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

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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.

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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 CAancer 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

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[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 (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.

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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

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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, neuro-muscular 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

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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

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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].

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Data Analysis

Descriptive statistics will be provided for all study participants and measures at all times 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

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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].

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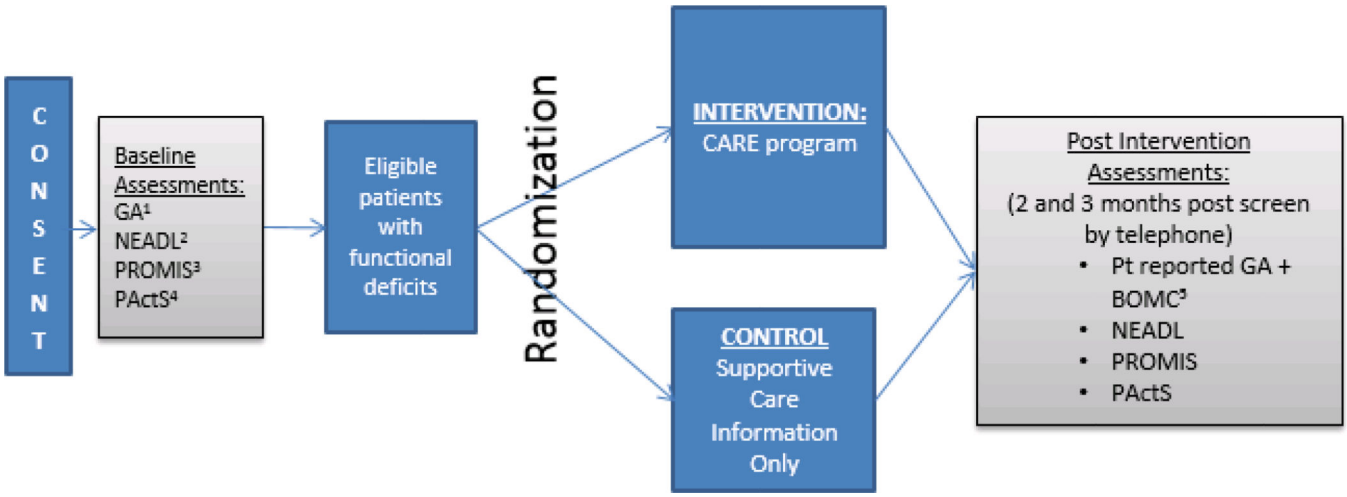

Figure 1.

CARE program schema

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

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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

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[10] 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.