups.

Methods

This was a two-arm, single institution, randomized control trial testing outpatient cancer rehabilitation services. The study protocol has been described in a previous publication²³ and is briefly summarized here. The study was registered with Clinicaltrials.gov (NCT02306252) and approved by the protocol review committee of a comprehensive cancer center and the Institutional Review Board (IRB number 14–1159) at the University of North Carolina.

Participants

Participant eligibility included: an appointment in the university's outpatient cancer clinic; diagnosis of cancer or recurrence within the last five years; and at least one functional need for rehabilitation determined by a geriatric assessment (GA).²⁴ Eligible GA impairments were assumed to be modifiable by OT/PT and included: decreased cognition, function and/or physical health status, and reporting previous falls.

Screening measures.—GA measures were used to detect eligible impairments: Blessed Orientation-Memory-Concentration (BOMC) scale (score ≤ 11 considered at risk for cognitive impairment);²⁵ Timed Up and Go (TUG; fall risk >13.5 seconds);^{26, 27} subscale Multi-dimensional Functional Assessment Questionnaire Older Adults Resource and Services (OARS) (score <14 considered dependency in any IADL);^{28–30} Medical Outcomes Study (MOS) physical health scale (dependency in bathing/dressing or an overall score of 70 or below as evidence of decreased physical ability);³¹ presence of falls in the last 6 months; and low 30 second sit to stand test performance (cut off value determined by age).^{23, 27, 32}

Older adults with cancer were excluded if they were already receiving OT or PT or were enrolled in hospice. The authors acknowledge that adults enrolled in hospice could still benefit from cancer rehabilitation; however, this study was designed for patients receiving outpatient care with a longer life expectancy.

Procedures

Enrolled patients completed written informed consent and baseline assessments (see Measures). Randomization to intervention or control group was stratified by treatment status (active or completed), using blocks of size 6. For participants randomized to intervention arm, research assistants worked with treating oncologists to enter the referral for OT/ PT. Patients were contacted by telephone at 2 and 3 months for follow-up.

Intervention

Patients were Medicare beneficiaries 65 years old who were eligible to receive billable outpatient PT and OT services at an outpatient clinic associated with the university-affiliated hospital for their OT and/or PT treatment. A Plan of Care was developed in collaboration with the patient, with treating therapists (PT/OT) determining duration and intensity. OT focused on improving the patient's functioning in performing IADL/ADL such as bathing, food preparation, managing medications, upper extremity function, and social participation. PT focused on decreasing pain and improving movement for greater activity and participation. OT's and PT's completed an hour of training on cancer rehabilitation in person, with follow-up phone calls to discuss intervention as needed. Follow-up phone calls were conducted by the study coordinator to: ensure OT/PT appointments were made, kept, and rescheduled as needed, and to collect final post assessment data at 3 months.

Usual Care

Patients randomized to usual care arm received a brochure outlining services and contact information for supportive care programs available at the Lineberger Comprehensive Cancer Center. Usual care arm participants were not restricted from receiving OT/PT services if they desired, however, they were not assisted with getting a referral. At follow up, participants in usual care group were asked if they received OT/PT services during the trial and if they were interested in receiving services after trial completion.

Supportive care program

Comprehensive Cancer Support Program at UNC was available to both groups; supportive care program services included: mental health services, oncology-certified registered dietitians, geriatricians, pharmacist and nurse who help manage the symptoms of cancer and its treatments (e.g. chronic pain management), and a clinical social worker.

Measures at baseline and post-assessment

Nottingham Extended Activities of Daily Living (NEADL)—NEADL is a patient-reported assessment of independence in IADL (i.e., functional status). Twenty-two questions cover four domains of activity -- mobility, leisure, kitchen, and domestic tasks. Scores range

from 0–66, with high scores indicating more independence with IADL, and clinically meaningful difference defined as 2 points.^{33–35}

Patient-Reported Outcomes Measure Information System® (PROMIS®)—Three PROMIS® assessments were: Global Health QOL 10-item, which measures global mental health (GMH) and global physical health (GPH); Ability to Participate in Social Roles and Activities (SR); and Physical Function (PF). All are validated health-related QOL measures rated on a 5-point Likert-type scale.³⁶ PROMIS is scored using T-scores, standardized to the U.S. general population, with a mean of 50 and standard deviation of 10.^{36, 37} Higher scores indicate better health and abilities. Clinical meaningful differences is as 3 points.³⁶

Possibilities for Activity Scale (PActS)

PActS measures the pressures of participation in meaningful activity in two sub domains: activity self-efficacy and activity expectations.³² These domains measure what older adults feel they should and could be doing which, in turn, is a strong predictor of participation in meaningful activity.³² Response options are in a Likert-type format ranging from ‘very little’ [1] to ‘quite a lot’ [5], and summed for a total score from 12–60. Higher scores indicate better congruence between what respondents feel they should/could be doing and their participation in meaningful activity.³²

Statistical Considerations

We assumed a decrease of five points on NEADL for the control group, and no change for the intervention group (indicating preservation of function). Planned study enrollment was 82 patients (37 evaluable patients in each arm) to detect an effect size of 0.667 with 80% power.

Descriptive statistics were used to summarize baseline characteristics of the sample. Change scores for patient-reported outcomes were evaluated using Wilcoxon Signed-Rank tests and compared between groups using Wilcoxon rank sum tests; medians were reported. Analyses were completed using SAS, version 9.4 (SAS Institute, Inc., Cary, NC).

Results

Study participants.

Due to recruitment difficulties, accrual was stopped early, short of the target of N=82. Sixty-three patients were consented and randomized; follow-up data were available for 51 (81%) participants (26 usual care, 25 intervention), constituting the final sample (Figure 1.) Nineteen patients (76%) in the intervention arm received PT/OT and were included in the analysis, as shown in Table 1. Mean age was 74 years (range 65–92). The most common cancer diagnoses were leukemia and lymphoma (30%), breast (30%), and colorectal (16%). The most common comorbid conditions were other cancers, arthritis, and high blood pressure, with 34% having 4 comorbidities (median = 3).

Geriatric Assessment, Screening Needs for Cancer Rehabilitation.

Of the 51 participants enrolled, almost half ($n = 24$, 47%) had 3 or more GA-identified needs for cancer rehabilitation. Twenty-three participants (45%) reported a recent fall; and 31 patients (61%) reported a difficulty with IADL and/or physical health, all suggesting the need for cancer rehabilitation services (Figure 2). Mean needs were 3 for control group and 2 for intervention, with the control group reporting more difficulties with IADL, but overall groups were similar.

Utilization/Implementation of OT/PT services.

Of 32 patients randomized to intervention arm, $n=7$ were lost to follow up – $n = 4$ received OT/PT but we were unable to contact them for follow-up and $n = 3$ did not receive OT/PT intervention due to hospitalization or becoming too ill. An additional 6 individuals did not receive the intervention and gave reasons including: too ill ($n = 4$), “too busy” ($n = 1$), too costly ($n = 2$), too far from home ($n = 2$) (Figure 1).

For the remaining 19 participants with follow-up data who were seen by OT and/or PT, the number of OT/PT visits ranged from 1–12 depending on patient needs (median=3 OT/PT sessions), with one participant still receiving rehabilitation at follow-up. Seven individuals started OT/PT and then dropped out and gave reasons including: became too ill ($n = 2$), too busy ($n=1$), costly ($n=1$), or not seeing value ($n=3$). Six participants (31.6%) were seen only once as an evaluation and discharge; five refused service (PT or OT); and eight reported long wait times to get an OT/PT referral or appointment.

Within the usual care group, no patients reported receiving OT/PT rehabilitation services during study period. Eleven (42 %) specifically stated they wanted rehabilitation services after study was completed.

Post assessment.

Participants were contacted for follow-up at 2 and 3 months-post baseline data collection, or until an assessment could be completed ($M=3.3\pm1.9$ months). On average, it took 4.7 calls per participant to attain follow-up data (range 2–12), and about an hour per phone call (30–90 mins). Within the usual care group, we were unable to contact one participant, one was too ill to answer follow-up questions, and three participants died during the trial.

At the follow-up assessment, there was a clinically and statistically significant decline in functional status in both groups as measured by the NEADL ($p = 0.02$ intervention, $p = 0.03$ control); and between intervention and usual care there was no significant difference ($p = 0.88$), (Figure 2 and Table 2). The intervention group reported clinical improvement (met MICD criteria; change scores of 2.5– 6) from baseline to follow-up for PROMIS measures³⁸ including: SR (intervention $\Delta = 3.21$), PF ($\Delta = 2.6$), and global mental health ($\Delta = 2.55$), and trending in that direction for global physical health ($\Delta = 2.17$). Two scores met criteria for MICD favoring the intervention between groups, GMH and SR, although these did not achieve statistical significance. At follow up, there were statistically significant differences in PActS scores between groups ($\Delta = 3.11$ intervention and $\Delta = - 3.2$; $p = 0.04$).

Discussion

Our study is one of the first randomized controlled cancer rehabilitation trials designed specifically for older adults with functional impairments. The intervention was associated with a significant improvement in participant's perceived possibilities for activity compared to usual care. However, in the primary measure, functional status significantly declined in both intervention and control, with no difference between the two groups. The results from our trial must be interpreted with caution, as there were multiple challenges in the implementation of both our study design and the cancer rehabilitation program. There are lessons to be learned from our experience for future rehabilitation trials and OT/PT services for older adults with cancer.

With regard to the implementation of our study design, we have noted early termination of accrual to the study due to time and funding constraints, resulting in a smaller than planned final sample. Large numbers of patients declined to participate in the study or to start the intervention, generally due to the time, cost and travel distance necessary to participate in OT/PT rehabilitation. They could not see the value of OT/PT, even in light of GA-defined deficits. These barriers reflect real world issues such as: patient's valid concerns about cancer care cost,³⁹ lack of awareness of the potential value of rehabilitation, and poor integration of rehabilitation services within cancer care.^{40, 41} A better understanding of how to get past the first barrier to participation in rehabilitation: willingness to consider OT/PT, is an important consideration for future efforts to study and/or build an OT/PT program for older patients. And then, close to a third of patients were lost to follow-up, some for unavoidable reasons such as death or illness, while others simply could not be contacted despite repeated labor-intensive efforts to reach them.

Among patients enrolled in the study, the transitions from patient interest/enrollment in the study to provider referral to OT/PT service were by far the greatest struggle. The first delay was difficulty getting OT/PT referrals into the electronic medical record and written correctly. Upon referral, some patients then had to wait over a month for their first OT/PT appointment. This difficulty in securing an appointment in a timely manner could be due to the process of traditional triage used in outpatient rehabilitation clinics which prioritizes patients who are in an acute phase or patients with orthopedic needs, over patients with a chronic condition or more complex cases.^{42, 43} This delay caused some study participants in the intervention arm to decide against following through with therapy, without being seen by rehabilitation services.

For those who received PT/OT evaluation, patients faced yet another barrier. Although cancer-specific training was provided by study staff, rehabilitation clinicians, it appears, were not adequately prepared to meet the preventative and chronic-condition care/management needs throughout the cancer-care continuum. This represents an important issue not only in our study, but in clinical practice. Because rehabilitation practitioners have become accustomed to the typical outpatient rehabilitation patient (e.g. someone recently discharged from hospital for stroke, or a knee replacement) the concept of prospective and participation-based interventions to improve health related quality of life (HRQOL) and prevent further decline may be foreign. About 37% of patients who were seen by an OT or

PT (or both), only had an evaluation. Considering patients met eligibility criteria (i.e., 1 functional limitation), we expected a greater percentage of follow-up visits would be initiated by the therapist and completed by the participant. Although we cannot be definitive, anecdotal evidence from therapists supported a lack of recognition and understanding of the long-term needs of this population. For older adults with cancer, the need for prospective, longitudinal assessment and treatment can be critical to align with patient values of independence and decreasing caregiver burden, participating in meaningful activities, and desire to maintain HRQOL.^{11, 44, 45}

In terms of the significant improvement in activity self-efficacy and expectations that we found in our study, this result is similar to what has been reported in other cancer and non-cancer studies. For example, Cooper (2014) found that OT for adults with cancer reduced stress and increased sense of control, allowing for better management of psychosocial needs. OT services for older adults with other chronic conditions can decrease the likelihood of re-hospitalization and use of skilled nursing services and has been shown to improve functioning and confidence in participation in social life.^{46–51} De Groef and colleagues⁵² found that outpatient PT can improve physical health and decrease pain. However, to our knowledge, ours is the first RCT to examine use of both OT and PT services for older adults with cancer and demonstrate clinical improvements in treatment groups, there is the promise of the OT/PT team improving care.

Future research should also investigate out of pocket costs and examine cost-benefit analyses to better examine value. If the cancer rehabilitation team was more integrated with cancer care this could potentially encourage patient engagement as being “a part” of the overall treatment plan. Engaging case managers or patient navigators to assist in the referral and appointment process could ease access and integration. If rehabilitation therapists were specifically trained and patients were informed about the potential benefits of rehabilitation for older cancer patients, OT and PT could potentially have significant impacts on health outcomes. Comprehensive therapist training, even cancer rehabilitation certification, could render better results. There is increasing interest in the role of cancer rehabilitation in national programs to provide non-pharmacological interventions for survivors,⁵⁸ to educate and certify specialists and test cancer rehabilitation services in the community.⁵⁹ With more therapists specializing in cancer rehabilitation, this could ease the triage bottleneck to allow for decreased wait times for appointments and more targeted therapeutic interventions. We also recommend studying and adding caregivers as patient-family centered practice and intervention, as both the caregiver and older cancer patient may need OT/PT attention. Although cancer rehabilitation shows promising clinical impact, through improvement in self-efficacy and activity expectations, research needs to continue to break down barriers and build on this trial to demonstrate value.

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Conflict of Interest

MP has no COI; This research was supported in part by the National Cancer Institute of the National Institutes of Health under award number **R25CA116339**; the University Cancer Research Fund, Lineberger Comprehensive Cancer Center (LCCC-0916); and Drs. Williams and Bryant were supported, in part, by the UNC Oncology Clinical Translational Research Training Program (NCI **5K12CA120780-07**). Our study was reviewed and approved by the Protocol Review Committee of the UNC Lineberger Comprehensive Cancer Center and the UNC Institutional Review Board. We would like to acknowledge Erin Coffman and Mallory Jolly for their help with recruitment and follow-up phone calls.

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Figure 1.
Consort diagram of RCT of Occupational and Physical Therapy for Older Adults with Cancer with Function Needs

Figure 2.
Percentage of Participants by Geriatric Assessment-based Occupational and Physical Therapy Need. IADL = Instrumental Activities of Daily Living. TUG = Timed Up and Go. ADL = Activities of Daily Living.

TABLE 1.

Sample demographics at baseline

Demographics	Full Sample N = 45	Usual Care <i>n</i> = 26	OT/ PT Intervention <i>n</i> = 19
Mean Age	74 (65–92: SD: 8)	75 (65–92: SD: 8)	73 (65–88: SD: 7)
Sex			
Female	24 (53 %)	12 (46 %)	12 (63 %)
Male	21 (47 %)	14 (54 %)	7 (37 %)
Race			
White	41 (92%)	23 (89 %)	18 (95%)
Education			
High School or Less	5 (10 %)	3 (12 %)	0 (0 %)
Some College	10 (22 %)	5 (19 %)	5 (26 %)
College and/or grad	30 (68 %)	18 (69 %)	14 (74 %)
Married	30 (67%)	15 (58 %)	15 (79 %)
Cancer type			
Hematologic	15 (32 %)	9 (35 %)	6 (32 %)
Breast	13 (30 %)	8 (31 %)	5 (11 %)
Gastrointestinal	9 (20 %)	6 (23 %)	3 (06 %)
Other	8 (18 %)	3 (11 %)	5 (11 %)
Cancer stage			
Stage 0–1	9 (20 %)	6 (23 %)	3 (23 %)
Stage 2–3	14 (31 %)	8 (31 %)	6 (32 %)
Stage 4	8 (23 %)	5 (19 %)	3 (16 %)
Other	4 (10 %)	7 (27 %)	7 (37 %)
In active cancer treatment *	26 (65%)	15 (63 %)	11 (69 %)
Mean NEADL	54 (23–66:SD: 11)	54 (32–66:SD:11)	55 (23–66:SD:12)
Mean PROMIS			
Global Mental **	47 (34–63: SD: 7)	47 (34–59: SD:8)	47 (36–63: SD:7)
Global Physical **	43 (30–54: SD: 7)	42 (32–54: SD:7)	45 (30–54: SD:7)
Social Roles	48 (37–64: SD: 6)	48 (37–64: SD:7)	48 (41–58: SD:5)
Physical Function	40 (23–61: SD: 5)	42 (32–48: SD:5)	41 (23–53: SD:7)
Mean PActS ^	46 (30–60: SD: 8)	46 (30–60: SD:7)	46 (33–59: SD:9)
Previous Fall	20 (44 %)	13 (50 %)	7 (37 %)

Note. NEADL = Nottingham Extended Daily Living Score (0–66). PROMIS = Patient-Reported Outcomes Measurement Information System (0–100). PActS=The Possibilities forActivity Scale (12–60).

*
n=40.

**
n= 44

^
n= 43.

Table 2.

Baseline and post assessment scores in usual care and intervention

	Usual care (<i>n</i> = 26) Mean (SD)			OT/PT (<i>n</i> = 19) Mean (SD)			<i>p</i> - value
	<i>Baseline</i>	<i>Post</i>	Δ	<i>Baseline</i>	<i>Post</i>	Δ	
Functional Status *	53.7 (10.8)	49.4 (12.1)	-4.4 (9.7)	55.2 (12.1)	51.2 (13.2)	-4.0 (6.9)	0.88
PROMIS®							
QOL GMH	47.6 (7.6)	46.7 (7.9)	-1.0 (5.9)	47.4 (6.9)	49.9 (9.9)	2.6 (6.7)	0.08
QOL GPH	42.5 (6.6)	42.5 (5.6)	-0.0 (5.1)	45.0 (6.7)	47.2 (7.8)	2.2 (5.5)	0.18
Physical Function	39.8 (4.3)	41.3 (6.6)	1.5 (4.3)	41.7 (6.6)	44.4 (9.1)	2.6 (5.2)	0.49
SR QOL	48.2 (6.4)	48.3 (8.0)	0.1 (6.8)	48.6 (5.5)	52.0 (8.7)	3.2 (7.0)	0.16
PActS	45.5 (7.3)	42.2 (12.5)	-3.2 (12.1)	46.0 (8.6)	49.1 (7.8)	3.1 (6.9)	0.04 *

Note. *N*= 45; SD = standard deviation.

* Functional Status measured by Nottingham Extended Daily Living Score (NEADL), PROMIS®=Patient-Reported Outcomes Measure Information System. GMH =Global Mental Health. QOL = quality of life. GPH= Global Physical Health. SR = Participation in Social Roles. PActS= The Possibilities for Activity Scale (activity expectations and self-efficacy).