Published in final edited form as:

Contemp Clin Trials. 2015 September ; 44: 89–94. doi:10.1016/j.cct.2015.07.021.

A Randomized Controlled Trial of Outpatient Cancer REhabilitation for Older Adults: The CARE Program

Mackenzi Pergolotti, PhD, OTR/L^{a,b}, Allison M Deal, MS^b, Grant R. Williams, MD^c, Ashley L. Bryant, PhD, RN-BC, OCN^d, Bryce B. Reeve, PhD^b, and Hyman B. Muss, MD^c

^aCancer Care Quality Training Program, 1102G McGavran-Greenberg Hall, CB# 7411, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599 USA

^bDepartment of Health Policy and Management, 1102G McGavran-Greenberg Hall, CB# 7411, The University of North Carolina at Chapel Hill, Chapel Hill, NC 27599 USA

^bBiostatistics Core Facility, The University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center, 170 Manning Drive, Chapel Hill, NC 27599 USA

^cGeriatric Oncology Program, The University of North Carolina at Chapel Hill, Lineberger Comprehensive Cancer Center, 170 Manning Drive, Chapel Hill, NC 27599 USA

^dSchool of Nursing, The University of North Carolina at Chapel Hill, Carrington Hall, CB #7460, Chapel Hill, NC 27599-7460

Abstract

Background—Large numbers of older adults (aged 65 years or older) are surviving cancer; however, many survivors report decreased quality of life (QOL) and limitations in activities of daily living (ADL) and instrumental activities of daily living (IADL) both during and after treatment [1–3]. Occupational and physical therapy (OT/PT) are services focused on improving functional status and QOL that are largely unexplored and underutilized in cancer survivorship care [4, 5].

Methods/Design—This is a randomized, single-blind, two-arm, single institution pilot study. Eighty-two patients will be recruited from a university-affiliated outpatient oncology clinic. Inclusion criteria include the following: aged 65 years or older, diagnosis of cancer within 5 years, English speaking, has at least one functional deficit, and able to safely participate in an outpatient rehabilitation program. Exclusion criteria are: currently receiving rehabilitation or eligible for hospice. Consented patients will be randomized into two groups: (1) the CARE (CAncer REhabilitation) Program consisting of outpatient OT/PT and (2) standard of care. Primary outcome: change in Nottingham Extended Activities of Daily Living (NEADL) scores from baseline to 3 months between CARE and control.

Corresponding Author: Mackenzi Pergolotti, PhD, OTR/L, Telephone: 919-966-7382, Fax: 919-966-6961, pergolot@email.unc.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Trial Registration: ClinicalTrials.gov: Identifier NCT02306252

Discussion—This study is one of the first RCTs aimed at examining the effect of OT/PT in older adults with cancer. If positive, findings from this study will suggest the potential for outpatient OT/PT to improve the functional ability and QOL of older adults with cancer.

Keywords

Occupational Therapy; Physical Therapy; Cancer Rehabilitation; Geriatric Oncology

Introduction

Currently, there are about 7 million cancer survivors over the age of 65 years [6] and by 2030, older adults will be about 70% of the overall cancer survivors population [7]. Advancing age is associated with a decline in functional ability [7, 8]; however, older adults with a cancer diagnosis have a greater likelihood than same age counterparts without a cancer history to report decreased quality of life (QOL) and limitations in activities of daily living (ADLs) and instrumental activities of daily living (IADL) [1, 2, 9]. Adults with functional deficits are at an increased risk for falls, hospital admission, higher readmission rates, and longer inpatient stays due to caregiver burden, difficulty with symptom control, and poor QOL [1, 9–12].

Occupational and Physical therapy (OT/PT) are supportive services aimed at improving functional status (ADL and IADL), physical health, and QOL, yet they remain largely unexplored and under-utilized in this population [4, 13]. Both OT and PT differ from most basic exercise interventions because they are more highly individualized and during every session, patients are re-evaluated and treatment plans adapted as needed. Examples of some of the OT services that could be especially helpful for older cancer survivors are self-care management and adaptation, environmental assessment and adaptation, energy conservation, cognitive rehabilitation, and fall prevention techniques. Similarly, the following examples are some of the PT services could be especially helpful for older cancer survivors, individualized exercise plans, balance and endurance training, and adaptive equipment provision and training (cane, walker etc.). Only recently has research within this field expanded to include problem-solving techniques utilizing OT and specific OT/PT modalities, such as exercise, stretching, and cognitive rehabilitation but again, they are mostly evaluated with women with breast cancer [14] and at times not tested in real-life pragmatic settings [15, 16].

There is a great need to establish the evidence base for outpatient OT/PT services in cancer survivorship care. This paper presents the design and protocol for a randomized controlled trial (RCT) comparing OT/PT services (Intervention) with usual care (Control) in older cancer survivors (age 65+ years) who have ADL or IADL deficits.

The intervention is the CAncer REhabilitation for Older Adults (CARE) program which provides focused rehabilitation through an outpatient OT/PT program. The OT and PT services offered through the CARE program are not new; instead, they are already available in the hospital where study participants will be recruited. What is innovative is having these existing OT and PT services utilized by a wider range of patients – beyond breast cancer patients seeking relief from lymphedema – with a specific focus on older cancer patients

[17]. This trial aims to evaluate the CARE program's impact on maintaining or improving functional status/ability, improve QOL, and decrease disability in older cancer patients compared to usual care (no OT/PT services).

Methods/Design

The study was prospectively registered with [Clinicaltrials.gov](https://clinicaltrials.gov) (registration number NCT02306252) and approved by the protocol review committee of the Institutional Review Board. All participants will sign an informed consent prior to participation in the study.

Study Sample

Potential study participants will be identified through daily review of patients scheduled for an outpatient oncology appointment. Their medical records will be reviewed for eligibility criteria and identified patients will be approached, screened and enrolled on a consecutive basis. To be eligible for the study, patients must be 65 years or older and with a diagnosis of cancer (any type) within the last 5 years. Participants must not be eligible for hospice and be able to safely participate in an outpatient OT/PT rehabilitation program. Participants will be considered safe to participate in therapy at the discretion of the oncology provider. Adults who are unable to read English are not eligible because our measures have not been tested or validated in a non-English speaking population at this time.

Once initial eligibility has been determined, and the printed consent forms have been signed, participants will complete all baseline measures. A brief geriatric assessment (GA) [18, 19] that our research team has used in several geriatric oncology studies [5, 20–23] will be used to determine if the patient has a functional deficit. The specific scales within the GA used for this functional deficit screen are described in detail below. Patients with one or more GA-identified functional deficits will be randomized into either CARE program (Intervention) or usual care (Control). Participants without GA-identified functional deficits at baseline will not have any further follow-up assessments or study activities.

Determining Eligibility with the GA as a Screener Tool

To determine eligibility for study participation and the extent of OT and/or PT needed for cancer rehabilitation, the following GA sections/scales and cutoffs will be used:

1. the Blessed Orientation-Memory-Concentration scale (BOMC, scores 11 or greater);
2. Timed Up and Go (TUG, scores greater than 13.5 seconds),
3. The IADL subscale of the Multidimensional Functional Assessment Questionnaire (MFAQ): Older American Resources and Services (OARS) (scores less than 14);
4. Answers either “limited a lot” or “limited a little” to ADL question within the Medical Outcomes Study (MOS) Physical Health scale;
5. MOS Physical Health (scores 70 or below);
6. One or more falls within 6 months.

If a patient has only a cognitive deficit (defined by BOMC score) and is randomized into CARE program, only an OT referral is needed.

Randomization

Stratified randomization will be used to separate patients actively receiving chemotherapy or radiation treatment from those who are not and then randomized 1:1 to the Intervention (CARE program) or Control arm. The randomization schedule will not be available to study recruiters and treating clinicians with allocation being concealed until after baseline assessment completed and intervention assigned. This is the only point in which interviewers/recruiters will be blind. Only our study coordinator has access to the randomization schedule. All participants, regardless of their randomization, will receive a supportive care brochure with information about auxiliary services available for patients.

Intervention

The CARE program will be implemented by the University of North Carolina (UNC) OT/PT rehabilitation clinic. Patients randomized to the Intervention will be contacted within three days to make an appointment for an outpatient OT and PT initial evaluation. Based upon results from the rehabilitation-specific assessments (described below in Measures), the type and frequency of treatment will be determined by the treating OT and PT. Most interventions will last approximately 6 weeks. At discharge from CARE program, all intervention assessments will again be performed by the OT/PT to evaluate changes in all measures. Telephone calls will be made to ensure appointments are made, kept and rescheduled as needed. Patients who decline to keep study appointments will be contacted via telephone for final post assessments (2 and 3 months) unless they withdraw from the study.

Occupational therapy (OT) evaluation and treatment

Occupational therapy will focus on improving patients' functioning in performing ADL and IADLs such as bathing, food preparation, and managing medications. Therapy will also focus on upper extremity function and social participation. Evaluation and treatment will be on a one-to-one basis and 'client-centered', meaning tailored for each patient with the patient having a shared responsibility for goal making. Treatments will follow the scope of practice and national guidelines as provided by the American Occupational Therapy Association (AOTA). Treatments will include but not be limited to the following domains within OT scope of practice: ADL, IADL, functional ability, social limitations, goal setting, cognitive rehabilitation, adaptive and durable medical equipment provision, neuro-muscular treatment, massage, manual treatment, range of motion, therapeutic activities, self-care management, prevention of falls training, changing routines and habits, self-efficacy for specific tasks, splinting orthotic provision and management, modalities (such as ultrasound, electrical stimulation etc. as seen appropriate by the therapist and MD), fatigue management, exercise, energy conservation, home and community safety, and lifestyle changes.

Physical therapy (PT) evaluation and treatment

Physical therapy will focus on improving range of motion, strength, and endurance. Evaluation and treatment will be on a one-to-one basis, patient-centered and tailored for

each patient. Treatments will follow the scope of practice and national guidelines of the American Physical Therapy Association (APTA). Treatments will include but may not be limited to the following domains: goal setting, exercise, massage, balance training, neuromuscular treatment, ambulation, pelvic floor training, deconditioning, range of motion, manual treatment stretching, strengthening exercises, endurance building, prevention of falls training, adaptive and durable medical equipment provision, modalities, orthotic provision and management, fatigue management, home and community safety, and manual treatment (used to treat soft structures for the purpose of pain control, improving range of motion, and stability of a joint).

Control arm: supportive care brochure only

Patients randomized to the Control arm will receive contact information and a brochure outlining the services available through the Comprehensive Cancer Support Program (CCSP), which does not include OT and PT. The CCSP offers many different programs, including mental health services to provide support and symptom management for psychological issues, oncology-certified registered dietitians who provide nutritional counseling, and geriatricians who specialize in the care of older adults. The CCSP also has a pharmacist and nurse team to help patients manage the symptoms of cancer and its treatments including chronic pain management, and a clinical social worker to assist with financial and supportive counseling. We will use self-report to determine use of OT/PT within control arm at follow-up phone calls.

Study Endpoints and Assessments

Measures were chosen based on the strength of their psychometric properties, usability, cost, and minimal burden for the study participant. Table 1 provides an overview of all assessments and measures and specific time points.

Geriatric Assessment (GA)

The GA used in this study, originally developed by Hurria and colleagues [24], will screen potential participants for functional deficits [21, 24, 25]. There are two sections of the GA, one is completed with the assistance of a trained research assistant and the other is patient-reported. The first section contains basic demographic questions then the BOMC scale, the Karnofsky Performance Status tool (KPS), and the TUG [24]. The BOMC is a basic cognitive assessment which asks questions regarding orientation, memory and attention [26, 27]. The KPS is a common scale used by physicians to rate performance status [28, 29]. The TUG is a balance assessment where the participant is asked to stand up from a chair, walk ten feet, turn around and return to a seated position. This balance test is also a good measure of fall risk [24, 28–31].

Following completion of the staff administered portion of the GA, the patient will complete the patient questionnaire. The initial section includes more demographic questions. The first tool asks about IADLs and is a subsection of the MFAQ: OARS (7 questions) [32, 33]. Each question is scored from 0 (completely unable) to 2 (without help) and sums to a score of 0–14. Higher scores indicate more independence with activities such as laundry, preparing

meals or doing housework. This is followed by the Physical Health (10 items) subscale of the MOS, which measures engagement in activities related to physical abilities such as walking and climbing stairs. The patient-reported KPS is also included in this section [34]. This scale measures a participant's perception of their own performance status. Additionally, we ask patients to report the number of times they have fallen in the last 6 months.

This GA also includes a patient-reported co-morbidity scale (the Physical Health Section of the OARS) [35] which contains a list of current illnesses and conditions an individual might have and the degree to which they impair daily activities, as well as a request for the patient to list all current medications they are taking. A brief section on nutrition follows, comprised of 3 brief questions that examine unintentional weight loss in the last 6 months. The GA measures mental health with the Mental Health Index (MHI-17), social functioning with the MOS Social Activity Limitations Measure (4 questions) and social support with the MOS Social Support Survey: Emotional/Information and Tangible subscales (12 items).

Primary Endpoint Nottingham

Extended Activities of Daily Living Scale (NEADL)—NEADL is a patient-reported assessment of independence in ADL and IADLs. The tool is frequently used in rehabilitation and geriatric oncology research and has been shown to be able to document activity/ability over time [36, 37]. Twenty-two questions cover four domains of activity -- mobility, leisure, kitchen and domestic tasks. Scores range from 0–66, with higher scores representing greater independence and a score of 44 or higher represents no need for assistance [38, 39]. A clinically meaningful difference has been defined as 2 points. This scale can be used in person or over the telephone. [36–38, 40–42].

Secondary endpoints

Patient-Reported Outcome Measurement Information System® (PROMIS®)—The following PROMIS short forms are used: Physical Function-10 items, Satisfaction with Participation in Social Roles-4 items, Ability to Participate in Social Roles and Activities-4 items, and Global Health- 10 items. All are validated instruments with items ranked on a 5 point scale with higher scores indicating better health-related quality of life. PROMIS is scored on a T-score metric, which are standardized to the U.S. general population and have a mean of 50 and a standard deviation of 10 [43, 44].

Possibilities for Activity Scale (PActS)—The PActS measures the internalized pressures of participation in meaningful activity in two sub-domains: activity self-efficacy and activity expectations. These measure what older adults feel like they *should be* and *could be* doing, which is a strong predictor of participation in meaningful activity [22, 45]. Questions are answered in a Likert-type format with answers ranging from 'very little' [1] to 'quite a lot' [5]. Items are summed for a total score ranging from 12–60 [45]. Higher scores represent more perceived possibilities for participation in activity.

Measures used within intervention arm only

These measures will be assessed both before and after rehabilitation. The OT will administer the Disabilities of the Arm, Shoulder and Hand (DASH) and the Montreal Cognitive

Assessment (MoCA). The DASH outcome questionnaire is a self-administered, 30 item disability/symptom scale scored 0–100 with increasing scores corresponding to increasing disability [46, 47]. The MoCA is a rapid screening tool for mild deficits in cognition. Cognitive domains assessed include the following: attention and concentration, executive functions, memory, language, visuospatial skills, conceptual thinking, calculations, and orientation. Maximum score is 30, anything below a 26 is considered impaired [48]. Patients with only cognitive deficit are an exception (because they will only be seen by OT) and will at a minimum be assessed with the MoCA. The OT will also complete the Canadian Occupational Performance Measure (COPM). This measures a patient's perception of performance and satisfaction in activities they find meaningful. This tool is used to aid in goal making and direct client-centered care [49, 50].

The PT will administer the Berg Balance Scale (BBS) and the Dynamic Gait Index (DGI). The BBS is a performance-based measure of balance in older adults [51]. The BBS is a 14 item scale that is scored between 0–4. Maximum score is 56 and higher scores correlate with better balance and decreased risk of falling [52–54]. The DGI is a tool designed to evaluate vestibular dysfunction, functional mobility, and gait dysfunction in older adults. Scores are based on a 4-point scale from no gait dysfunction (3) to severe impairment (0) with a highest score is 24, with a score of 19 or lower indicating fall risk [55, 56]. These assessments will be used to define rehabilitation needs and to measure change after rehabilitation. The PT will also use the Outpatient Physical Therapy Improvement in Movement Assessment Log (OPTIMAL). This test measures perceived difficulty and confidence with different physical activity tasks such as walking, bending/stooping and others. This tool was also designed to assist in client-centered care and goal making [57, 58].

Follow-up Interviews/Calls

Follow-up assessments include the following: (1) patient-reported GA plus the (2) BOMC, (3) NEADL, (4) PROMIS, and (5) PActS. The post-intervention assessments will be completed via telephone by study coordinator or research assistant at 2 and 3 months post-screening. The interviewers will not be blind to the participant's status within the study when performing the follow up assessments.

Statistical Analysis

Sample Size

For the primary outcome (NEADL), a two-group *t*-test will be used to compare change scores between groups. Based on published data, we anticipate seeing an average change in NEADL score of 0 for the Control group and +5 for the Intervention group [59]. A sample size of 37 in each group will have 80% power to detect a difference in means of 5, assuming a common standard deviation of 7.5, at a 0.05 two-sided significance level (nQuery 7.0). This translates to an effect size of 0.667. A final sample size of 74 (N=37 in each group) is needed; therefore, to account for about 10% drop-out, we aim to recruit 82 patients. Based on our prior research, 65% of older cancer patients who complete the GA will not have any deficits; therefore, we anticipate screening 126 patients to enroll the 82 patients needed for the study [5].

Data Analysis

Descriptive statistics will be provided for all study participants and measures at all time points, as well as for recruitment and retention over the course of the study. Change scores between baseline and 2 months and baseline and 3 months will be calculated and compared between groups using two group *t*-tests. Due to the pragmatic nature of this trial, there will be heterogeneity within our data. To address this we plan on completing exploratory analyses which will stratify by time of treatment (pre, during and post treatment) as well as by cancer type. We hypothesize that patients during treatment will have lower baseline functional scores and will have smaller changes in status due to the treatment procedures. We also hypothesize that patients with shorter life expectancies will not demonstrate as much improvement as other groups. For the Intervention group only, the changes in the Intervention arm measures will be reported and paired *t*-tests will be used to evaluate if significant improvements in score were seen over the intervention period. Multivariable linear regression modeling will also be used to evaluate the scores at 2 and 3 months adjusting for baseline score and Intervention group, and including other covariates of interest.

Due to the desire to evaluate a real-life clinical scenario, an intent-to-treat principle will be used. However, patients who drop-out will be compared to those who remain in the study, to see if any association with assignment exists. Missing data will also be investigated, although it is expected to be minimal since follow-up measures can be administered over the phone; thus, imputation will likely not be employed.

For intervention group only, we will describe the variability within the evaluations and the intervention completed by provider and by duration and intensity of treatments to capture the essence of a pragmatic trial. We will then examine the changes in intervention measures (DASH, DGI, BBS, MoCA, COPM & OPTIMAL) used to assess severity of deficits from the beginning of treatment (evaluation) to the finish of treatment (discharge). We will also describe the feasibility of the CARE program by reporting enrollment and retention. And lastly, we plan on evaluating the program with a short interview with CARE team members to assess program design, implementation and impacts.

Limitations

This study is not without its limitations. The pragmatic nature of this trial leads to a potential lack of uniformity and standardization of treatments provided by the OT/PT team. In order to address this, while keeping the trial pragmatic, we are specifying baseline evaluations to be completed by the OT and PT to streamline the interventions and standardize initial evaluations. These measures include the COPM, which specifically measures patients' performance ability with activities and the satisfaction with that performance in activity. This is qualitatively and quantitatively used to guide goal making. The PT's will complete the OPTIMAL test, which was specifically designed to aid in the client-therapist relationship and assist in goal writing that targets what the patient themselves feels is most important. These assessments, along with others the therapists will complete, will allow for each patient to be evaluated at least initially with the same measures. Each OT and PT may have individual preferences in terms of certain treatments and lengths of therapy they personally

favor; however we plan on describing this in terms of variability in types of intervention, duration and intensity of treatments provided. Therapists will not be blinded to the treatment group when evaluating the CARE measures. Other potential limitations include the diverse heterogeneity of the sample that includes all cancer types and stages of cancer across the cancer continuum; however, we will be limiting our sample to only patients with a functional deficit.

Discussion

Recent studies examining the need for and barriers to cancer rehabilitation have found a majority (65–60%) of adults who need rehabilitation do not receive this care [3, 5]. Furthermore, functional impairment and unmet needs for rehabilitation for adults with cancer is significantly associated with a decrease in quality of life [3]. Although some cancer rehabilitation programs exist, there are only a few of them within the US, and with the growing numbers of older adults with cancer who may need cancer rehabilitation, the supply is limited [60]. Efforts within this field need to focus on both improving access and determining ways in which existing rehabilitation programs can be utilized to meet this growing need. There is also an urgent need to develop the evidence base for OT and PT rehabilitation within the specific context of care for persons with a cancer diagnosis.

The pragmatic trial described in this paper – the CARE program -- aims to meet those needs by providing an entryway for access to cancer rehabilitation and by testing the effectiveness of a rehabilitation program. All interventions used in this study are standard care provided by OT and PT in an outpatient clinic already developed and integrated within our hospital and community setting and interventions and assessments are a part of everyday practice. Our primary objective is to compare the change in functional status – widely used NEADL scores -- from baseline to 3 months between patients who receive the CARE program and those who receive standard care.

The participants will be recruited from outpatient oncology clinics and treated in the outpatient rehabilitation clinic within the same institution. If this study is successful, it will provide important information on recruitment and clinical outcomes necessary to inform a larger multi-institutional trial with a greater availability of outpatient cancer rehabilitation facilities for the patients to choose from. This study aims to contribute to the knowledge of OT/PT for this population and to begin to break down actual and perceived barriers to cancer rehabilitation care and build the evidence base for its use [61, 62].

Acknowledgements

The research presented in our manuscript is supported 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 Dr. Bryant is 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.

References

1. Hewitt M, Rowland JH, Yancik R. Cancer survivors in the United States: age, health, and disability. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences*. 2003; 58:M82–M91.
2. Reeve BB, Potosky AL, Smith AW, Han PK, Hays RD, Davis WW, et al. Impact of cancer on health-related quality of life of older Americans. *Journal of the National Cancer Institute*. 2009; 101:860–868. [PubMed: 19509357]
3. Hansen DG, Larsen PV, Holm LV, Rottmann N, Bergholdt SH, Sondergaard J. Association between unmet needs and quality of life of cancer patients: a population-based study. *Acta oncologica* (Stockholm, Sweden). 2013; 52:391–399.
4. Pergolotti M, Cutchin MP, Weinberger M, Meyer AM. Occupational therapy use by older adults with cancer. *The American journal of occupational therapy : official publication of the American Occupational Therapy Association*. 2014; 68:597–607. [PubMed: 25184473]
5. Pergolotti M, Deal AM, Lavery J, Reeve BB, Muss HB. The prevalence of potentially modifiable functional deficits and the subsequent use of occupational and physical therapy by older adults with cancer. *J Geriatr Oncol*. 2015
6. Institute NC. Cancer statistics. US National Institutes of Health. 2013
7. Smith BD, Smith GL, Hurria A, Hortobagyi GN, Buchholz TA. Future of cancer incidence in the United States: burdens upon an aging, changing nation. *Journal of Clinical Oncology*. 2009; 27:2758–2765. [PubMed: 19403886]
8. Yancik R, Ries LA. Aging and cancer in America. Demographic and epidemiologic perspectives. *Hematology/oncology clinics of North America*. 2000; 14:17–23. [PubMed: 10680069]
9. Yabroff KR, Lawrence WF, Clauser S, Davis WW, Brown ML. Burden of illness in cancer survivors: findings from a population-based national sample. *J Natl Cancer Inst*. 2004; 96:1322–1330. [PubMed: 15339970]
10. Cheville, AL. *Seminars in oncology*. Elsevier; 2005. Cancer rehabilitation; p. 219-224.
11. Overcash J. Prediction of falls in older adults with cancer: a preliminary study. *Oncol Nurs Forum*. 2007; 34:341–346. [PubMed: 17573298]
12. Wedding U, Pientka L, Höffken K. Quality-of-life in elderly patients with cancer: a short review. *European Journal of Cancer*. 2007; 43:2203–2210. [PubMed: 17662595]
13. Pergolotti MC MP, Weinberger M, Meyer AM. Occupational Therapy Utilization by Older Adults with Cancer. *American Journal of Occupational Therapy*. in press.
14. Lyons KD, Erickson KS, Hegel MT. Problem-solving strategies of women undergoing chemotherapy for breast cancer. *Canadian Journal of Occupational Therapy-Revue Canadienne D Ergotherapie*. 2012; 79:33–40. [PubMed: 22439290]
15. De Groef A, Van Kampen M, Dieltjens E, Christiaens MR, Neven P, Geraerts I, et al. Effectiveness of Postoperative Physical Therapy for Upper-Limb Impairments After Breast Cancer Treatment: A Systematic Review. *Arch Phys Med Rehabil*. 2015
16. Ercoli LM, Petersen L, Hunter AM, Castellon SA, Kwan L, Kahn-Mills BA, et al. Cognitive rehabilitation group intervention for breast cancer survivors: results of a randomized clinical trial. *Psychooncology*. 2015
17. Alappattu MJ, Coronado RA, Lee D, Bour B, George SZ. Clinical characteristics of patients with cancer referred for outpatient physical therapy. *Phys Ther*. 2015; 95:526–538. [PubMed: 25504482]
18. Hurria A, Gupta S, Zauderer M, Zuckerman EL, Cohen HJ, et al. Developing a cancer-specific geriatric assessment: a feasibility study. *Cancer*. 2005; 104:1998–2005. [PubMed: 16206252]
19. Hurria A, Gupta S, Zauderer M, Zuckerman EL, Cohen HJ, Muss H, et al. Developing a cancer-specific geriatric assessment. *Cancer*. 2005; 104:1998–2005. [PubMed: 16206252]
20. Williams GR, Deal A, Jolly T, Alston S, Gordon B, et al. Feasibility of geriatric assessment in community oncology clinics. *J Geriatr Oncol*. 2014 (accepted for publication March 2014).
21. Williams GR, Deal AM, Nyrop KA, Pergolotti M, Guerard EJ, Jolly TA, et al. Geriatric assessment as an aide to understanding falls in older adults with cancer. *Support Care Cancer*. 2015

22. Pergolotti M, Cutchin MP, Muss HB. Predicting participation in meaningful activity for older adults with cancer. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*. 2014
23. Jolly TA, Deal AM, Nyrop KA, Williams GR, Pergolotti M, Wood WA, et al. Geriatric Assessment-Identified Deficits in Older Cancer Patients With Normal Performance Status. *Oncologist*. 2015
24. Hurria A, Gupta S, Zauderer M, Zuckerman EL, Cohen HJ, Muss H, et al. Developing a cancer-specific geriatric assessment: a feasibility study. *Cancer*. 2005; 104:1998–2005. [PubMed: 16206252]
25. Williams GR, Deal AM, Jolly TA, Alston SM, Gordon BB, Dixon SA, et al. Feasibility of geriatric assessment in community oncology clinics. *Journal of geriatric oncology*. 2014; 5:245–251. [PubMed: 24703978]
26. Kawas C, Karagiozis H, Resau L, Corrada M, Brookmeyer R. Reliability of the Blessed Telephone Information-Memory-Concentration Test. *Journal of geriatric psychiatry and neurology*. 1995; 8:238–242. [PubMed: 8561839]
27. Katzman R, Brown T, Fuld P, Peck A, Schechter R, Schimmel H. Validation of a short Orientation-Memory-Concentration Test of cognitive impairment. *The American journal of psychiatry*. 1983; 140:734–739. [PubMed: 6846631]
28. Crooks V, Waller S, Smith T, Hahn TJ. The use of the Karnofsky Performance Scale in determining outcomes and risk in geriatric outpatients. *Journal of gerontology*. 1991; 46:M139–M144. [PubMed: 2071835]
29. Schag CC, Heinrich RL, Ganz PA. Karnofsky performance status revisited: reliability, validity, and guidelines. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*. 1984; 2:187–193. [PubMed: 6699671]
30. Huisman MG, van Leeuwen BL, Ugolini G, Montroni I, Spiliotis J, Stabilini C, et al. "Timed Up & Go": a screening tool for predicting 30-day morbidity in onco-geriatric surgical patients? A multicenter cohort study. *PloS one*. 2014; 9:e86863. [PubMed: 24475186]
31. Criter RE, Honaker JA. Identifying Balance Measures Most Likely to Identify Recent Falls. *Journal of geriatric physical therapy* (2001). 2015
32. Sherbourne CD, Stewart AL. The MOS social support survey. *Soc Sci Med*. 1991; 32:705–714. [PubMed: 2035047]
33. Stewart, AL., Ware, JE. Measuring functioning and well-being: the medical outcomes study approach. Duke University Press; 1992.
34. Loprinzi CL, Laurie JA, Wieand HS, Krook JE, Novotny PJ, Kugler JW, et al. Prospective evaluation of prognostic variables from patient-completed questionnaires. North Central Cancer Treatment Group. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*. 1994; 12:601–607. [PubMed: 8120560]
35. Fillenbaum GG, Smyer MA. The development, validity, and reliability of the OARS multidimensional functional assessment questionnaire. *Journal of gerontology*. 1981; 36:428–434. [PubMed: 7252074]
36. Young J, Robinson M, Chell S, Sanderson D, Chaplin S, Burns E, et al. A prospective baseline study of frail older people before the introduction of an intermediate care service. *Health & social care in the community*. 2005; 13:307–312. [PubMed: 15969701]
37. Wu, C-y, Chuang, L-l, Lin, K-c, Lee, S-d, Hong, W-h. Responsiveness, minimal detectable change, and minimal clinically important difference of the Nottingham Extended Activities of Daily Living Scale in patients with improved performance after stroke rehabilitation. *Archives of physical medicine and rehabilitation*. 2011; 92:1281–1287. [PubMed: 21807147]
38. Lincoln NB, Gladman JR. The extended activities of daily living scale: a further validation. *Disability & Rehabilitation*. 1992; 14:41–43. [PubMed: 1586760]
39. Kristjansson SR, Nesbakken A, Jordhøy MS, Skovlund E, Audisio RA, Johannessen H-O, et al. Comprehensive geriatric assessment can predict complications in elderly patients after elective surgery for colorectal cancer: A prospective observational cohort study. *Critical reviews in oncology/hematology*. 2010; 76:208–217. [PubMed: 20005123]

40. Nouri F, Lincoln N. An extended activities of daily living scale for stroke patients. *Clinical rehabilitation*. 1987; 1:301–305.
41. Harwood R, Ebrahim S. The validity, reliability and responsiveness of the Nottingham Extended Activities of Daily Living scale in patients undergoing total hip replacement. *Disability & Rehabilitation*. 2002; 24:371–377. [PubMed: 12022787]
42. Young J, Green J, Forster A, Small N, Lowson K, Bogle S, et al. Postacute care for older people in community hospitals: a multicenter randomized, controlled trial. *Journal of the American Geriatrics Society*. 2007; 55:1995–2002. [PubMed: 17979957]
43. Reeve BB, Hays RD, Bjorner JB, Cook KF, Crane PK, Teresi JA, et al. Psychometric evaluation and calibration of health-related quality of life item banks: plans for the Patient- Reported Outcomes Measurement Information System (PROMIS). *Medical care*. 2007; 45:S22–S31. [PubMed: 17443115]
44. Cella D, Riley W, Stone A, Rothrock N, Reeve B, Yount S, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005–2008. *Journal of clinical epidemiology*. 2010; 63:1179–1194. [PubMed: 20685078]
45. Pergolotti M, Cutchin MP. The Possibilities for Activity Scale (PActS): Development, validity, and reliability La Possibilits for Activity Scale (PActS): dveloppement, validit et fiabilit. *Canadian Journal of Occupational Therapy*. 2014 0008417414561493.
46. Gummeson C, Atroshi I, Ekdahl C. The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: longitudinal construct validity and measuring self-rated health change after surgery. *BMC musculoskeletal disorders*. 2003; 4:11. [PubMed: 12809562]
47. Hudak PL, Amadio PC, Bombardier C. Development of an upper extremity outcome measure: the DASH. *Am J Ind Med*. 1996; 29:602–608. [PubMed: 8773720]
48. Nasreddine ZS, Phillips NA, Bdrian V, Charbonneau S, Whitehead V, Collin I, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *Journal of the American Geriatrics Society*. 2005; 53:695–699. [PubMed: 15817019]
49. Eyssen IC, Steultjens MP, Oud TA, Bolt EM, Maasdam A, Dekker J. Responsiveness of the Canadian occupational performance measure. *Journal of rehabilitation research and development*. 2011; 48:517–528. [PubMed: 21674402]
50. Dedding C, Cardol M, Eyssen IC, Dekker J, Beelen A. Validity of the Canadian Occupational Performance Measure: a client-centred outcome measurement. *Clin Rehabil*. 2004; 18:660–667. [PubMed: 15473118]
51. Berg K. Measuring balance in the elderly: preliminary development of an instrument. *Physiotherapy Canada*. 1989; 41:304–311.
52. Berg K, Wood-Dauphinee S, Williams J. The Balance Scale: reliability assessment with elderly residents and patients with an acute stroke. *Scandinavian journal of rehabilitation medicine*. 1995; 27:27–36. [PubMed: 7792547]
53. Berg KO, Wood-Dauphinee SL, Williams JI, Maki B. Measuring balance in the elderly: validation of an instrument. *Canadian journal of public health Revue canadienne de st publique*. 1991; 83:S7–S11. [PubMed: 1468055]
54. Muir SW, Berg K, Chesworth B, Speechley M. Use of the Berg Balance Scale for predicting multiple falls in community-dwelling elderly people: a prospective study. *Physical therapy*. 2008; 88:449–459. [PubMed: 18218822]
55. Whitney S, Hudak M, Marchetti G. The dynamic gait index relates to self-reported fall history in individuals with vestibular dysfunction. *Journal of Vestibular Research*. 2000; 10:99–105. [PubMed: 10939685]
56. Herman T, Inbar-Borovsky N, Brozgol M, Giladi N, Hausdorff JM. The Dynamic Gait Index in healthy older adults: The role of stair climbing, fear of falling and gender. *Gait & Posture*. 2009; 29:237–241. [PubMed: 18845439]
57. Guccione AA, Mielenz TJ, Devellis RF, Goldstein MS, Freburger JK, Pietrobon R, et al. Development and testing of a self-report instrument to measure actions: outpatient physical therapy improvement in movement assessment log (OPTIMAL). *Physical therapy*. 2005; 85:515–530. [PubMed: 15921473]

58. Elston B, Goldstein M, Makambi KH. Item Response Theory Analysis of the Outpatient Physical Therapy Improvement in Movement Assessment Log (OPTIMAL). *Physical therapy*. 2013; 93:661–671. [PubMed: 23431211]
59. Wu CY, Chuang LL, Lin KC, Lee SD, Hong WH. Responsiveness, minimal detectable change, and minimal clinically important difference of the Nottingham Extended Activities of Daily Living Scale in patients with improved performance after stroke rehabilitation. *Arch Phys Med Rehabil*. 2011; 92:1281–1287. [PubMed: 21807147]
60. Canestraro A, Nakhle A, Stack M, Strong K, Wright A, Beauchamp M, et al. Oncology Rehabilitation Provision and Practice Patterns across Canada. *Physiotherapy Canada Physiotherapie Canada*. 2013; 65:94–102. [PubMed: 24381389]
61. Cheville AL, Tchou J. Barriers to rehabilitation following surgery for primary breast cancer. *Journal of Surgical Oncology*. 2007; 95:409–418. [PubMed: 17457830]
62. Stubblefield MD, Hubbard G, Cheville A, Koch U, Schmitz KH, Dalton SO. Current perspectives and emerging issues on cancer rehabilitation. *Cancer*. 2013; 119(Suppl 11):2170–2178. [PubMed: 23695929]

Figure 1.

CARE program schema

¹GA = Geriatric Assessment ²NEADL = Nottingham Extended Activities of Daily Living, ³PROMIS = Patient Reported Measurement Information System: Global Health, Physical Function, Satisfaction with Participation in Social Roles, Ability to Participate in Social Roles and Activities, ⁴PActS = Possibilities for Activity Scale, ⁵BOMC = Blessed Orientation Memory Concentration Test

Table 1

Measures during the trial period

All subjects		Intervention arm only Intervention		All subjects	
	Baseline	CARE specific measures	Post CARE specific measures	2 months post screen	3 months post screen
GA ¹	X			X [*]	X [*]
NEADL ²	X			X	X
PROMIS ³	X			X	X
PActS ⁴	X			X	X
BBS ^{5***}		X	X		
DGI ^{6***}		X	X		
DASH ^{7***}		X	X		
MoCA ^{8***}		X	X		
COPM ^{9***}		X	X		
OPTIMAL ^{10**}		X	X		

Note.

¹ Geriatric Assessment

² Nottingham Extended Activities of Daily Living

³ Patient-reported Outcome Measurement Information System

⁴ Perceived Occupational Possibilities Scale

⁵ Berg Balance Scale

⁶ Dynamic Gait Index

⁷ Disabilities of the Arm, Shoulder and Hand Outcome Questionnaire

⁸ Montreal Cognitive Assessment

⁹ Canadian Occupational Performance Measure

Author Manuscript

Author Manuscript

Author Manuscript

Author Manuscript

Outpatient Physical Therapy Improvement in Movement Assessment Log
Patient-reported GA only (section II of GA minus demographic questions)
Measures only within intervention arm
Patients with cognitive only deficits will at a minimum receive the MoCA assessment during CARE program.