LCCC 1848: Feasibility and Acceptability of A RN-Led Palliative and Collaborative Care Intervention for Adults with Acute Myeloid Leukemia

Principal Investigator
Ashley Leak Bryant PhD, RN-BC, OCN
401 Carrington Hall
Campus Box 7460
Chapel Hill, NC 27599-7460
The University of North Carolina at Chapel Hill
919-966-5329 (Phone)
919-843-9900 (Fax)
ashley_bryant@unc.edu

Co-Investigator(s)
Laura C. Hanson MD
Susan Coppola OTD, OT/L
Ruth Anderson PhD, RN
Daniel Richardson, MD
Matthew Foster MD
Rachel Hirschey PhD, RN
Dierdra Ricks BS, PT
Crista Creedle, RN, BSN
Summer Cheek RN, BSN
Farrell Wiggins OT
Korre Scott PT
Laura Andrews PT
Alexis Petteway OT
Ashley Lewis PT
Michelle Leblanc PT
Rebekah Jarrett OT
Stephanie Mattondo OT
Christopher Jensen MD
Katie Buhlinger PharmD, CPP
Benyam Muluneh PharmD

Biostatistician
Xianming Tan, PhD
Email: xianming@email.unc.edu

Consultant
Mackenzi Pergolotti PhD, OTL/R

Study Coordinator
Ya-Ning Chan, MSN, RN

Research Assistant

Stephanie Betancur Grondona BSN, RN
Katie Lowe BSN, RN, OCN

Other
Courtney Berry BS, MA, BSN, RN, OCN
Amy Elinoff BSN, RN, OCN

Patient-Reported Outcomes- Core
Mattias Jonsson
Michelle Johnson

Sponsor: UNC Lineberger Comprehensive Cancer Center
Funding Source: Lineberger Development Grant

Version 1 Date: November 4, 2019 **Version 2 Date: July 14, 2020** **Version 3 Date: November 24, 2020**	

LCCC 1848**:** Feasibility and Acceptability of A RN-Led Palliative and Supportive Care Intervention for Adults with Acute Leukemia

Principal Investigator
Ashley Leak Bryant PhD, RN-BC, OCN
401 Carrington Hall
Campus Box 7460
Chapel Hill, NC 27599-7460
The University of North Carolina at Chapel Hill
919-966-5329 (Phone)
919-843-9900 (Fax)
ashley_bryant@unc.edu

Signature Page

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable U.S. federal regulations and ICH guidelines.

Principal Investigator (PI) Name:_____

PI Signature: _____

Date:_____

TABLE OF CONTENTS

1.0 BACKGROUND AND RATIONALE

1.1 Study Synopsis

This single institution feasibility and acceptability of study methods are to examine change in pre and post measures of symptoms, function, and QOL comparing 10 control and 10 intervention patients with acute myeloid leukemia (AML). AML is the most common type of acute leukemia. This study is designed to examine a novel palliative and collaborative care intervention in which registered nurses (RNs), occupational therapists (OTs) and physical therapists (PTs) address the physical activity needs of older adults (≥60 years) with AML during cycles 1 and 2 (approximately 60 days) of a **P**alliative **a**nd **C**ollaborative **C**are in**T**ervention (PACT) (intervention arm only). The eligible population will include patients at the North Carolina Cancer Hospital (NCCH) with a diagnosis of AML, age ≥60 years, and receive hypomethylating agents (HMA) or low-dose cytarabine + Venetoclax.

1.2 Study Population Background

AML is an aggressive, serious hematologic cancer resulting from rapid, uncontrolled growth of immature blood cells. Prognosis is poor: 19,940 people will be diagnosed in 2020,[1] and 11,180 will die.[1] Patients with AML are treated in highly specialized referral cancer hospitals and clinics offering rapid comprehensive assessments and evaluations. Long-term survival of AML is typically achieved through intensive multi-agent chemotherapy, exposing patients to significant risks of treatment-related complications, heavy symptom burden, functional decline, and loss of QOL.[2,3] Until recently, induction chemotherapy regimens, such as cytarabine plus an anthracycline, were delivered in the inpatient setting. These "intensive induction" regimens require 7 days of continuous cytarabine intravenously and 3 days of intermittent anthracyclines during a 4-6 week hospitalization. This combination chemotherapy commonly caused profound fatigue, frequent nausea and vomiting, and often led to complications such as systemic infections.[1]

In 2018 the treatment paradigm changed for older AML patients with the approval of multiple new effective oral agents. The most widely used regimen is venetoclax (VEN; taken orally) in addition to low-dose cytarabine or a hypomethylating agent (HMA Cycle 2, days 31-37, starts either in the hospital or clinic depending on the patients' clinical status. Patients return home from days 38-60 while taking VEN until they return to the hospital for another bone marrow biopsy. The patient takes VEN throughout the entire cycle by injection or infusion) (Figure 1). HMA or low-dose cytarabine +VEN can result in complete remission rates of up to 70%, similar to rates for historical inpatient chemotherapy.[4] Patients have substantially fewer acute side effects associated with HMA or low-dose cytarabine +VEN than with inpatient induction chemotherapy. However, patients still experience cumulative fatigue, functional decline, and are often admitted to the hospital for complications even with support from their caregivers.[5-7] Although HMA or low-dose cytarabine +VEN can be delivered entirely in the outpatient setting, it is often given initially in the inpatient setting over 1-7 days due to the risk of acute complications such as tumor lysis and infection. Patients leave the hospital and return home for days 8-30 while taking VEN, after which they undergo a bone marrow biopsy. Patients stay on HMA or low-dose cytarabine +VEN for at least two 30-day cycles and, if responding, indefinitely until disease relapse. In our study, we will follow patients for the first 4 cycles.

Substantial opportunity exists to intervene during initial treatment to help patients maintain or improve functional and QOL outcomes.[8,9] Currently, the HMA or low-dose cytarabine +VEN regimen is often given at large cancer centers; in the future this location of treatment likely will continue for high-risk patients but will occur in community cancer centers for low-risk and non-complicated AML patients**.**

Since 2012, RCTs have demonstrated that among patients with advanced cancer, palliative care in conjunction with standard oncology care maintains or improves symptoms, QOL and even survival.[10,11] In 2017, the American Society of Clinical Oncology published clinical practice guidelines based on strong clinical and research evidence for integration of palliative care into standard oncology care. Despite known benefits of early palliative care, initiation of *formal* palliative care early in hematological cancers is limited.[12,13] Thus, we suggest that integrated palliative and collaborative care is more accessible because it is delivered by usual care staff and is an innovative model to close the gap in care for older adults with AML.

1.3 Symptom Management Intervention

The proposed symptom management intervention, PACT, utilizes a collaborative, multidisciplinary, integrated team including RNs, OTs and PTs. The PACT intervention is unique in its interdisciplinary approach and was designed to facilitate the integration among the team to plan, implement and evaluate outcomes.

The RN, OT and PT will use the Adaptive Leadership Framework for Chronic Illness[8] as a guide for the intervention.

1. The RN will complete a symptom assessment within 2 days of patient admission and will continue to monitor the patient's symptoms daily throughout hospitalization. OT and PT project staff will assess and monitor function and physical health status within 2 days of patient admission and will continue to monitor the patient's symptoms at baseline, day 4 and at discharge.
2. Collaborating with the patient, RN, OT, and PT will identify and monitor symptoms of AML treatment-related and chronic illness symptoms that might interfere with the patent's ability to engage in functional and physical activities, such as dressing, grooming, or walking and getting out of bed.
3. The RN, OT, and PT will meet with the patient to exchange information and develop a shared understanding, defined by acknowledgement of symptoms and treatment related challenges and an agreed-upon plan for each OT and PT visit. Shared understanding will be determined by evaluating electronic notes and consensus between the RN, PT, and OT.
4. This shared understanding becomes the basis for developing a plan of care jointly that will be reviewed and updated as the patient's symptoms, functional level and/or physical health changes. *For example, if the patient shares with the RN, OT, and PT that he/she is experiencing fatigue (an adaptive challenge), then the RN, OT, and PT will add to the shared meaning by explaining the essential need for movement to increase the patient's ability to engage in functional and physical health activities to reduce fatigue. The joint plan will define shared meaning across team members with the patient.*
5. The RN, OT, and PT will address technical challenges, *for example, if a patient has difficulty sleeping, RN can address medication administration, the OT can provide*

strategies for sleep hygiene and address fatigue, and the PT can address staying active during hospitalization to maintain physical health needed for improved sleep.

6. The PACT team and patient will use the shared understanding of adaptive challenges to find creative ways to do the adaptive work to reduce the impact of symptoms, function, and physical health.
7. The patient and PACT team will establish Smart, Measurable, actionable, Realistic, and Timed (SMART) goals, which are reassessed twice weekly and located on the patient's dry erase board in their hospital room. The adaptive work can be introduced in small, achievable goals to optimally engage in PACT.

1.4 Wearable Physiological Monitoring (Garmin Vivofit4)

Accelerometry is a method of tracking physical activity through monitoring and detecting changes in movement, thus allowing for assessments of total activity (e.g. steps per day) and intensity of activity (e.g. mild, moderate, vigorous) on a daily and even hourly basis. In previous studies, physical activity assessment by accelerometry has discriminated cancer patients from controls [17, 18] and has been associated with functional status and quality of life [19]. Accelerometry has also been used in an interventional way to help attenuate the effects of cachexia and to increase physical activity in cancer survivors. [20, 21]

Wearable technology activity monitor: Participants will be provided with a Garmin Vivofit 4® activity monitor, which they are asked to wear continuously for up to 6 months. This is a wrist-worn device that contains functions such as displaying steps, distance, calories and sleep/rest time. Briefly, the Garmin Vivofit4® does not need to be charged (it uses a built-in battery lasting 1 year), and it provides inactivity alerts visually via a red bar on the display and an audible beep. The move bar is reset by walking for a few minutes. One limitation of most wearable technologies that provide such inactivity alerts is that they may count standing time as inactive time. Therefore, participants will be counselled to ignore prompts that occur when they are moving or standing but encouraged to take some extra steps to reset the move bar. The device can store movement and sleep data for up to 7 days; these data are uploaded to the Garmin app via Bluetooth. Participants are helped to install the smartphone/tablet/PC application, and to activate their online account, during the face-to-face session with a research staff member.

Preliminary evidence shows significant associations between pedometry data and patient-reported outcomes. A recent study conducted at the University of North Carolina evaluated a pre-transplant exercise intervention in adult patients undergoing hematopoietic stem cell transplant (HSCT) for treatment of leukemia, lymphoma, myeloma, and other disease. Patients wore pedometers and completed PRO assessments with 7-day recall during post-transplant hospitalization (4 weeks) and up to 4 weeks post-discharge. On average, participants took 3253 (SD=2282) steps per day. Figures 1 and 2 show the average symptoms scores and average daily steps per each week of treatment and illustrate the correlation of symptoms and steps. When within-patient changes over time, from prior week to current week, were compared between symptoms and steps, regression model coefficients (beta) indicated a decrease in average daily steps associated with unit increase in pain (beta=750 fewer steps per increase in pain score, $p<0.003$), shortness of breath (beta=978, $p<0.004$), and dizziness (beta=861, $p<0.031$). Reduced physical activity and reduced physical health were not significantly associated with fewer steps within-patient, but were strongly associated with differences in steps between patients (reduced

physical activity: beta=849, p<0.002; reduced physical health: beta=676, p<0.031). The measures of mental health and emotional well-being were not significantly associated with daily steps. In this sample of HSCT recipients, more severe symptoms including pain and fatigue, impaired physical health, and restrictions in the performance of usual daily activities were associated with statistically significant decrements in average daily steps.

In the past, highly specialized and expensive equipment has been needed to monitor activity. Recently there has been a proliferation of relatively inexpensive, wearable devices that accomplish this goal. FitBit, Nike, and Jawbone now offer user-friendly devices that allow for activity tracking over extended periods of time. Devices such as the FitBit Flex offer not only accelerometry but other longitudinal physiological data streams, such as sleep monitoring. A user can capture total minutes slept and times awakened on a nightly basis by tapping the wristband before going to sleep and upon waking up.

Garmin Vivofit4 description

Device	Image	Description
Garmin Vivofit4 www.garmin.com		- Step counter via tri-axial accelerometer - Automatic activity detection - 1+ year battery life - Can control whether step count is or is not displayed on device face

1.5 Symptom Reporting and Assessment

Patient-Reported Outcomes (PROs) refer to "any report on the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" [3]. Symptoms are one type of PRO.

Standardized electronic PRO surveys asking patients about specific symptoms offer the ability to identify symptoms of concern and provide clinicians with an opportunity to remedy each of these deficiencies. There are now several standardized symptom assessment questionnaires available for routine care including the PRO version of the Common Terminology for Adverse Events (CTCAE), developed at the National Cancer Institute. The PRO-CTCAE, developed under a contract with Dr. Ethan Basch at the University of North Carolina at Chapel Hill, is a tool that allows patients to self-report symptom-based adverse events (AEs) listed in the NCI's CTCAE. In total, there are 78 questions that assess different attributes (e.g., frequency, severity, interference, presence of condition) of 81 symptoms that are represented in both the CTCAE (version 4) and the Medical Dictionary for Regulatory Activities (MedDRA) adverse event lexicons. These 78 questions have been extensively evaluated by cancer patients using cognitive testing methods and found to be clear, comprehensible, and capable of measuring the symptoms

of interest.

In this study, we will use the 19 patient-reported symptoms from the CTCAE to calculate a symptom score that may range from 0-76 each day. This symptom score represents the symptom burden for the patient on that particular day.

Table 1 uses the adaptive leadership framework to link theory-based behavior change methods used in this proposed study, the timing of when the collaborative work will be conducted, and details of the PACT PT, OT, and PT assessments.

Table 1. Adaptive Leadership Framework Collaborative Work of RN, OT, and PT During Cycle 1 and 2
Bolded examples suggest action is needed.

Collaborative Work and Timing	Details of Clinician Assessments (bolded)
• Days 1-7 & 31-37 daily: **Collaborative Work**, RN and patient; 2x a week, RN, OT, PT and patient • Days 8-30 & 38-60: RN will call patient 2x/week	• **Discuss with patient** and review knowledge about collaborative work plans.[14] • **Shift perspective** to understand patient's view of progress. [15] • ***Review existing care guidelines for symptoms and function*** • **Review outcome and behavioral goals** using the elements of collaborative work described previously.[16,17]
• Days 1-7 & 31-37: RN **Monitors symptoms & function daily**; 2x week for PT and OT • Days 8-30 & 38-60: RN will call patient 2x/week	• **Assess** and **monitor** 19 symptoms using PRO-CTCAE. • **Discuss** results with patient to increase patient's knowledge about interrelatedness of symptoms. [14] • **Discuss** patient's experience of the symptom • ***Discuss oral medications and adherence with patients***
• Days 1-7 & 31-37: **Assess adaptive challenges** • Days 8-30 & 38-60: RN will call patient 2x/week	• **Plan coping responses** to identify challenges associated with symptoms that impede engagement in self-management and function and ways to overcome them. [18] • Engage in collaborative work with patient (and PT/OT when appropriate) to **shift perspective** of staff beliefs about what challenges mean to the patient. [15]
• Days 1-7 & 31-37**: Exchange information** (daily: RN and patient; 2x a week: RN, OT, PT and patient Days 8-30 & 38-60: RN will call patient 2x/week	• **Elicit** patient's understanding of the symptoms and adaptive challenges and how these interfere with his/her ADLs. • RN leads **discussion** to verify that he/she understands the patients' perspective and to increase patient knowledge about symptoms and function[14]. • RN, OT and PT probe the patient to **elaborate** on what they have learned during their discussion.[19]
• Days 1-7 & 31-37 **Shared understanding** (daily: RN and patient; 2x a week: RN, OT, PT and patient • Days 8-30 & 38-60: RN will call patient 2x/week	• RN **leads** the patient and team to synthesize the various perspectives to develop shared understanding of challenge(s), confirming the meaning for the patient. This discussion may lead to **shift in each other's perspectives** to establish a shared basis for the plan of work.[15]
• **Joint plan of work** (daily: RN and patient; 2x a week: RN, OT, PT and patient): RN, PT, OT facilitate patient to establish behavioral goals[16] • Days 8-30 & 38-60: RN will call patient 2/week	• Use results of assessments to **establish** appropriate technical work for RN, PT and OT to address symptom management (e.g., medications, assistive devices). • Using results of RN assessments and identified challenges, RN **suggests** patient self-management strategies. • Using results of OT assessments and identified challenges, OT **suggests** strategies to address barriers to occupational activity (e.g. energy conservation strategies, problem solving). [18] • Using results of PT assessments and identified challenges**;** PT **suggests coping** strategies to address barriers to movement (e.g. routine to decrease risk for falls). [18] • Collaboratively **set** Smart, Measurable, Actionable, Realistic, and Timed (*SMART) goals[20] to address technical and/or adaptive work.

Training of team (RNs, OTs, and PTs). The PACT intervention team consists of existing employees of the study site. We will train 4 RNs, 2 OTs, and 2 PTs so they can provide coverage

as needed (i.e. a team member gets sick). The RNs are bachelor's-prepared and OTs and PTs are master's-prepared therapists, all with clinical backgrounds in oncology. The training will be facilitated by oncology and palliative care educators and experts: Drs. Bryant (PI), Hanson (Co-I), and Anderson (Co-I) will facilitate 32 hours of training of didactic (e.g. webinars and self-paced course) and experiential (e.g. role-playing) learning in palliative care and use of adaptive leadership approaches to engage in collaborative work with patients and facilitate behavior change. The team (RN, OT, PT) will perform intervention activities on a pre-arranged modified schedule and have a decreased workload when completing study activities. The OT/PT administrative director and nurse manager's letters of support address decreased workload.

Palliative care training (16 hours): Dr. Hanson is an active Palliative Care Research Cooperative (PCRC) member with substantial palliative care education and expertise. Dr. Bryant has clinical expertise in supportive care needs and attended the PCRC 2020 Palliative Care Trial Intensive in February 2020, where she received feedback to strengthen the intervention training and other sections in the proposal. The palliative care expert, Dr. Hanson, will review the ASCO and ASH clinical practice guidelines for integration of palliative care into standard oncology care.[21,33] The experts will provide basic management of pain, depressive symptoms, anxiety, sleep, change in cognition, AML symptoms and treatment-related symptoms, discussion of prognosis, goals of care and code status (see **Table 3**). Dr. Bryant will discuss supportive care needs including a description of concepts and differentiate the roles of the RN, OT and PT in this intervention (see **Table 3**). Dr. Bryant will provide an overview of AML and explain how the disease process often leads to high symptom burden and functional decline. Intervention training will include case scenarios and resources on providing holistic care in discomfort, symptoms, and distress of older adults with AML. Resources will include self-paced courses from the Center to Advance Palliative Care such as "An In-Depth Look at Palliative Care and Its Services," and case scenarios from the Hospice and Palliative Nurses Association, the American Physical Therapy Association, and the American Occupational Therapy Association.

Table 3. Palliative Care Training for Intervention Team

Training	Goal/Outcome
Palliative Care[21]	**Basic management/knowledge of:** * pain, depressive symptom, anxiety, sleep and AML symptoms * prognosis, goals of therapy, code status
Collaborative Care Model	*Describe concepts of collaborative care. *Differentiate role of RN, OT, and PT

Adaptive Leadership Training (16 hours): Dr. Anderson, also and PCRC member has substantial experience training interventionists from her research.[22] Topics will include the collaborative work (Figure 3) process for eliciting patients' challenges and developing a tailored care plan. Through case scenarios, trainees will learn to: a) describe concepts of adaptive leadership; b) assess and distinguish technical vs. adaptive challenges; c) identify appropriate technical work to address technical challenges; and d) identify appropriate adaptive work to facilitate behavior change and skill development for self-management. We will use role-play to reinforce skill development. After the training sessions, each team member will demonstrate ability to implement the intervention with a patient while being observed by Drs. Anderson and Bryant. Sessions are audio-recorded so the team can review together to provide feedback and improve skills (Table 4). These steps will be repeated until team members and Drs. Anderson and Bryant are assured that the intervention team follows the protocol. Dr. Anderson will prepare

Dr. Bryant to conduct training and fidelity checking. Academic detailing sessions will be monthly with study RNs, OTs and PTs. During academic detailing, a strategy Dr. Anderson used in her R01 (NR003178-13),[22] the PACT team will consult with Drs. Anderson, Bryant, Coppola, and Hanson about patients with difficult adaptive challenges, symptoms, or functional issues. Together, the group will model the case and explore difficult aspects. Dr. Pergolotti will use videoconferencing to join Dr. Coppola for on-site training. Videoconferencing allows face-to-face discussions, sharing screens, recording of sessions, and provides a web link for viewing later, which has been successful in other virtual teams[23].

Intervention Fidelity. We will use the treatment fidelity developed by the Treatment Fidelity Workgroup of the NIH Behavior Change Consortium to reduce unsystematic variation in delivery that could impact internal and external validity.[24] *DESIGN.* To ensure design fidelity[24], we standardized the intervention protocol to a specified dose in terms of number, frequency, and set of intervention activities. (Table 2). *TRAINING*. The protocol specifies training content, structured practice, and role-play exercises to ensure that interventionists' skills meet established standards. *DELIVERY.* To ensure that PACT is delivered as specified, the PI will observe and audio-record the PACT member 20% of the times he/she completes standardized checklists. The interventionists, the PI and Dr. Anderson will discuss the results and problem-solve barriers to adherence with repeat of concepts and role-play as needed (Table 3). *RECEIPT OF INTERVENTION.* For PACT patients, the protocol provides an opportunity to systematically assess patients' understanding of the intervention. Collaborative work is designed to ensure the patient identifies SMART goals and discusses them with the PACT RN, OT and PT. The RN, OT, and PT will ensure the patient can use appropriate behavioral skills (e.g. self-management or activities) by observing their activities and discussing use of their skill. *PATIENT ENACTMENT OF SKILLS.* The PI will assess enactment between the RN, OT, and PT and the patient systematically. The project OT or PT will use a checklist to determine how often the patient engages in activity.

Table 4. Adaptive Leadership Training and Goals for Intervention Team

Learning Adaptive Leadership Role	*Describe concepts of adaptive leadership. *Distinguish technical vs adaptive challenges. *Identify types of technical and adaptive work. *Develop skills for collaborative work (Figure 3).
Demonstrate Competence	*Role play to help reinforce skill development. * RN, OT, and PT will demonstrate ability to implement intervention. *Sessions audio-recorded & feedback given to improve skill.
Academic Detailing	*Monthly training sessions with RN, OT, PT *Collectively, group will model the case & explore aspects that were difficult.

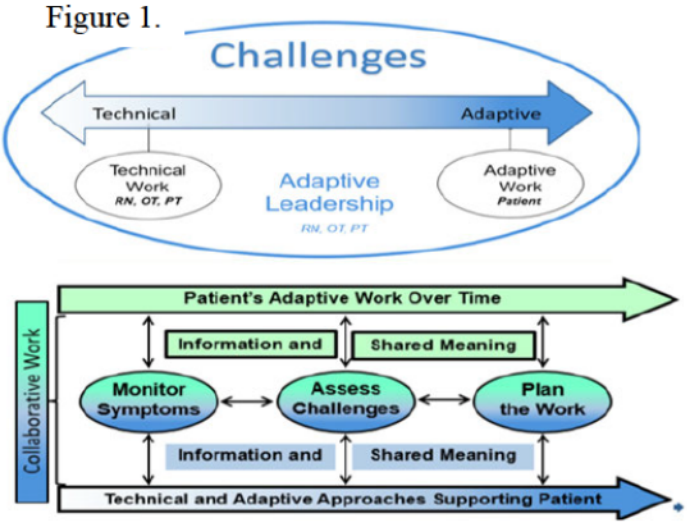
1.6 Adaptive Leadership Framework

We will use a multidisciplinary cancer rehabilitation team approach to address complex symptoms. This approach is critical given the complexity of interacting, fluctuating symptoms during initial and maintenance therapy that can affect functional status and QOL negatively. This approach brings together relevant disciplines (nursing, OT, PT) to reduce symptom burden by managing complex symptoms, and to personalize intervention approaches to maximize patients' engagement in their own care. Yet, research in cancer rehabilitation has been traditionally underutilized by oncology providers. The majority of the cancer rehabilitation literature focuses narrowly on physical impairments after they have occurred. Our (PACT) intervention brings an

interdisciplinary approach to symptom management during and beyond hospitalization to improve overall symptom burden and function.[25]

The Adaptive Leadership Framework for Chronic Illness[8] which guides the intervention, has three central concepts: technical challenges, adaptive challenges, and patients' adaptive work over time. The upper portion of Figure 1 shows how symptoms fluctuate over time and as symptoms fluctuate so do the types of challenges patients face. Technical challenges have known solutions that can be implemented on the patient's behalf by an expert (e.g., symptom management by a nurse administering pain medication; use of assistive devices suggested by OT or PT). Adaptive challenges are owned by the patient and require change in behavior; the work involved is called adaptive work. A diagnosis of AML is life-altering, requiring the patient to engage in adaptive work adjusting to a new, potentially life-limiting illness and its treatment. Adaptive leaders are able to evaluate a problem and determine which aspects are technical (can be addressed by expert care staff) and which are adaptive (must be addressed by the patient). The adaptive leader's role is to facilitate the patient in gaining the skills, knowledge, energy, motivation, etc. to engage in the adaptive work needed to address their symptom and functional concerns.

Figure 1.



In our proposed intervention, the integrated care team (RN, OT, PT) provides adaptive leadership through collaborative work (bottom half of Figure 2) by monitoring symptoms and function, assessing adaptive challenges, developing shared understanding among the team and patient to create the individuals plan of work. The patient's adaptive work happens over time during the hospitalization. The integrated care team functioning as adaptive leaders will guide and foster patient behavior changes and skill development. They distinguish between technical and adaptive challenges, which guides how the adaptive work is carried out. Together the patient and integrated care team plan the work, developing individualized solutions to manage technical and adaptive challenges of fluctuating symptoms and function. For example, a patient's response to symptoms creates adaptive challenges suggesting adaptive work that the patient can do to manage symptoms. Typically, a patient's adaptive work is concurrent with technical work that a member of the integrated care team can do to alleviate symptoms. Jointly, the integrated care team members and patient plan the work to be implemented across time to alleviate symptoms and enhance function. Each are involved in monitoring and sharing symptoms and symptom responses as they change over time. The 2-way arrows suggest that the interactions between the patient and integrated care team members require a trusting relationship in which the patient can share concerns, be heard and be understood. In context of a trusting relationship, patients and team members develop a shared meaning of the patient's responses to challenges. Furthermore, through assessment of the patient's personal skills and psychological resources to engage in adaptive work, team members can determine the need for new skills, supporting patients as they

develop any new skills needed for adaptive work. Thus, our intervention will facilitate adaptive leadership among the RN, OT, and PT integrated care team members to carry out appropriate technical work and to empower the patient in accomplishing adaptive work to manage symptoms, lessen functional decline and maintain or improve QOL.

1.7 Rationale

This proposal addresses a central challenge in cancer prevention and control - developing an effective intervention using a multidisciplinary team. Older adults with acute myeloid leukemia (AML) are at risk for worsening symptoms and functional decline during initial treatment. Symptom management and consistent monitoring are needed to identify symptom and functional needs early to improve symptoms and minimize functional decline.

This study will provide new findings in three important areas. First, we will test PACT, the first multi-disciplinary and integrated intervention designed to improve function for persons diagnosed with acute leukemia, who are at high risk for poor QOL, symptom burden, and functional decline. Second, because of limited access to specialty-trained palliative care providers, this intervention trains non-specialty providers in the disciplines of nursing, OT, and PT to provide palliative and supportive care, thus filling a gap in care. Third, we recognize that managing symptoms and function alone is not sufficient to achieve meaningful behavior change; by framing the intervention in the Adaptive Leadership Framework for Chronic Illness, we address the patients' adaptive challenges, such as emotional, motivational, attitudinal barriers, so that patients engage more fully in work required of self-management for reducing symptoms and functional decline.

2.0 STUDY PURPOSE AND DESIGN

This is a single institution, feasibility trial of 20 (10 control and 10 intervention) patients with the primary objective of assessing feasibility, acceptability, and change in pre and post measures of symptoms, function, and QOL by administering the PACT intervention.

Study subjects will be identified by the Study Coordinator through pre-screening through the electronic health record after being referred by the oncologists and pharmacists. Eligible patients will be approached by the Study Coordinator to confirm eligibility, which includes requesting permission of the patient's attending physician. Seven days prior to and within three days after initiation 1st cycle HMA or low-dose cytarabine + VENE, written informed consent will be obtained (A total of 10 days of recruitment period and baseline assessment).

First, ten participants in the control group will receive usual care. After the control patients have completed the study, then 10 intervention participants will receive the PACT intervention, a novel symptom management intervention, which aims to build patient skills to manage AML treatment-related, and chronic illness symptoms. Because patients receive chemotherapy during the first 7 days of hospitalization or clinic visit, the intervention will start at day 1 or day 2 of chemotherapy. During hospitalization, the PACT RN will assess AML symptoms daily (using PRO-CTCAE), and PACT OT and PT will assess function at baseline (day 1 or 2), days 3 or 4, and days 6 or 7. This study uses UNC hired staff of RNs, OTs, and PTs to deliver the intervention.

3.0 STUDY OBJECTIVES/ENDPOINTS

3.1 Primary Objective

Determine feasibility and acceptability of study methods and examine changes in pre- and post-treatment measures of function, patients' self-report of symptoms and QOL, and patients and caregivers' post self-report of readiness for discharge. We will include 10 control and 10 intervention patients.

Feasibility: We plan enrollment of 60% of those approached; achieve 75% retention rate, 75% of intended data collection; and no intervention-related adverse events. The PACT intervention team will have a reduced workload; we will record effort required to deliver the PACT intervention. These feasibility data will inform if, or to what extent, workload is affected to plan future studies and implementation. The team will receive 32 hours of training in palliative care and adaptive leadership approaches. Adherence will be monitored by electronic tracking from OT and PT notes and by self-report.

Acceptability: Assessed by interviews and surveys with patients and their caregivers about their experiences.

Changes in pre-and-post QOL, symptoms, and function. Compare changes between control and intervention.

3.4 Primary Endpoint

3.4.1 Feasibility will be defined as: % approached, retention rate (% of consented patients who completed the intervention); % intended data collection, safety (# of adverse events).

3.4.2 Adherence will be monitored by electronic tracking from OT and PT notes and by self-report during the intervention.

3.5 Exploratory Outcomes

[redacted]

4.0 PATIENT ELIGIBILITY

Eligible patients are those who have been diagnosed with AML and will receive HMA or low-dose cytarabine+ Venetoclax.

4.1 Inclusion Criteria

1. ≥60 years of age

2. Diagnosis of AML
3. Plan to receive HMA or low-dose cytarabine + Venetoclax
4. Have caregiver(s) willing to participate

4.2 Exclusion Criteria

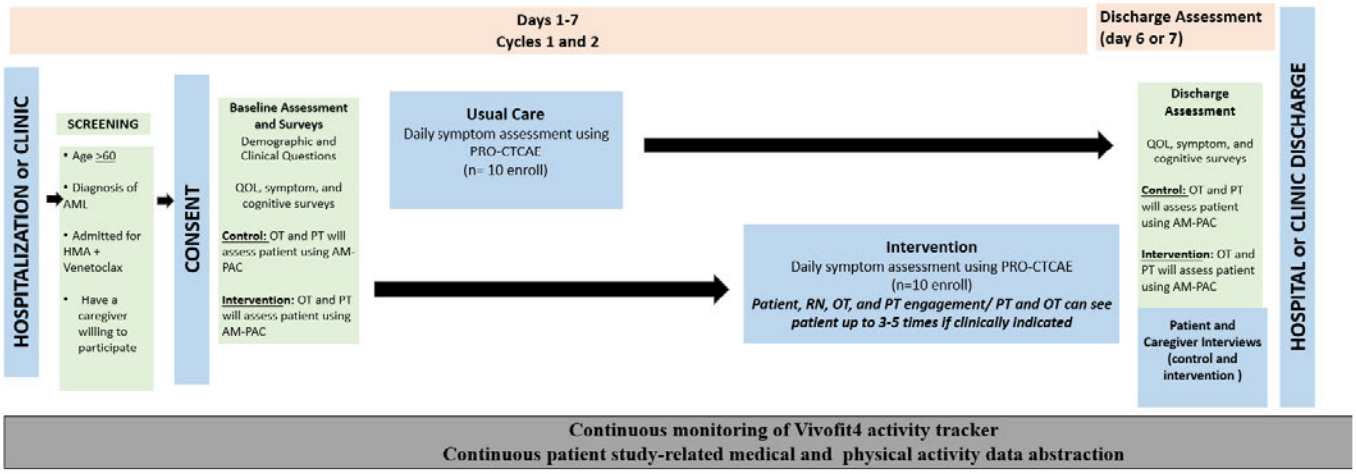
1. Patients receiving hospice care
2. Patients will be excluded if they are unable to participate per their oncology provider

5.0 STUDY PLAN

5.1 Patient Identification and Consent /Study Schema

Potentially eligible patients will be identified through pre-screening the Electronic Health Record after referring by oncologists or pharmacists. Eligible patients will be approached to confirm eligibility (which includes requesting permission of the patient's attending physician). The study coordinator will provide information about the study and invite participation. Seven days prior to and within three days after initiation 1st cycle HMA or low-dose cytarabine + VENE, written informed consent will be obtained from those eligible and interested in participating. If applicable, reasons for declining participation in the study will be recorded.

Study Schema



Recruitment of Patients

Approximately 100-150 patients with acute leukemia are admitted to UNC for treatment annually. We aim to enroll 20 patients (10 control and 10 intervention) with AML over 2 years. Given that recruitment to a pilot cluster randomized feasibility and acceptability trial may be lower than for an observational study, we project achieving our target sample within this timeframe.

Potentially eligible patients (diagnosis with AML) will be approached for enrollment by the study coordinator. Oncologists and nurse navigators will be provided a recruitment flier for the

study containing the purpose, a brief explanation of study protocols, and research team members' information. If the patient expresses interest in participating, the physician or pharmacist will relay this information to a research team member, who will provide more information about criteria for participation and a brief explanation of the study. Eligible patients will have up to 7 days before and within 3 days after initiation of chemotherapy to enroll in the study, and, if applicable, reasons for declining participation in the study will be recorded.

The first 10 patients will be assigned to the control group. All patients (assigned to either intervention or control groups) will undergo the exact same battery of quality of life, symptom, and functional measures at baseline (prior to beginning the intervention), and throughout different time points throughout the study (see Data Collection Procedures/timeline below). Once consent is provided, study personnel may contact enrolled participants up to 2 years from their acute leukemia diagnosis. All patients cluster randomized into the intervention group will receive standard care plus the PACT intervention for the duration of the study.

5.2 Study Assessments

At the time of baseline assessment, patients with no contraindications to activity will undergo quality of life, symptom, OT and PT assessments, as well as medical chart abstraction.

At follow up time points, participants will complete the assessments and questionnaires per the Time and Events table (see section 8.0). We have completed daily and weekly measures with adults undergoing a hematopoietic transplant[26,27] and those with acute leukemia during their hospitalization.[28,29] Patients are able to complete daily assessments within 5 minutes.

5.3 Description of Assessments and Questionnaires

Assessment Tool	Discipline	Indication
European Organization for Research and Treatment of Cancer QLQ-C30	PI or Research Assistant	Self-report QOL: functional scale & symptom scale
PRO version of the Common Terminology for Adverse Events (PRO-CTCAE)	PI or PACT RN	19 items**(diarrhea, chills, heartburn, nausea, appetite, mouth sores, vomiting, constipation, cough, rash, shortness of breath, fatigue, anxiety, sadness, nothing will cheer me up, pain, insomnia, concentration, and memory)
Activity Measure in Post-Acute Care (AM-PAC)	OT & PT	Guides discharge planning; guides resource utilization; provides insight re: patient mobility
Karnofsky Performance Scale (KPS)	PI or Research Assistant	Classified participants' functional impairment
Possibilities for activity Scale (PACTS)	PI or Research Assistant	Assessing self-efficacy and motivation of performing meaningful activity

Timed Up and Go~10 feet (3 meters)	PT	Assesses patient mobility, balance and fall risk
BERG Balance	PT	Falls Risk
Muscle Strength	OT	Prognostic & Predictive Marker, Handheld Dynamometry
Modified Canadian Occupational Performance Measure (COPM)	OT	Self-care, leisure, and productivity outcomes; goal attainment scale
Performance Assessment of Self-care Skills (PASS)	OT	Ability to perform daily tasks
Clock Drawing	OT	Assess cognitive abilities
Demographics and Clinical Characteristics	PI or Research Assistant	**Demographic:** date of birth/age, sex, race/ethnicity, insurance, education, income, marital/partner status, number of people in the household, employment status, insurance type, falls in last 6 months **Clinical:** type of acute leukemia, white blood cell, hemoglobin, hematocrit, platelets, lactate dehydrogenase, neutrophil count, cytogenetics and blast percentage, height and weight, comorbidity, and treatment type(s)
Care Transitions Measure (CTM)	PI or Research Assistant	Assesses readiness for discharge
Patient Activation Measure (PAM)	PI or Research Assistant	Assesses self-management
Preparedness for Caregiving Scale	PI or Research Assistant	Assesses preparedness for caregiving
FACT-Leu Additional Concern subscale	PI or Research Assistant	Assess disease burden

5.3.1 QOL Assessment

Quality of life

The European Organization for Research and Treatment of Cancer QLQ-C30, widely used to assess QOL in patients with cancer, has 30 questions, grouped and scored to obtain both multi-item scales and single-item measures. It includes five functional scales, three symptom scales, one global health status/QOL scale and six symptom items. Functional scales are cognitive, emotional, physical, role, and social. Symptom scales are fatigue, nausea/vomiting, and pain; a global health status/QOL scale and 5 single items assess additional symptoms appetite loss, constipation, diarrhea, dyspnea, sleep disturbance, and perceived financial impact.

Scores of scales and single-item measures range from 0-100; higher scores indicate better QOL. Conversely, in symptom scales and symptom items, higher scores represent worse QOL.[30] We will use the PRO version of the Common Terminology for Adverse Events (PRO-CTCAE)[31] to provide a detailed view of daily treatment-related symptoms and how they fluctuate.

5.3.2 PRO-CTCAE (daily measures)

This 78-item measure, developed at the National Cancer Institute (NCI) allows patients to self-report symptom-based adverse events. We will use a subset of 19 symptoms to assess symptom attributes (e.g., presence, frequency, severity, interference with symptom) deemed relevant for cancer patients; these symptom-items have been extensively evaluated by cancer patients using cognitive interview[32] methods and found to be clear, comprehensible, and capable of measuring the symptoms of interest and are most relevant for this population, such as nausea and vomiting. In our bone marrow transplant study (preliminary study 3, in which most of the patients had some type of leukemia, these items captured symptoms of fatigue, diarrhea, heartburn, nausea, appetite, anxiety, mouth sores, vomiting, pain, constipation, sadness, cheering-up, insomnia, cough, rash, and shortness of breath. In the proposed study, both the control and intervention groups will be asked to answer the 19 questions daily to capture changes over time. Recent data have shown that daily collection of patient-reported symptoms is feasible and acceptable to bone marrow transplant patients in the inpatient setting, who are often patients with AML.[33] We will calculate a total symptom score. This symptom score represents treatment-related symptom burden for that patient on that particular day.

5.3.3 Functional Assessments

The following assessments will consist of the physical performance evaluation: Rate of Perceived Exertion, Activity Measure in Post-Acute Care, Clinician rated Karnofsky Performance Scale (KPS), Possibilities for Activity Scale (PACTS)[34](activity self-efficacy and expectations, related to engagement in meaningful activity), Timed Up and Go, muscle strength using hand dynamometer, BERG balance, Performance Assessment of Self-care Skills (PASS), clock drawing, and Canadian Occupational Performance Measure (COPM).

Role	Assessments
OT	PASS- Performance Rate Assessment of Self-Care Skills, Hand grip strength, Activity Measure for Post-Acute Care (AM-PAC) "6 clicks" - 6 items for OT, clock drawing
PT	Berg balance test, Timed Up and Go, Activity Measure for Post-Acute Care (AM-PAC) "6 clicks" - 6 items for OT; 6 items for PT; α = .92 - .94

AM-PAC: OT and PT clinicians will objectively measure function using the activity Measure in Post-Acute Care (AM-PAC) "6 clicks." The AM-PAC "6 clicks" is a valid tool for assessing function in patients receiving post-acute care.[35] The tool includes three domains: basic mobility function, and another form assesses daily activity function. Each item scores from 1 to 4, the lower the score, the lower the function. Due to the clinic environment consideration, we will only assess 5 items in the PT components (excluding "climbing 3-5 steps with a railing").

Karnofsky Performance Scale (KPS) clinician-rated: The KPS index allows patients to be

classified as to their functional impairment. This can be used to compare effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the survival for most serious illnesses. We will use the clinician rated KPS.[36,37]

Possibilities for activity Scale (PACTS)[34] measures the meaningful activity participants participated in. The scale includes two subdomains: activity self-efficacy and activity expectations.[34] Each item is scored in a Likert-type format ranging from 1 corresponds with "very little" to 5 represents "quite a lot". The total score ranges from 12 to 60 with higher scores indicating that participants had higher self-efficacy and expectation on participating in meaningful activity.[34]

Timed Up and Go: The Timed Up and Go is a performance test of physical mobility, and measures how long it takes the patient, in seconds, to stand up from a standard arm chair, walk a distance of approximately 10 feet, turn, walk back to the chair, and sit down again (Vincent et al, 2010).

BERG balance scale[38] is a 14-item scale used to measure balance of the older adult in clinical setting. Participants will be asked to perform their balance ability following the instructions, such as standing to sitting or standing on one foot. These tasks are common movement in daily life.[38] Each item is scored from 0 to 4, the higher the score, the higher the level of function.

Muscle Strength: Maximal muscle strength of the forearm flexor muscles will be measured using portable dynamometers (NexGen Ergonomics, Quebec, Canada). Maximal muscle strength of the forearm flexors will be performed in a standing position with each forearm flexed at 90 degrees. With the hand in a neutral (handshake) position, the participant will be instructed to inhale. Then, during the exhale, maximally grip the dynamometer for 3- 5 seconds while straightening the forearm longitudinally to the body.

Canadian Occupational Performance Measure (COPM)[39], administered by OT, is a tool to identify, prioritize, and evaluate patient's perception of performing daily activity. Based on this tool, OTs will be able to identify prioritizing occupational task and develop goals for participants in the intervention group.

Performance Assessment of Self-care Skills (PASS)[40], administered by OT, is a tool to assess function. There are several components in the PASS. In our study, we will only use the medication management component, which will assess independence, safety, and adequacy. Additionally, based on the oral hygiene and toileting management components, our OT team develop washing hands component.

Clock Drawing, administered by OT, is a tool to assess cognition. This assessment tool has been identified to be a reliable tool to screen dementia and cognitive impairment, which is easily administered.[41]

Demographic and Clinical Characteristics: We plan to use National Institutes of Nursing Research (NINR) demographic common data elements: date of birth/age, sex, race/ethnicity, insurance, education, income, marital/partner status, number of people in the household,

employment status, insurance type, falls in last 6 months. We will obtain clinical data on type and amount of prior cancer treatment, medical comorbidities and medications, type/dose/date of AML treatment, days hospitalized during cancer treatment (including outside hospitalization if directly transferred to UNC from another facility), subsequent hospitalizations, date of death (if appropriate), electronic notes of occupational and physical therapy, blood test results (such as white blood cell count, Absolute neutrophil count, hemoglobin, platelet, lactate dehydrogenase, C-Reactive Protein), and remission status.

FACT-Leu additional concern subscale is a 17-item questionnaire. Each item is assessed by 0 to 4, the higher the score, the better the QOL.

5.4 Duration of Study

Active participation by a given subject will be complete approximately 6 months after cycles 1, 2, 3, and 4 based on participants' treatment schedule. Ongoing data collection through medical record abstraction will continue for collection of use of UNC services.

5.5 Abstraction of Medical Records and Patient Follow-up Contact

Data abstraction will occur periodically throughout the duration of the study at least weekly.

Variables that will be extracted from the medical records for each patient include, but are not limited to: age, gender, race, ethnicity, diagnosis, education level, type and amount of prior cancer treatment, medical comorbidities and medications, type/dose/date of AML treatment, days hospitalized during cancer treatment (including outside hospitalization if directly transferred to UNC from another facility), subsequent hospitalizations, date of death (if appropriate), electronic notes of occupational and physical therapy, blood test results (such as white blood cell count, Absolute neutrophil count, hemoglobin, platelet, lactate dehydrogenase, C-Reactive Protein), and remission status.

6.0 ASSESSMENT OF SAFETY

Safety will be monitored in all patients from the time of enrollment.

7.0 ASSESSMENT OF EFFICACY

Patients with absolute contraindications to activity monitoring including bilateral lower extremity amputation, unilateral lower extremity amputation without prosthesis and unstable angina or myocardial infarction during the previous month will not be excluded from the study. These patients, therefore, will not be included in any analyses requiring these measures.

8.0 TIME AND EVENTS TABLE

Table 5. Measures							
Variable Measured	**Measure Description and Reliability**	**Baseline cycles 1 & 2** **(7 days prior or within 3 days of infusion initiation)**	**Symptom and QOL** **BOTH GROUPS** **(About days 1-60)**	**HMA or low-dose cytarabine completion at cycle 1 & 2** **(within 2 days or up to 7 days after the end of infusion)**	**Post-discharge, 2x week assessments Monday & Thursday** **INTERVENTION ONLY** **days 8-30**	**Before cycle 4** **(About day 90)**	**Data Collector**
Demographic and clinical variables	Age, sex, race/ethnicity, insurance, education, income, employment status, marital/partner status, number of people in the household. Treatment type, comorbidities, remission status, blood test results, height and weight.	X	Continuously monitor clinical characteristic, ex: blood result, remission status				**Research Assistant**
Health Care Utilization	Number and reasons for: emergency department visits, rehospitalizations Length of hospital	Electronic chart abstraction and self-report					**Research Assistant**
Quality of Life							
QOL	EORTC QLQ-C30[30], α = .89 (5 functional scales, global health status/QOL scale, cognition, financial impact)	X	X (baseline of cycle 3)			X	**Research Assistant**
Symptoms							
AML symptoms	PRO-CTCAE 19 items[42] (diarrhea, chills, heartburn, nausea, appetite, mouth sores, vomiting, constipation, cough, rash, shortness of breath, fatigue, anxiety, sadness*, nothing will cheer me up, pain, insomnia, concentration, and memory)	X	X	X	X	X	**PACT RN**
Disease burden	FACT-Leu Additional Concern subscale	X				X	**Research Assistant**
Function							
Participation in Meaningful Activity	Possibilities for Activity Scale (PActS)[34] - 12 items stratified α = .77 – internal consistency .91 -. 89	X				X	**Research Assistant**
Performance Status	Clinician reported Karnofsky Performance Scale[37] - 1 item for clinician; *r* = .89	X		X		X	**Research Assistant**
Self-care	PASS- Performance Rate Assessment of Self-Care Skills	X					**PACT OT**
Grip Strength	Hand grip strength	X					**PACT OT**
Balance	Berg balance test	X					**PACT PT**
Mobility	Timed Up and Go (3 meter)	X					**PACT PT**
Function	Activity Measure for Post-Acute Care (AM-PAC) "6 clicks" - 6 items for OT; 6 items for PT; α = .92 - .94	X					**PACT OT and PT**
Cognition abilities	Clock Drawing Assessment	X					**PACT OT**
Readiness for Discharge and Self-Management							
Readiness for Discharge	Care Transitions Measure[43], 15 items, α = .93			X			**PACT RN**
Self-management	Patient Activation Measure[44], 13 items, α = .87			X			**PACT RN**
Preparedness for Caregiving	Preparedness for Caregiving Scale			X			**PACT RN**
Other							
Patient and Caregiver Interview				X			**Research Assistant**

9.0 EXPECTED RISKS/UNANTICIPATED PROBLEMS/SAFETY MONITORING

9.1 Expected Risks

To minimize the risk of infections, since the leukemia population becomes very susceptible to infections during treatment, all members of the research team will follow standard neutropenic and protective precautions. Also, the research team will attempt to isolate each piece of exercise equipment to a particular patient room. In case a particular piece of equipment needs to be moved from one room to another, the equipment will be disinfected following standard protocols already in place on the oncology floors. During the study, no equipment will leave the oncology floors. If a research team member is ill, he or she will not be assigned to see any patients during the illness. Also, due to the stringent criteria for participation in the study, only patients deemed capable by their oncologists will be enrolled in the study.

9.1.1 Physical Risks

Timed walk testing requires physical exertion and may result in musculoskeletal injury. Patients with contraindications to physical activity will not be asked to participate in walking. Previously published data[16] have demonstrated that exercise testing in the target patient population is feasible and safe. The research team will take all appropriate precautions to prevent injury. In the unlikely event of injury during the fitness assessments, such as muscle distensions and joint trauma, medical professionals on the research team will provide the appropriate care.

9.1.2 Emotional Risks

Some questions in the patient questionnaires could create emotional distress or confusion. Patients will be instructed that the questionnaires are for research purposes only and any problem or symptom should also be reported to their transplant physician or nurse.

9.2 Protection Against Risks

Risks of physical performance testing will be minimized by providing careful supervision with contact guard posture assistance to provide stability. Patients will be instructed to report any symptoms of fatigue, shortness of breath or chest discomfort, immediately prompting discontinuation of activity and appropriate medical management. Assessments will be carried out in 4 Oncology (inpatient medical oncology) units, infusion clinic, or oncology clinic with full and immediate medical response capacity available. The activity intervention will take place in the hospital in the presence of trained personnel to minimize risks. Patients will receive careful instruction on the activity technique, and each session will be tailored to the individual's level of functioning, symptoms and confidence. Prior to approaching each patient on a daily basis, the interventionist will review a checklist with the patient’s nurse to identify any medical contraindications to participation. In addition, the participants supervising attending oncologist will confirm medical eligibility of each subject prior to enrollment on study.

Confidentiality of data is maintained by using research identification numbers that uniquely identify each patient. Appropriate measures are taken to prevent unauthorized use of study information. The research ID number will be used. Any paper research records will be kept in a

locked cabinet in the study coordinator's office. The files matching participants' names and demographic information with research ID numbers will be kept separately in a password protected data file. Only selected study personnel will have access to these files. After the study is completed, paper records will be stored with other completed research studies in a secured storage vault. Data will be used only in aggregate and no identifying characteristics of individuals will be published or presented.

9.2.1 Patient Confidentiality

We do not anticipate any breach of confidentiality as no records will be shared with any personnel outside the clinicians caring for the patients and the research team. Any information about participants obtained from this research will be kept as confidential as possible. All data obtained either through: Lineberger PRO-Core software, patient chart review, or by direct patient contact will be stored with a study ID rather than patient identifiers. A list of patient names and their study IDs will be kept in a locked cabinet. Electronic data will be de-identified and stored on a secure server.

9.3 Unanticipated Problems

9.3.1 Definition

As defined by UNC's IRB, unanticipated problems involving risks to study subjects refers to any incident, experience, or outcome that:

- Is unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Is related or possibly related to a subject's participation in the research; and

Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) related to the research than was previously known or recognized.

9.4 Removal of Patients from Protocol

Patients will be removed from the study if they indicate they no longer wish to participate and if they are not able to complete the activity due to disease/treatment complications. Additionally, exclusions will occur if the oncologist requests that his/her patient is excluded from the study for medical or emotional concerns.

9.4.1 Reporting

Any unanticipated problem that occurs during the conduct of this study and that meets **at least** the first two criteria listed in section 9.3.1~~9.2.1~~ must be reported to the UNC IRB by the Study Coordinator using the IRB's web-based reporting system (see section 11.5.3).

9.5 Data and Safety Monitoring Plan

The Principal Investigator will provide continuous monitoring of patient safety in this trial with periodic reporting to the Data and Safety Monitoring Committee (DSMC) as required.

Meetings/teleconferences will be held at a frequency dependent on study accrual, and in consultation with the study Biostatistician. At these meetings, the research team will discuss all issues relevant to study progress, including enrollment, safety, regulatory, data collection, and the team will produce summaries or minutes of these meetings. These summaries will be available for inspection when requested by any of the regulatory bodies charged with the safety of human subjects and the integrity of data including, but not limited to, the oversight (Office of Human Research Ethics (OHRE) Biomedical IRB, the Oncology Protocol Review Committee (PRC) or the North Carolina TraCS Institute Data and Safety Monitoring Board (DSMB).

10.0 STATISTICAL CONSIDERATIONS

10.1 Study Design

This is a pilot clinical trial of the PACT intervention in older adults with AML. The primary objective is to assess the feasibility (recruitment and retention) and acceptability of PACT intervention and examine change in pre and post measures of symptoms, function, and QOL comparing 10 control and 10 intervention patients with AML.

Qualitative research does not necessarily predict what might occur, but helps to understand in depth the characteristics of the situation and the meaning brought by participants and what is happening to them at that moment.

Interviews will be semi-structured, face to face with follow-up questions and probes to facilitate a deeper understanding of the patient, caregiver perceptions of the intervention. Interviews will take place on 4 oncology in patient's hospital room or private clinic room and will not last longer than one hour. An interview guide, developed in advance of data collection, will be used to provide a structure to the process (Appendix 13.1).

The interview prompts will focus on the overall perception of the PACT intervention. Each interview will be digitally audio-recorded. Brief field notes will be made before, during (in a non-discrete manner) and after the interviews to make note of points thought to be relevant at the time.

Pseudonyms will be used to protect the identity of the participants. The pseudonym will be linked to demographic and clinical information in a master log. The master log of study participants' names and study codes will be kept in a secure file cabinet in the investigator's locked office.

10.2 Sample Size and Accrual

Sample size for this study is mainly determined by time and resource (budget) constraints. We will allocate 26 patients to the two groups (12 per group). We assume 20% of values will be missing or otherwise unusable, yielding complete data for 10 patients per group for analyses. As stated

above, estimation rather than statistical inference is our focus, and so it is not this project's goal to have adequate statistical power. We can focus instead on precision, and for the primary outcome of QOL (standardized), the half-width of a two-sided 95% confidence interval would be .9SD, assuming 10 patients per randomized group. We obtained this result using nQuery Advisor v7.0 software.

We claim such a study as feasible if and only if both (a) recruitment rate (p) is high enough and (b) retention rate (q) is sufficiently high, i.e., if both p and q are large enough. More specifically, this is to test the following hypothesis:

H0: p <= 50% or q <= 50% vs H1: p >= 80% and q >= 70%.

Denote N as the number of eligible patients we try to recruit, and Y as the number of patients who are recruited, X as the number of patients (among the Y who are enrolled) who complete the PACT intervention. The target value of Y is 20, and we assume (1) N follows a negative binomial distribution, NB(20, p), (2) X, conditional on (Y = 20), follows a binomial distribution B(20, q). We further assume that N and X are independent. We list cut-offs and associated type I error and power under different N and X values for rejecting the hypothesis of p <= 50% and the hypothesis of q <= 50%.

Recruitment (N: total number of patients being approached)

Y	Rejection Area	Type I error (p <=50%)	Power (p >= 0.80)
20	N <= 20+12	0.108	0.994
20	N <= 20+13	0.148	0.997
20	**N <= 20+14**	**0.196**	**0.999**
20	N <= 20+15	0.250	0.999

Retention (X: total number of patients who complete the intervention**)**

Y	Rejection Area	Type I error (q <=50%)	Power (q >= 0.70)
20	X > 8	0.748	0.995
20	X > 9	0.588	0.983
20	X > 10	0.412	0.952
20	**X > 11**	**0.252**	**0.887**

Under the independence assumption, the overall Type I error rate is the product of two individual type I errors, and the overall power is the product of power of two individual powers. We will reject the hypothesis of p <= 50% if N <= 34, and reject the hypothesis of q <= 50% if X > 11. The resulted overall type I error is 4.9%, while the overall power is 88.6%.

10.3 Data Analysis Plans

Feasibility Data Management and Analysis

Data will be collected on feasibility metrics. These include collecting and recording data on all patients approached for recruitment, along with an indicator of whether each patient is enrolled or not. The proportion of those enrolling, along with its 95% confidence interval, will be

computed. Of those enrolled, we will record whether there is attrition prior to each patient's end of follow-up, as well as the reasons for such attrition. The proportion of those retained, along with its 95% confidence interval, will be computed as 1 minus the proportion who experienced attrition from the study. The frequency of data values will also be tracked, and the proportion of non-missing data values, along with its 95% confidence interval, will be computed. The frequency and type of adverse events, including intervention-related adverse events, will be recorded. Staff hours reflecting the effort required to deliver the intervention to each patient enrolled into the intervention arm will be tracked; its mean and standard deviation will be computed across patients.

Acceptability Data Management and Analysis

Interviews will be transcribed by a professional transcription agency. Using Atlas.ti for analysis, Drs. Bryant and Richardson will read transcripts to derive codes. They will review and discuss labels to group codes into related categories and identify major themes through this process. After we define each major theme, we will identify corresponding exemplar quotes. We will address trustworthiness of analysis procedures and findings through creation of an audit trail to record data collection, coding, and analysis decisions. The interviewer (Dr. Bryant) will make reflexive memos after each interview and review memos with corresponding audio recordings to discern linkages, gaps, and questions. When the two coders do not agree on their initial code, code negotiation and transcript review will occur.

Analysis of Change in Pre-and-Post QOL, Symptom, and Function

Analyses will be conducted following an intention to treat approach, such that patients are analyzed as allocated. Descriptive statistics will be computed on all analysis variables at each time point separately for each condition. These values will be compared between the conditions at baseline to determine whether any imbalanced. These include means and standard deviations for continuous variables, and frequencies and percentages for categorical variables. As the primary analysis of pre and post values, we will fit an analysis of covariance (ANCOVA) model for each post outcome, with a main effect for group (intervention versus control) while controlling for the covariate of the corresponding baseline (pre) value. Sensitivity analyses will repeat this ANCOVA but adding demographic variables that are imbalanced at baseline, subject to sufficient sample size. This approach will allow us to assess whether the mean post values differ between groups for each measure through the regression coefficient for the main effect of group, as well as its 95% confidence interval. This information will be useful in planning for the subsequent R01, and we will calculate effect sizes for the post measure as the ratio of the mean difference between the intervention and the control groups to its standard deviation. For measures where more than one follow-up measure is collected, this approach can be extended through a linear mixed effects model approach to repeated measures analysis, and within-patient correlation can be estimated. If extensive (e.g., greater than 10%), multiple imputation will be considered for missing values. No formal significance testing will occur, as the intention is to evaluate and estimate effect sizes rather than formal hypothesis testing, and hence multiplicity is not a concern from this perspective.

11.0 STUDY MANAGEMENT

11.1 Institutional Review Board (IRB) Approval and Consent

It is expected that the IRB will have the proper representation and function in accordance with

federally mandated regulations. The IRB should approve the consent form and protocol.

In obtaining and documenting informed consent, the investigator should comply with the applicable regulatory requirement(s), and should adhere to Good Clinical Practice (GCP) and to ethical principles that have their origin in the Declaration of Helsinki.

Before recruitment and enrollment onto this study, the patient will be given a full explanation of the study and will be given the opportunity to review the consent form. Each consent form must include all the relevant elements currently required by the FDA Regulations and local or state regulations. Once this essential information has been provided to the patient and the investigator is assured that the patient understands the implications of participating in the study, the patient will be asked to give consent to participate in the study by signing an IRB-approved consent form.

Prior to a patient's participation in the trial, the written informed consent form should be signed and personally dated by the patient and by the person who conducted the informed consent discussion.

11.2 Required Documentation

Before the study can be initiated at any site, the following documentation must be placed on file (as applicable).

- A copy of the official IRB approval letter for the protocol and informed consent
- IRB membership list
- CVs and medical licensure for the principal investigator and any sub-investigators who will be involved in the study.
- Investigator's signature documenting understanding of the protocol and providing commitment that this trial will be conducted according to all stipulations of the protocol

11.3 Registration Procedures

All subjects must be registered with the Lineberger Comprehensive Cancer Center. After initial consultation with Paul Jones (paul_e_jones@med.unc.edu, 966-4432), the subjects will be registered and entered into the web based clinical research platform, Oncore®.

11.4 Data Management and Monitoring/Auditing

All study data will be collected, managed, and stored via PRO Core Survey System using a unique patient identifier. PRO Core is a secure platform for collecting data via web-enabled devices. It facilitates study management through patient tracking reports and email reminders to project staff. It allows symptoms to be tracked from baseline up to 24 weeks post discharge. Data are stored in a secure database managed by the Information Technology Science (ITS) Research Computing group at UNC.

As an investigator-initiated study, this trial may be audited by the Lineberger Cancer Center audit committee.

11.5 Adherence to the Protocol

Except for an emergency situation in which proper care for the protection, safety, and well-being of the study patient requires alternative treatment, the study shall be conducted exactly as described in the approved protocol.

11.5.1 Emergency Modifications

UNC and Affiliate investigators may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior UNC or their respective institution's IRB/IEC approval/favorable opinion.

For any such emergency modification implemented, a UNC IRB modification form must be completed by UNC Research Personnel within five (5) business days of making the change.

11.5.2 Single Patient/Subject Exceptions

Any request to enroll a single subject who does not meet all the eligibility criteria of this study requires the approval of the UNC Principal Investigator and the UNC IRB.

11.5.3 Other Protocol Deviations/Violations

According to UNC's IRB, a protocol deviation is any unplanned variance from an IRB approved protocol that:

- Is generally noted or recognized after it occurs
- Has no substantive effect on the risks to research participants
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected
- Did not result from willful or knowing misconduct on the part of the investigator(s).

An unplanned protocol variance is considered a violation if the variance meets any of the following criteria:

- Has harmed or increased the risk of harm to one or more research participants.
- Has damaged the scientific integrity of the data collected for the study.
- Results from willful or knowing misconduct on the part of the investigator(s).
- Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

If a deviation or violation occurs, please follow the guidelines below:

Protocol Deviations: UNC personnel will record the deviation in OnCore®, and report to any sponsor or data and safety monitoring committee in accordance with their policies. Deviations should be summarized and reported to the IRB at the time of continuing review.

Protocol Violations: Violations should be reported by UNC personnel within one (1) week of the investigator becoming aware of the event using the same IRB online mechanism used to report Unanticipated Problems.

Unanticipated Problems:
Any events that meet the criteria for "Unanticipated Problems" as defined by UNC's IRB must be reported by the Study Coordinator using the IRB's web-based reporting system.

11.6 Amendments to the Protocol

Should amendments to the protocol be required, the amendments will be originated and documented by the Principal Investigator at UNC. It should also be noted that when an amendment to the protocol substantially alters the study design or the potential risk to the patient, a revised consent form might be required.

The written amendment, and if required the amended consent form, must be sent to UNC's IRB for approval prior to implementation.

11.7 Record Retention

Study documentation includes all eCRFs, data correction forms or queries, source documents, Sponsor-Investigator correspondence, monitoring logs/letters, and regulatory documents (e.g., protocol and amendments, IRB correspondence and approval, signed patient consent forms).

Source documents include all recordings of observations or notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the clinical research study.

Government agency regulations and directives require that all study documentation pertaining to the conduct of a clinical trial must be retained by the study investigator. In the case of a study with a drug seeking regulatory approval and marketing, these documents shall be retained for at least two years after the last approval of marketing application in an International Conference on Harmonization (ICH) region. In all other cases, study documents should be kept on file until three years after the completion and final study report of this investigational study.

11.8 Obligations of Investigators

The Principal Investigator is responsible for the conduct of the clinical trial at the site in accordance with Title 21 of the Code of Federal Regulations and/or the Declaration of Helsinki. The Principal Investigator is responsible for personally overseeing the treatment of all study patients. The Principal Investigator must assure that all study site personnel, including sub-investigators and other study staff members, adhere to the study protocol and all FDA/GCP/NCI regulations and guidelines regarding clinical trials both during and after study completion.

The Principal Investigator will be responsible for assuring that all the required data will be collected and entered into the eCRFs. Periodically, monitoring visits will be conducted and the Principal Investigator will provide access to his/her original records to permit verification of proper entry of data. At the completion of the study, all eCRFs will be reviewed by the Principal Investigator and will require his/her final signature to verify the accuracy of the data.

12.0 REFERENCES

1. Society AC. Acute Myeloid Leukemia https://www.cancer.org/cancer/acute-myeloid-leukemia/about/key-statistics.html. Published 2020. Accessed.
2. Albrecht TA. Physiologic and psychological symptoms experienced by adults with acute leukemia: an integrative literature review. *Oncology nursing forum.* 2014;41(3):286-295.
3. Burhenn PS, Bryant AL, Mustian KM. Exercise Promotion in Geriatric Oncology. *Current oncology reports.* 2016;18(9):58.
4. Mukherjee S, Sekeres, M. Emerging and Novel Therapies for AML *Seminars in Oncology Nursing* 2019;in press.
5. DiNardo CD, Pratz K, Pullarkat V, et al. Venetoclax combined with decitabine or azacitidine in treatment-naive, elderly patients with acute myeloid leukemia. *Blood.* 2019;133(1):7-17.
6. Winters AC, Gutman JA, Purev E, et al. Real-world experience of venetoclax with azacitidine for untreated patients with acute myeloid leukemia. *Blood advances.* 2019;3(20):2911-2919.
7. Grover S, Rina K, Malhotra P, Khadwal A. Caregiver Burden in the Patients of Acute Myeloblastic Leukemia. *Indian journal of hematology & blood transfusion : an official journal of Indian Society of Hematology and Blood Transfusion.* 2019;35(3):437-445.
8. Anderson RA, Bailey DE, Jr., Wu B, et al. Adaptive leadership framework for chronic illness: framing a research agenda for transforming care delivery. *ANS Advances in nursing science.* 2015;38(2):83-95.
9. Corazzini KN, Anderson RA. Adaptive leadership and person-centered care: a new approach to solving problems. *North Carolina medical journal.* 2014;75(5):352-354.
10. Ferrell BR, Temel JS, Temin S, et al. Integration of Palliative Care Into Standard Oncology Care: American Society of Clinical Oncology Clinical Practice Guideline Update. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology.* 2017;35(1):96-112.
11. Temel JS, Greer JA, Muzikansky A, et al. Early palliative care for patients with metastatic non-small-cell lung cancer. *The New England journal of medicine.* 2010;363(8):733-742.
12. El-Jawahri A, Traeger L, Greer JA, et al. Effect of Inpatient Palliative Care During Hematopoietic Stem-Cell Transplant on Psychological Distress 6 Months After Transplant: Results of a Randomized Clinical Trial. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology.* 2017;35(32):3714-3721.
13. El-Jawahri A, LeBlanc T, VanDusen H, et al. Effect of Inpatient Palliative Care on Quality of Life 2 Weeks After Hematopoietic Stem Cell Transplantation: A Randomized Clinical Trial. *Jama.* 2016;316(20):2094-2103.
14. Petty RE BJ, Wheeler SC. . *In: DiClemente RJ, Crosby RA, Kegler MC, eds. Emerging Theories in Health Promotion Practice and Research.* 2nd edition ed: Jossey-Bass; 2009.
15. Batson CD, Polycarpou MP, Harmon-Jones E, et al. Empathy and attitudes: can feeling for a member of a stigmatized group improve feelings toward the group? *Journal of personality and social psychology.* 1997;72(1):105-118.
16. Michie S, Richardson M, Johnston M, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the

reporting of behavior change interventions. *Annals of behavioral medicine : a publication of the Society of Behavioral Medicine.* 2013;46(1):81-95.

17. Bryant AL, Deal, A., Phillips, B., Bailey, C., Pergolotti, M., Hackney, A.C., Battaglini, C. Cancer related fatigue, quality of life and intervention adherence: Exercise and Quality of Life trial preliminary results *Geronotological Society of America.* 2015;68th Annual Scientific Meeting (November 16-20, 2015).
18. Marlatt GA DD. *Relapse Prevention* 2nd edition ed: Guilford Press; 2005.
19. RM S. *Conquering the Content: a Step-by-Step Guide to Web-Based Course Development.* San Franciso, CA: Jossey-Bass; 2008.
20. Bovend'Eerdt TJ, Botell RE, Wade DT. Writing SMART rehabilitation goals and achieving goal attainment scaling: a practical guide. *Clinical rehabilitation.* 2009;23(4):352-361.
21. Quill TE, Abernethy AP. Generalist plus specialist palliative care--creating a more sustainable model. *The New England journal of medicine.* 2013;368(13):1173-1175.
22. Anderson KH, Friedemann ML, Bűscher A, Sansoni J, Hodnicki D. Immersion research education: students as catalysts in international collaboration research. *International Nursing Review.* 2012;59(4):502-510.
23. Gilson LL, Maynard, T.M., Jones Young N.C., Vartiainen, M., Hakonen, M. Virtual Teams Research: 10 Years, 10 Themes, and 10 Opportunities. *Journal of Management* 2015;41(5):1313-1337.
24. Bellg AJ, Borrelli B, Resnick B, et al. Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health psychology : official journal of the Division of Health Psychology, American Psychological Association.* 2004;23(5):443-451.
25. Menzin J, Lang K, Earle CC, Kerney D, Mallick R. The outcomes and costs of acute myeloid leukemia among the elderly. *Archives of internal medicine.* 2002;162(14):1597-1603.
26. Bryant AL, Coffman EM, Bullard E, et al. Experiences of Inpatient Bone Marrow Transplantation Nurses and Providers Using Electronic Symptom Reporting. *Journal of oncology practice.* 2018;14(8):e496-e504.
27. Bryant AL, Coffman E, Phillips B, et al. Pilot randomized trial of an electronic symptom monitoring and reporting intervention for hospitalized adults undergoing hematopoietic stem cell transplantation. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer.* 2019.
28. Leak Bryant A, Coffman EM, Phillips B, et al. Symptoms, Mobility and Function, and Quality of Life in Adults With Acute Leukemia During Initial Hospitalization. *Oncology nursing forum.* 2018;45(5):653-664.
29. Bryant AL, Deal AM, Battaglini CL, et al. The Effects of Exercise on Patient-Reported Outcomes and Performance-Based Physical Function in Adults With Acute Leukemia Undergoing Induction Therapy: Exercise and Quality of Life in Acute Leukemia (EQUAL). *Integrative cancer therapies.* 2018;17(2):263-270.
30. Aaronson NK, Ahmedzai S, Bergman B, et al. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *Journal of the National Cancer Institute.* 1993;85(5):365-376.
31. Guidelines. CTEPNCTCfAECvOIa. Cancer Therapy Evaluation Program NCI. Common Terminology Criteria for Adverse Events (CTCAE) v3.0 Online Instructions and

Guidelines. https://webapps.ctep.nci.nih.gov/webobjs/ctc/webhelp/welcome_to_ctcae.htm. Published 2009. Accessed.

32. Institute NC. Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™). Published 2017. Accessed.
33. Basch E, Deal AM, Kris MG, et al. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology.* 2016;34(6):557-565.
34. Pergolotti M, Cutchin MP. The Possibilities for Activity Scale (PActS): Development, validity, and reliability. *Canadian journal of occupational therapy Revue canadienne d'ergotherapie.* 2015;82(2):85-92.
35. Haley SM, Coster WJ, Andres PL, et al. Activity outcome measurement for postacute care. *Medical Care.* 2004:I49-I61.
36. 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(4):M139-144.
37. 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(3):187-193.
38. Berg K, Wood-Dauphine S, Williams J, Gayton D. Measuring balance in the elderly: preliminary development of an instrument. *Physiotherapy Canada.* 1989;41(6):304-311.
39. Law MC, Baptiste S, Carswell A, McColl MA, Polatajko H, Pollock N. *Canadian occupational performance measure: COPM.* CAOT Publ. ACE; 1998.
40. Holm MB, Rogers J, Hemphill-Pearson B. The performance assessment of self-care skills (PASS). *Assessments in occupational therapy mental health.* 2008;2:101-110.
41. Agrell B, Dehlin O. The clock-drawing test. *Age and ageing.* 1998;27(3):399-403.
42. Basch E, Reeve BB, Mitchell SA, et al. Development of the National Cancer Institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE). *Journal of the National Cancer Institute.* 2014;106(9).
43. Coleman EA, Smith JD, Frank JC, Eilertsen TB, Thiare JN, Kramer AM. Development and testing of a measure designed to assess the quality of care transitions. *International journal of integrated care.* 2002;2:e02.
44. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health services research.* 2004;39(4 Pt 1):1005-1026.

13.0 APPENDICES

13.1 Appendix I – Interview Guide

13.1.1 For patient (control group)
13.1.2 For caregiver (control group)
13.1.3 For patient (intervention group)
13.1.4 For caregiver (intervention group)

13.1.1 For patient (control group)

Greeting
Thank you for being here today. We really appreciate you taking the time to participate in this discussion. My name is _____ and will lead the discussion today.

Role
My role today will be to ask some specific questions and to keep the conversation going. We have a lot to cover, so I may need to change the subject or move ahead with the discussion. However, please stop me if you want to add anything or if you have any questions. The interview today will last about 20-30 minutes.

Purpose
The main thing we are interested in today is hearing from you, the expert. We want to hear your experiences about being diagnosed with acute leukemia and the initiation of chemotherapy. Your experiences will help us gain valuable insight on challenges that patients with AML face during chemotherapy. This information will guide us to further develop interventions to manage these challenges in the acute leukemia population.

I would like to state that our conversation is being audiotaped to help us remember what is said. You may ask me to turn off the recorder at any time or simply say you do not want to answer a question. Everything said here today will be confidential. Nothing you say will be connected with your name.

Any questions before we begin?

This section will be conducted at discharge assessment of cycle 1 and cycle 2.

1. How would you describe your mobility before your diagnosis?
2. How would you describe your mobility before your diagnosis now?
3. What do you think will help you continue to stay active?
4. How would you describe your (physical/psychological) symptoms?
5. What has your experience been while being home?

Closing (5 minutes)
Is there anything else we have not yet discussed that you would like to mention related to what we've been talking about?

13.1.2 For caregiver (control group)

Greeting

Thank you for being here today. We really appreciate you taking the time to participate in this discussion. My name is _____ and will lead the discussion today.

Role

My role today will be to ask some specific questions and to keep the conversation going. We have a lot to cover, so I may need to change the subject or move ahead with the discussion. However, please stop me if you want to add anything or if you have any questions. The interview today will last about 20-30 minutes.

Purpose

The main thing we are interested in today is hearing from you, the experts. We want to hear your experiences about noticing [patient's name] cognitive changes after being diagnosed with acute leukemia and receiving chemotherapy. These changes may include difficulties thinking and processing, concentrating, memorizing or any changes you notice may be related. Your experiences will help us gain valuable insight on challenges that patients with AL and caregivers face during chemotherapy. This information will guide us to have an in-depth understanding of cognitive impairment and to further develop intervention to manage these challenges in acute leukemia population and caregivers.

I would like to state that our conversation is being audiotaped to help us remember what is said. You may ask me to turn off the recorder at any time or simply say you do not want to answer a question. Everything said here today will be confidential. Nothing you say will be connected with your name.

Any questions before we begin?

This section will be conducted at discharge assessment of cycle 1 and cycle 2.

1. What would you have wished you had known about [patient's name] acute leukemia?
2. What else might we have done to be helpful to you during the [hospitalization/clinic visit]?

Closing (5 minutes)

Is there anything else we have not yet discussed that you would like to mention related to what we've been talking about?

13.1.3 For patient (Intervention group)

Greeting

Thank you for being here today. We really appreciate you taking the time to participate in this discussion. My name is _____ and will lead the discussion today.

Role

My role today will be to ask some specific questions and to keep the conversation going. We have a lot to cover, so I may need to change the subject or move ahead with the discussion. However, please stop me if you want to add anything or if you have any questions. The interview today will last about 20-30 minutes.

Purpose

The main thing we are interested in today is hearing from you, the experts. We want to hear your experiences about noticing [patient's name] cognitive changes after being diagnosed with Acute Leukemia and receiving chemotherapy. These changes may include difficulties thinking and processing, concentrating, memorizing or any changes you notice may be related. Your experiences will help us gain valuable insight on challenges that patients with acute leukemia and caregivers face during chemotherapy. This information will guide us to have an in-depth understanding of cognitive impairment and to further develop interventions to manage these challenges in the acute leukemia population and with their caregivers.

.

I would like to state that our conversation is being audiotaped to help us remember what is said. You may ask me to turn off the recorder at any time or simply say you do not want to answer a question. Everything said here today will be confidential. Nothing you say will be connected with your name.

Any questions before we begin?

Intervention Feedback (15-20 minutes)

This section will be conducted during cycles 1 and 2 (days 6 or 7). We will ask questions within 30 days of cycle 3.

1. How would you describe your mobility before your diagnosis and now?
2. What was it like for you to have your RN talk with you daily about your symptoms?
3. What was it like for you to have your OT and PT visit with you during your hospital stay?
4. Describe your experience in the joint meetings to help you develop your SMART goals.
5. What do you think will help you continue to stay active?
6. What did you find the most beneficial about working with your study team during your hospital stay?
7. Do you have general suggestions for improvement of the intervention?

13.1.4 For caregiver (Intervention group)

Greeting

Thank you for being here today. We really appreciate you taking the time to participate in this discussion. My name is Ya-Ning Chan. I am a 3rd year PhD student in nursing and also the research assistant of the study.

Role

My role today will be to ask some specific questions and to keep the conversation going. We have a lot to cover, so I may need to change the subject or move ahead with the discussion. However, please stop me if you want to add anything or if you have any questions. The interview today will last about 30-45 minutes.

Purpose

The main thing we are interested in today is hearing from you, the experts. We want to hear your feedback about the intervention and experiences about noticing [patient's name's] cognitive changes after being diagnosed with AML and receiving chemotherapy. Your feedbacks will help us gain valuable insight on challenges that patients with AML face during chemotherapy. This information will guide our further intervention development to manage symptoms in AML population.

I would like to state that our conversation is being audiotaped to help us remember what is said. You may ask me to turn off the recorder at any time or simply say you do not want to answer a question. Everything said here today will be confidential. Nothing you say will be connected with your name.

Any questions before we begin?

Intervention Feedback (30 minutes)

This section will be conducted during cycles 1 and 2 (days 6 or 7). We will ask questions within 30 days of cycle 3.

1. What would you have wished you had known about [patient's name] acute leukemia?
2. What did you find most helpful about the intervention?
3. What did you find least helpful about the intervention?
4. What else might we have done to be helpful to you during the hospitalization?
5. Do you have general suggestions for improvement of the intervention?

Closing (5 minutes)

Is there anything else we have not yet discussed that you would like to mention related to what we've been talking about?

13.2 Measures

13.2.1 EORTC QLQ-C30
13.2.2 PRO-CTCAE
13.2.3 Activity Measure for Post-Acute Care (AM-PAC) "6 clicks"
13.2.4 Patient and clinician reported Karnofsky Performance Scale (KPS)
13.2.5 Possibilities for Activity Scale (PACTS)
13.2.6 Timed Up and Go
13.2.7 PASS-Performance Assessment of Self-Care Skills (PASS)
13.2.8 BERG Balance Scale
13.2.9 Muscle Strength
13.2.10 Modified Canadian Occupational Performance Measure (COPM)
13.2.11 Baseline assessment of demographic and clinical characteristic
13.2.12 Comorbidity Assessment
13.2.13 Clock Drawing
13.2.14 Care Transitions Measure
13.2.15 Patient Activation Measure
13.2.16 Preparedness for Caregiving Scale
13.2.17 Fall and Health Care utilization

13.2.1 EORTC QLQ-C30

ENGLISH

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials: _____

Your birthdate (Day, Month, Year): _____

Today's date (Day, Month, Year): 31 _____

	Not at All	A Little	Quite a Bit	Very Much
1. Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2. Do you have any trouble taking a long walk?	1	2	3	4
3. Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4. Do you need to stay in bed or a chair during the day?	1	2	3	4
5. Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:	Not at All	A Little	Quite a Bit	Very Much
6. Were you limited in doing either your work or other daily activities?	1	2	3	4
7. Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8. Were you short of breath?	1	2	3	4
9. Have you had pain?	1	2	3	4
10. Did you need to rest?	1	2	3	4
11. Have you had trouble sleeping?	1	2	3	4
12. Have you felt weak?	1	2	3	4
13. Have you lacked appetite?	1	2	3	4
14. Have you felt nauseated?	1	2	3	4
15. Have you vomited?	1	2	3	4
16. Have you been constipated?	1	2	3	4

Please go on to the next page

ENGLISH

During the past week:	**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
17. Have you had diarrhea?	1	2	3	4
18. Were you tired?	1	2	3	4
19. Did pain interfere with your daily activities?	1	2	3	4
20. Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21. Did you feel tense?	1	2	3	4
22. Did you worry?	1	2	3	4
23. Did you feel irritable?	1	2	3	4
24. Did you feel depressed?	1	2	3	4
25. Have you had difficulty remembering things?	1	2	3	4
26. Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27. Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28. Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

13.2.2 PRO-CTCAE

The following 19 symptoms will be assessed daily by both the control and intervention patients:

diarrhea, chills, heartburn, nausea, appetite, mouth sores, vomiting, constipation, cough, rash, shortness of breath, fatigue, anxiety, sadness, nothing will cheer me up, pain, insomnia, concentration, and memory

13.2.3 Activity Measure for Post Acute Care (AM-PAC) "6 clicks"

AM-PAC Domains

The AM-PAC instrument examines a set of 269 functional activities that are likely to be encountered by most adults during daily routines within the context of either an inpatient episode of care or outpatient post acute services. (i.e., the item bank). Because functional activity is multidimensional, AM-PAC item banks are organized into three functional areas: Basic Mobility (131 items), Daily Activity (88 items), and Applied Cognitive (50 items). Items for the AM-PAC have been drawn from two sources: (1) a set of *new items* that examine the functional content domains listed above; and (2) items from *existing outcome instruments* used in rehabilitation and post acute programs. The items in the AM-PAC assess multiple aspects (i.e., difficulty, assistance, limitations) of an individual's ability to perform specific daily activities.

Factor analytic work identified three distinct, interpretable factors that accounted for 72% of the variance: *Applied Cognitive* (44%), *Daily Activities* (19%) and *Basic Mobility* (9%). (Haley et al. 2004). Using Item Response Theory (IRT), items in each domain were scaled along a continuum of item difficulty. Items that were redundant or did not fit the model were eliminated. The remaining items formed the AM-PAC item banks, which included a wide range of items calibrated along a continuum of difficulty.

Basic Mobility Domain:

- Bend/stand/carry
- Ambulation
- Transfers
- Wheelchair skills

Daily Activity Domain:

- Grooming & Hygiene
- Feeding and Meal Preparation
- Personal Care

Applied Cognitive Domain:

- Communication
- Print Information
- New learning and applying knowledge

13.2.4 Patient and clinician reported Karnofsky Performance Scale (KPS)

Clinician reported Karnofsky Performance Status Scale

Value	Level of functional capacity	Definition
100	Normal, no complaints, no evidence of disease	Able to carry on normal activity and to work; no special care needed
90	Able to carry on normal activity, minor signs or symptoms of disease	
80	Normal activity with effort, some signs or symptoms of disease	
70	Cares for self, unable to carry on normal activity or to do active work	Unable to work; able to live at home and care for most personal needs; various degrees of assistance needed
60	Requires occasional assistance, but is able to care for most needs	
50	Requires considerable assistance and frequent medical care	
40	Disabled, requires special care and assistance	Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly
30	Severely disabled, hospitalization is indicated although death is not imminent	
20	Hospitalization is necessary, very sick, active supportive treatment necessary	
10	Moribund, fatal processes progressing rapidly	
0	Dead	

13.2.5. Possibilities for Activity Scale (PACTS)

Please **circle** the number that corresponds to how much you BELIEVE (1=Very Little, 5=Quite A Lot) that a person of your age and diagnosis SHOULD be involved with each type of activity.

How much do you BELIEVE that a person of your age and diagnosis SHOULD BE...

	Very Little		⟷		***Quite A Lot***
Doing creative activities *(e.g. crafts/hobbies, cultural activities*	1	2	3	4	5
Doing spiritual activities *(e.g. prayer/meditation, religious activities)*	1	2	3	4	5
Getting around town *(e.g. driving, using public transportation)*	1	2	3	4	5
Communicating with others *(e.g. writing letters/cards, talking on the telephone, computer use for email)*	1	2	3	4	5
Doing physical exercise	1	2	3	4	5
Keeping up with traditional media *(e.g. listening to the radio, watching TV, reading newspapers and magazines)*	1	2	3	4	5
Doing service activities *(e.g. volunteer activities, community organization activities)*	1	2	3	4	5

13.2.6 Timed Up and Go

ASSESSMENT

Timed Up & Go (TUG)

Patient _____

Date _____

Time _____ ☐ AM ☐ PM

Purpose: To assess mobility

Equipment: A stopwatch

Directions: Patients wear their regular footwear and can use a walking aid, if needed. Begin by having the patient sit back in a standard arm chair and identify a line 3 meters, or 10 feet away, on the floor.

NOTE: Always stay by the patient for safety.

① **Instruct the patient:**

When I say "Go," I want you to:

1. Stand up from the chair.
2. Walk to the line on the floor at your normal pace.
3. Turn.
4. Walk back to the chair at your normal pace.
5. Sit down again.

② **On the word "Go," begin timing.**

③ **Stop timing after patient sits back down.**

④ **Record time.**

Time in Seconds: _____

An older adult who takes ≥12 seconds to complete the TUG is at risk for falling.

OBSERVATIONS

Observe the patient's postural stability, gait, stride length, and sway.

Check all that apply:

- ☐ Slow tentative pace
- ☐ Loss of balance
- ☐ Short strides
- ☐ Little or no arm swing
- ☐ Steadying self on walls
- ☐ Shuffling
- ☐ En bloc turning
- ☐ Not using assistive device properly

These changes may signify neurological problems that require further evaluation.

CDC's STEADI tools and resources can help you screen, assess, and intervene to reduce your patient's fall risk. For more information, visit www.cdc.gov/steadi

Centers for Disease Control and Prevention
National Center for Injury Prevention and Control

2017

STEADI Stopping Elderly Accidents, Deaths & Injuries

13.2.7 PASS-Performance Assessment of Self-Care Skills (PASS)

PASS Clinic Version

Task # C14: IADL-C Medication Management

CLINIC CONDITIONS: Table and

1. Seven-day medication sheet with 4 subdivisions for each day – Morning, Noon, Evening, Bedtime
2. Hand held magnifier, calendar opened to current month
3. 1 prescription type bottle with child-proof lid (C-P) containing red vitamin pills (candies) and a typed label that reads "Take 1 after each meal and at bedtime".
4. 1 prescription type bottle with non-child-proof lid (N-C-P) containing yellow vitamin pills (candies) and a typed label that reads "Take 1 with breakfast and 1 at bedtime."
5. Wall clock
6. Items 1-2 on table in front of Client; Medication organizer directly in front of Client, calendar and magnifier at top of organizer
7. Client seated at the table with wall clock visible

CLINIC INSTRUCTIONS:

"The next task involves managing medications.

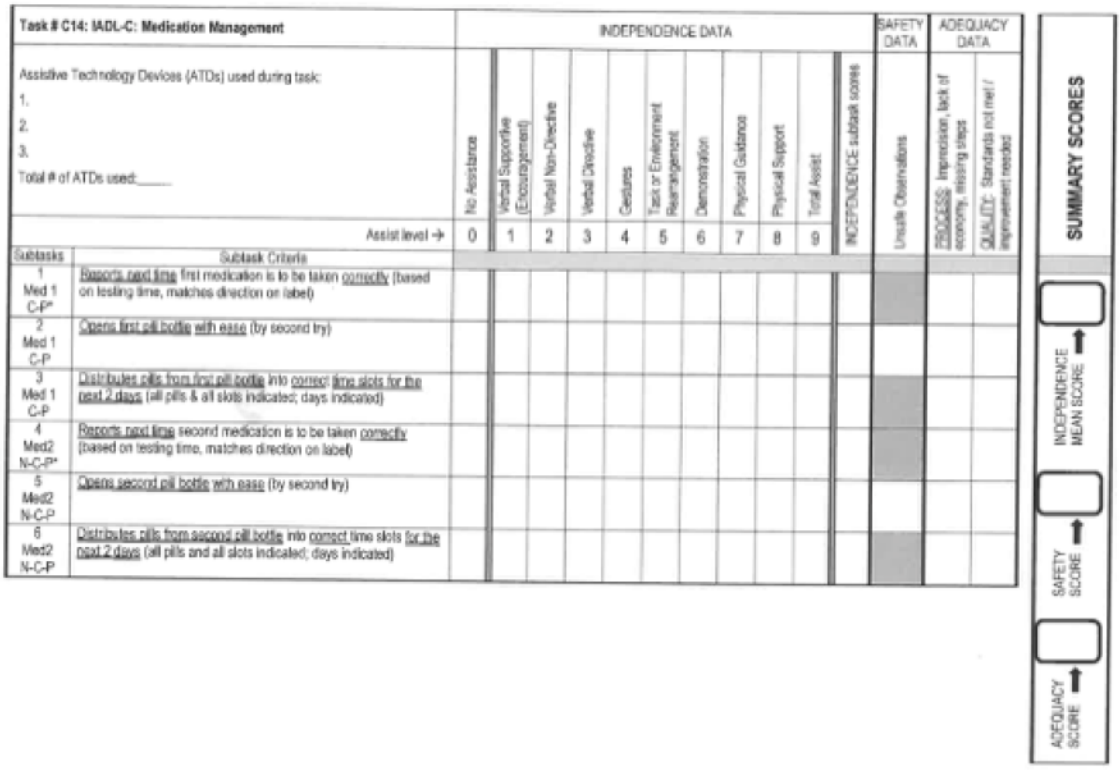
"Please read the prescription label and find the directions for taking this medication [Hand Client bottle with child-proof lid and wait until Client looks up]. If you were taking this medication today, when would you have to take the next pill?" [Wait for response].

"This medication organizer is like a pillbox. It has the days of the week across the top [Point] and the time of the day [Point] along the side. Using the organizer, distribute the pills to be taken tomorrow and the following day according to the directions on the prescription label. Do you know what you are to do? Do you have everything that you need?" [Wait for response]

"Now, please read the prescription label on this bottle and find the directions for taking this medication [Hand Client bottle with non-child-proof lid and wait until Client looks up]. If you were taking this medication today, when would you have to take the next pill?" [Wait for response]

"Again, using the organizer, distribute the pills to be taken tomorrow and the following day according to the prescription directions on the label. Do you know what you are to do?" [Wait for response]

SCORE	INDEPENDENCE	SAFETY	ADEQUACY	
			PROCESS	QUALITY
3	No assists given for task initiation, continuation, or completion	Safe practices were observed	Subtasks performed with precision & economy of effort & action	Optimal (performance matches the quality standards listed in each subtask)
2	No Level 7-8 assists given, but occasional Level 1-6 assists given	Minor risks were evident but no assistance provided	Subtasks generally performed w/ precision & economy of effort & action; occasional lack of efficiency, redundant or extraneous action; no missing steps	Acceptable (Performance, for the most part, matches or nearly matches the quality standards listed in each subtask)
1	No Level 8 assists given; or occasional Level 7 or 8 assists given; or continuous Level 1-6 assists given	Risks to safety were observed and assistance given to prevent potential harm	Subtasks generally performed w/ lack of precision and/or economy of effort & action; consistent extraneous or redundant actions; steps may be missing	Marginal (Performance, for the most part, does not match the quality standards listed in each subtask)
0	Level 8 assists given; or continuous Level 7 or 8 assists given; or unable to initiate, continue, or complete subtask or task	Risks to safety of such severity were observed that task was stopped or taken over by assistor to prevent harm	Subtasks are consistently performed w/ lack of precision and/or economy of effort & action so that task progress is unattainable	Unacceptable (Performance does not match the quality standards listed in each subtask, perhaps with few exceptions)



Task # C14: IADL-C: Medication Management		INDEPENDENCE DATA											SAFETY DATA	ADEQUACY DATA	
Assistive Technology Devices (ATDs) used during task: 1. 2. 3. Total # of ATDs used:_____		No Assistance	Verbal Supportive (Encouragement)	Verbal Non-Directive	Verbal Directive	Gestures	Task or Environment Rearrangement	Demonstration	Physical Guidance	Physical Support	Total Assist	INDEPENDENCE subtask scores	Unsafe Observations	PROCESS: Impression, lack of economy, missing steps	QUALITY: Standards not met / improvement needed
	Assist level →	0	1	2	3	4	5	6	7	8	∞				
Subtasks	Subtask Criteria														
1 Med 1 C-P*	Reports next time first medication is to be taken correctly (based on testing time, matches direction on label)														
2 Med 1 C-P	Opens first pill bottle with ease (by second try)														
3 Med 1 C-P	Distributes pills from first pill bottle into correct time slots for the next 2 days (all pills & all slots indicated; days indicated)														
4 Med2 N-C-P*	Reports next time second medication is to be taken correctly (based on testing time, matches direction on label)														
5 Med2 N-C-P	Opens second pill bottle with ease (by second try)														
6 Med2 N-C-P	Distributes pills from second pill bottle into correct time slots for the next 2 days (all pills and all slots indicated; days indicated)														

SUMMARY SCORES

INDEPENDENCE MEAN SCORE

SAFETY SCORE

ADEQUACY SCORE

Washing Hands	OT reads clinic instructions and scores appropriately the following subtask criteria		
	SUBTASK 1: Adjusts water adequately		
	SUBTASK 2: Locates soap dispenser efficiently		
	SUBTASK 3: Manipulates soap dispenser to obtain adequate amount of soap on hands		
	SUBTASK 4: Washes all parts of hands thoroughly		
	SUBTASK 5: Rinses hands of soap thoroughly		
	SUBTASK 6: Turns off water faucet completely		
	SUBTASK 7: Locates paper towels efficiently		
	SUBTASK 8: Reaches for and gathers paper towel and maintains balance		
	SUBTASK 9: Dries all parts of hands thoroughly		
	SUBTASK 10: Locates trash bin efficiently		
	SUBTASK 11: Places paper towel into trash bin and maintains balance		

13.2.8 BERG Balance Scale

Description: 14-item scale designed to measure balance of the older adult in a clinical setting.

Equipment needed: Yardstick, 2 standard chairs (one with arm rests, one without), Footstool or step, Stopwatch or wristwatch, 15 ft walkway

Scoring: A five-point ordinal scale, ranging from 0-4. "0" indicates the lowest level of function and "4" the highest level of function. Score the LOWEST performance. Total Score = 56

Interpretation:

41-56 = independent
21-40 = walking with assistance
0 –20 = wheelchair bound

Berg K, Wood-Dauphinee S, Williams JI, Maki, B (1992). Measuring balance in the elderly: validation of an instrument. Can. J. Pub. Health July/August supplement 2:S7-11

Cut Off Scores:

- Score of < 45 indicates individuals may be at greater risk of falling (Berg, 1992)

  Berg K, Wood-Dauphinee S, Williams JI, Maki, B. (1992). Measuring balance in the elderly: validation of an instrument. Can. J. Pub. Health July/August supplement 2:S7-11

- History of falls and BBS < 51, or no history of falls and BBS < 42 is predictive of falls (91% sensitivity, 82% specificity) (Shumway-Cook, 1997)
- Score of < 40 on BBS associated with almost 100% fall risk (Shumway-Cook, 1997) (n = 44, mean age = 74.6 (5.4) years for non-fallers, 77.6 (7.8) for fallers)

  Shumway-Cook, A., Baldwin, M., et al. (1997). Predicting the probability for falls in community-dwelling older adults. Physical Therapy 77(8): 812-819 Retrieved 10-5-2014 from Rehab Measures Database. http://www.rehabmeasures.org/Lists/RehabMeasures/PrintView.aspx?ID=888

Comments: Potential ceiling effect with higher level patients. Scale does not include gait items

Minimal Detectable Change:

"A change of **4 points** is needed to be 95% confident that true change has occurred if a patient scores within 45-56 initially, **5 points** if they score within 35-44, **7 points** if they score within 25-34 and, finally, **5 points** if their initial score is within 0-24 on the Berg Balance Scale."

Donoghue D; Physiotherapy Research and Older People (PROP) group, Stokes EK. (2009). How much change is true change? The minimum detectable change of the Berg Balance Scale in elderly people. *J Rehabil Med*. 41(5):343-6.

Norms:

Table 4. Berg Balance Scale Scores: Means, Standard Deviations, and Confidence Intervals by Age, Gender, and Use of Assistive Device

Age (y)	Group	N	Mean	SD	CI
60-69	Male	1	51.0	—	35.3 – 66.7
	Female	5	54.6	0.5	47.6 – 61.6
	Overall	6	54.0	1.5	52.4 – 55.6
70-79	Male	9	53.9	1.5	48.7 – 59.1
	Female	10	51.6	2.6	46.6 – 56.6
	Overall	19	52.7	2.4	51.5 – 53.8
80-89	Male	10	41.8	12.2	36.8 – 46.8
	Female	24	42.1	8.0	38.9 – 45.3
	No Device	24	46.3	4.2	44.1 – 48.5
	Device	10	31.7	10.0	28.3 – 35.1
	Overall	34	42.0	9.2	38.8 – 45.3
90-101	Male	2	40.0	1.4	28.9 – 51.1
	Female	15	36.9	9.7	32.8 – 40.9
	No Device	7	45	4.2	40.9 – 49.1
	Device	10	31.8	7.6	28.4 – 35.2
	Overall	17	37.2	9.1	32.5 – 41.9

Lusardi, M.M. (2004). Functional Performance in **Community Living Older Adults**. *Journal of Geriatric Physical Therapy*, 26(3), 14-22.

Berg Balance Scale

Name: _____ Date: _____

Location: _____ Rater: _____

ITEM DESCRIPTION	SCORE (0-4)
1. Sitting to standing	_____
2. Standing unsupported	_____
3. Sitting unsupported	_____
4. Standing to sitting	_____
5. Transfers	_____
6. Standing with eyes closed	_____
7. Standing with feet together	_____
8. Reaching forward with outstretched arm	_____
9. Retrieving object from floor	_____
10. Turning to look behind	_____
11. Turning 360 degrees	_____
12. Placing alternate foot on stool	_____
13. Standing with one foot in front	_____
14. Standing on one foot	_____

Total _____

GENERAL INSTRUCTIONS
Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches. Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

Berg Balance Scale

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

Berg Balance Scale continued…..

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is place in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

12. PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touch the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.
( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

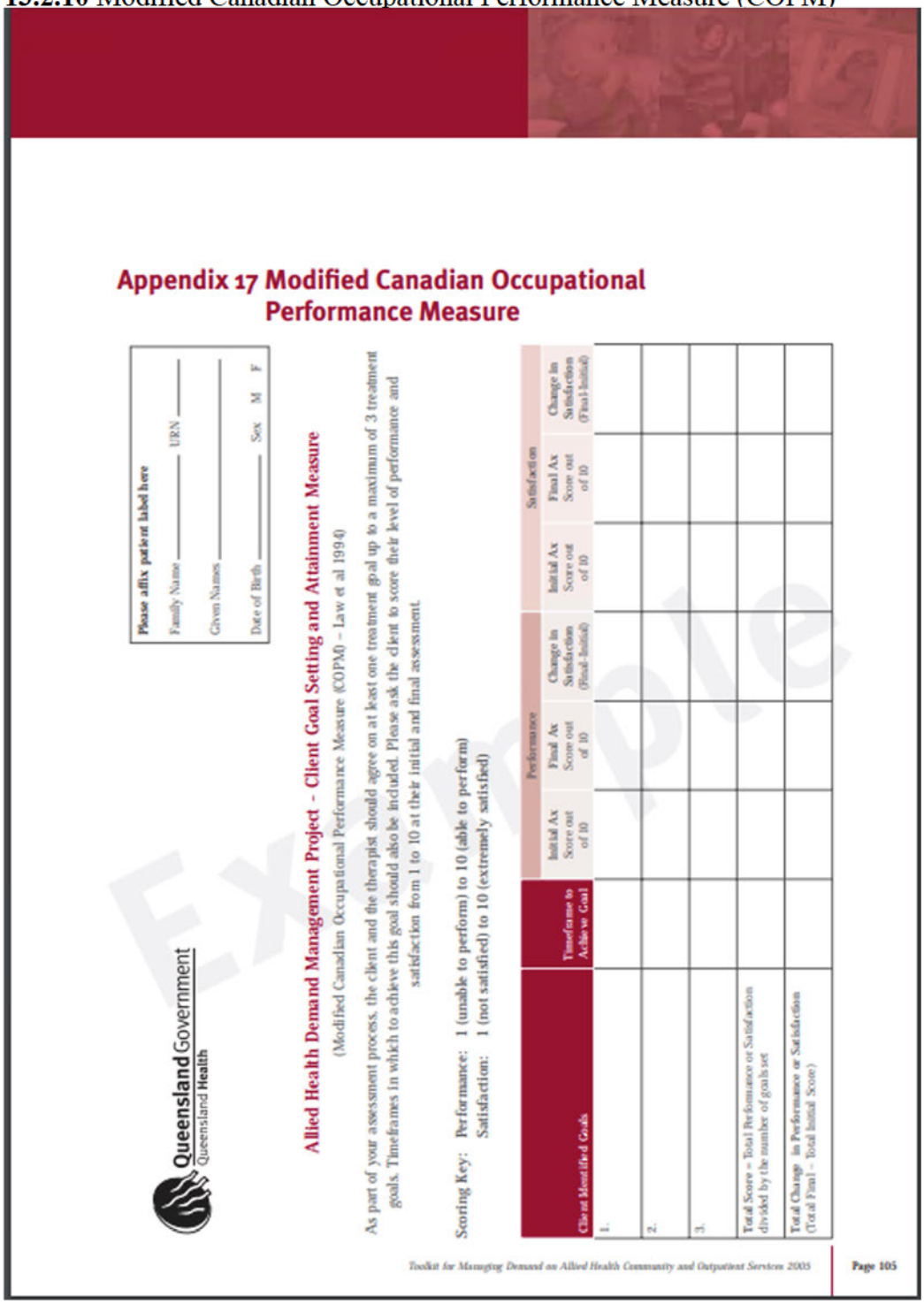
13.2.9 Muscle Strength

Date:_____ Data Collector Initials: _____ ID: _____

Muscle Strength assessed by the Hand Held Dynamometry

	Right hand		Left hand	
Dominant hand	Yes	No	Yes	No
Trial 1				
Trial 2				
Trial 3				
Mean				

13.2.10 Modified Canadian Occupational Performance Measure (COPM)



Appendix 17 Modified Canadian Occupational Performance Measure

Please affix patient label here

Family Name _____ URN _____

Given Names _____

Date of Birth _____ Sex M F

Queensland Government
Queensland Health

Allied Health Demand Management Project - Client Goal Setting and Attainment Measure

(Modified Canadian Occupational Performance Measure (COPM) - Law et al 1994)

As part of your assessment process, the client and the therapist should agree on at least one treatment goal up to a maximum of 3 treatment goals. Timeframes in which to achieve this goal should also be included. Please ask the client to score their level of performance and satisfaction from 1 to 10 at their initial and final assessment.

Scoring Key: Performance: 1 (unable to perform) to 10 (able to perform)
Satisfaction: 1 (not satisfied) to 10 (extremely satisfied)

Client Identified Goals	Timeframe to Achieve Goal	Performance			Satisfaction		
		Initial Ax Score out of 10	Final Ax Score out of 10	Change in Satisfaction (Final-Initial)	Initial Ax Score out of 10	Final Ax Score out of 10	Change in Satisfaction (Final-Initial)
1.							
2.							
3.							
Total Score = Total Performance or Satisfaction divided by the number of goals set							
Total Change in Performance or Satisfaction (Total Final - Total Initial Score)							

13.2.11 Baseline assessment of demographic and clinical characteristic

Subject ID: _____ Date: _____

Baseline Patient Assessment

The following questions aim to better understand your background, quality of life and symptom burden. Your answers to all following questions are important and may have a future impact on the care of patients in this population.

1. **How old are you?** - _____

2. **What is your gender?**
   Male Female Prefer not to answer I identify in another way

3. **Which category best describes your race *(select all that apply)***
   White Black or African American Asian Native Hawaiian or other Pacific Islander
   Native Indian or Alaskan Native Other: _____ Prefer not to answer

4. **With which ethnicity do you identify? -** Hispanic or Latino Non-Hispanic Prefer not to answer

5. **What is the highest level of school <u>completed</u> or the highest degree you have <u>received</u>?**
   1st-8th grades College Degree (Associates; B.A./B.S.)
   9th-11th grades Advanced Degree (MA, PhD, etc.)
   High school graduate/GED Prefer not to answer

6. **Which of the following categories best describes your total household income, before taxes, in the year prior *to your current hospital admission*?**
   <$20,000 annually $40,001–60,000 $80,001–100,000
   $20,001–40,000 $60,001–80,000 >$100,001
   Prefer not to answer

7. **Which of the follow best describes your current marital status?**
   Single, never married Separated Widowed
   Married/partnered Divorced Prefer not to answer

8. **Were you living with another person *prior to your current hospital admission?***
   Yes No Prefer not to say

9. **What is your zip code of residence?** - _____

10. **Were you employed *prior to your current hospital admission*?**
    Yes No Prefer not to say

11. **Do you CURRENTLY have insurance coverage, such as Medicaid, Medicare, or private insurance?**
    Yes No Prefer not to say

12. **How many falls *approximately* have you had in the last 6 months*?*** - _____

<u>If you have fallen, please describe each fall below *(i.e., when, where, why, and if it led to any diagnoses)*</u>

LCCC 1848– PI: Dr. Ashley Leak Bryant Version 01.25.2020

Subject ID: _____ Date: _____

Baseline Patient Assessment

The following questions aim to better understand your health and your reason for your hospitalization.

Type of Acute Leukemia: _____

Cytogenetics: _____

WBC: _____

ANC: _____

Hemoglobin: _____

Hematocrit: _____

Platelet: _____

LDH: _____

LCCC 1848– PI: Dr. Ashley Leak Bryant Version 01.25.2020

Subject ID: _____ Date: _____

The following questions aim to better understand your health and your reason for your hospitalization.

WBC: _____

ANC: _____

Hemoglobin: _____

Hematocrit: _____

Platelet: _____

LDH: _____

Remission status: _____

Subject ID: _____ Date: _____

Caregiver Assessment

The following questions aim to better understand your background and care of your loved one with cancer. Your answers to all following questions are important and may have a future impact on the care of patients in this population.

1. **How old are you?** - _____

2. **What is your gender?**
   Male Female Prefer not to answer I identify in another way

3. **Which category best describes your race *(select all that apply)***
   White Black or African American Asian Native Hawaiian or other Pacific Islander
   Native Indian or Alaskan Native Other: _____ Prefer not to answer

4. **With which ethnicity do you identify? -** Hispanic or Latino Non-Hispanic Prefer not to answer

5. **What is the highest level of school <u>completed</u> or the highest degree you have <u>received</u>?**
   1st-8th grades
   9th-11th grades
   High school graduate/GED
   College Degree (Associates; B.A./B.S.)
   Advanced Degree (MA, PhD, etc.)
   Prefer not to answer

6. **Which of the following categories best describes your total household income, before taxes, in the year prior *to your current hospital admission*?**
   <$20,000 annually
   $20,001–40,000
   $40,001–60,000
   $60,001–80,000
   $80,001–100,000
   >$100,001
   Prefer not to answer

7. **Which of the follow best describes your current marital status?**
   Single, never married
   Married/partnered
   Separated
   Divorced
   Widowed
   Prefer not to answer

8. **What is your zip code of residence?** - _____

13.2.12 Comorbidity Assessment

ID_____

Chronic Illness Assessment

1. Has patient had a history of arthritis or connective tissue disease (rheumatoid arthritis, severe osteoarthritis, degenerative joint disease)?
   No Yes

2. Has patient had a history of lung disease (asthma, emphysema, chronic bronchitis, or COPD [chronic obstructive pulmonary disease])?
   No Yes

3. Has patient had a history of diabetes mellites?
   No Yes

4. Has patient had a history of cardiovascular disease (including history of hypertension, hypercholesterolemia/hyperlipidemia, heart attack, congestive heart failure, peripheral vascular disease, or stroke)?
   No Yes

5. Has patient had a history of cancer?
   No Yes , Please specify location and year_____

6. Has patient had a history of renal disease (dialysis, serum creatinine>3 mg/dl, renal transplant, uremia)?
   No Yes

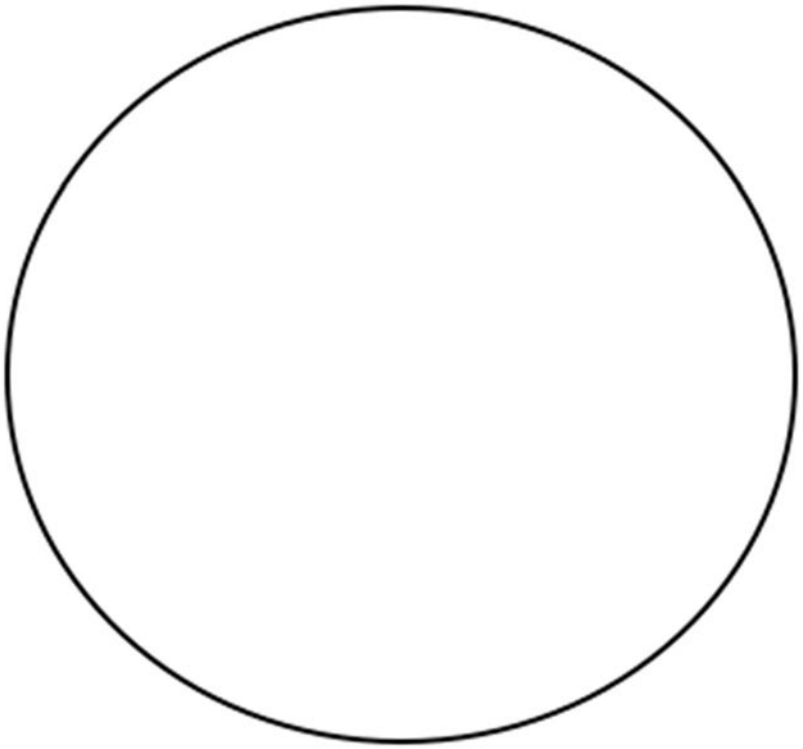
7. Has patient had a history of mental health issue (anxiety disorder or depression)?
   No Yes

8. Has patient had a history of liver disease (hepatitis, or cirrhosis)?
   No Yes

13.2.13 Clock Drawing

Draw a clock

- Put in all the numbers for a clock.
- Set the hands to "ten minutes after eleven."
- Be careful.
- Be neat.



ID: _____

CARE TRANSITIONS MEASURE (CTM-15)

Patient Name: _____ Date: _____

Who completed interview? θ Patient θ Caregiver

The first few statements are about the time you were in the hospital . . .

1. Before I left the hospital, the staff and I agreed about clear health goals for me and how these would be reached.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

2. The hospital staff took my preferences and those of my family or caregiver into account in deciding ***what*** my health care needs would be when I left the hospital.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

3. The hospital staff took my preferences and those of my family or caregiver into account in deciding ***where*** my health care needs would be met when I left the hospital.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

The next set of statements is about when you were preparing to leave the hospital . . .

4. When I left the hospital, I had all the information I needed to be able to take care of myself.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

5. When I left the hospital, I clearly understood how to manage my health.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

ID: _____

6. When I left the hospital, I clearly understood the warning signs and symptoms I should watch for to monitor my health condition.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

7. When I left the hospital, I had a readable and easily understood written plan that described how all of my health care needs were going to be met.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

8. When I left the hospital, I had a good understanding of my health condition and what makes it better or worse.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

9. When I left the hospital, I had a good understanding of the things I was responsible for in managing my health.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

10. When I left the hospital, I was confident that I knew what to do to manage my health.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

11. When I left the hospital, I was confident I could actually do the things I needed to do to take care of my health.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

ID: _____

The next statement is about your follow-up doctors' appointments . . .

12. When I left the hospital, I had a readable and easily understood written list of the appointments or tests I needed to complete within the next several weeks.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

The next set of statements is about your medications…

13. When I left the hospital, I clearly understood the ***purpose*** for taking each of my medications.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

14. When I left the hospital, I clearly understood ***how*** to take each of my medications, including how much I should take and when.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

15. When I left the hospital, I clearly understood the possible ***side effects*** of each of my medications.

Strongly Disagree	Disagree	Agree	Strongly Agree	Don't Know/ Don't Remember/ Not Applicable

13.2.15 Patient Activation Measure

ID: _____

Below are some statements that people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally by circling your answer. Your answers should be what is true for you and not just what you think others want you to say.

If the statement does not apply to you, circle N/A.

1. When all is said and done, I am the person who is responsible for taking care of my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
2. Taking an active role in my own health care is the most important thing that affects my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
3. I am confident I can help prevent or reduce problems associated with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
4. I know what each of my prescribed medications do	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
5. I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
6. I am confident that I can tell a doctor concerns I have even when he or she does not ask	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
7. I am confident that I can follow through on medical treatments I may need to do at home	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
8. I understand my health problems and what causes them	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
9. I know what treatments are available for my health problems	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
10. I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
11. I know how to prevent problems with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
12. I am confident I can figure out solutions when new problems arise with my health	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A
13. I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress	Disagree Strongly	Disagree	Agree	Agree Strongly	N/A

13.2.16 Preparedness for Caregiving Scale

The Preparedness for Caregiving Scale

YOUR PREPARATION FOR CAREGIVING

We know that people may feel well prepared for some aspects of giving care to another person, and not as well prepared for other aspects. We would like to know how well prepared you think you are to do each of the following, even if you are not doing that type of care now.

	Not at all prepared	Not too well prepared	Somewhat well prepared	Pretty well prepared	Very well prepared
1. How well prepared do you think you are to take care of your family member's physical needs?	0	1	2	3	4
2. How well prepared do you think you are to take care of his or her emotional needs?	0	1	2	3	4
3. How well prepared do you think you are to find out about and set up services for him or her?	0	1	2	3	4
4. How well prepared do you think you are for the stress of caregiving?	0	1	2	3	4
5. How well prepared do you think you are to make caregiving activities pleasant for both you and your family member?	0	1	2	3	4
6. How well prepared do you think you are to respond to and handle emergencies that involve him or her?	0	1	2	3	4
7. How well prepared do you think you are to get the help and information you need from the health care system?	0	1	2	3	4
8. Overall, how well prepared do you think you are to care for your family member?	0	1	2	3	4

9. Is there anything specific you would like to be better prepared for?_____

_____

_____

_____

_____

MEAN SCORE of the number of items answered: _____

Reprinted with permission from author.

Stewart & Archbold (1986, 1994)

ID_____

Health care and Fall Follow-up

1. Since leaving the hospital, have you used any health care services?
   No
   Yes

   1a. If yes, please specify what services have you used?
   hospital
   urgent care
   emergency department

   1b. Please specify the reason(s) for these services?
   (a section for open-ended answer)

2. How many falls have you had within the last 30 days?
   _____

   2a. Please specify any injuries as a result of the fall.
   (a section for open-ended answer)