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PROTOCOL TITLE:

Health Through Activity:
A pilot study of a rehabilitation intervention for people living with multiple myeloma

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1.0 Objectives

This is a single arm feasibility study of a rehabilitation intervention designed to reduce disability in people living with multiple myeloma.

Aim 1: To evaluate the feasibility of enrolling and retaining participants with multiple myeloma into a pilot test of the refined HTA intervention, delivered from MGH Institute of Health Professions (i.e., within the IMPACT Practice Center or clinical research laboratories) and via telehealth technology.

Aim 2: To evaluate the feasibility of administering the outcome assessment battery that includes patient-reported outcomes of disability, activity level, quality of life, fatigue, and exercise self-efficacy, and performance-based outcomes of balance, gait speed, and strength.

Aim 3: To assess the acceptability of the refined HTA intervention and assessment battery and utilize stakeholder feedback to identify further modifications to enhance acceptability.

2.0 Background

People living with multiple myeloma are at risk of developing disability

Multiple myeloma (MM) is a chronic malignancy of the plasma cells in bone marrow and is the second most common hematological cancer.[1] Most commonly diagnosed in people over the age of 65,[2] MM has a five-year relative survival rate of 58%.[3] Though considered incurable, more individuals are living with MM as a chronic health condition for years due to advancements in therapeutic approaches to managing MM.[4]

Many people living with MM experience distressing symptoms which limit their ability to engage in meaningful activities. While the impact of MM is variable, the most prevalent symptoms experienced are fatigue, pain, insomnia, and peripheral neuropathy.[1, 5-8] Additionally, up to 80% of individuals with MM develop osteolytic skeletal lesions which can cause bone pain and pathologic fractures.[1, 9] These sequelae of MM and its treatments, along with commonly reported symptoms of anxiety and depression,[10] may result in decreased physical functioning, limited health-related quality of life, and difficulty engaging in activities related to valued roles.[1, 5, 6] Furthermore, people living with MM are at an increased risk of falling,[11] and many fear pain or injury (e.g., pathological fractures) which can lead to avoidance of physical activity and exercise. Taken together, people with MM are at high risk for developing disability, i.e., a perceived limitation in and reduced frequency of activity engagement.[12-14]

Rehabilitation interventions to reduce disability

The primary goals of cancer rehabilitation are to reduce or prevent disability and maximize quality of life of people living with cancer. In his early description of cancer rehabilitation, Dietz suggested rehabilitation strategies could be categorized in terms of whether they were restorative, supportive, preventive, or palliative in intent.[15] The first two categories are most relevant to this proposal. When attempting to reduce disability, restorative strategies are utilized to reduce symptoms and restore physical and psychosocial capabilities to whatever degree possible. Exercise, balance training, and engagement in pleasurable activities are examples of restorative strategies that can improve strength, mobility, and reduce depressive symptoms. Supportive strategies involve adapting activities or modifying the physical or social environment in order to perform an activity, despite any residual symptoms or impairments. Examples of supportive strategies involve utilizing adaptive equipment, eliminating steps of an activity, or rearranging the environment to allow a person to sit while performing an activity.

To date, there has not been a definitive test evaluating the degree to which a comprehensive rehabilitative approach utilizing restorative and supportive strategies can reduce disability in people living with MM. Exercise is the most studied restorative strategy for this population.[16, 17] The Canadian Physiotherapy Association published clinical guidelines for the promotion of exercise for people living with MM, citing the feasibility and safety of exercise among individuals with MM as well as the positive impacts on functional mobility, self-care, physical performance (i.e., aerobic capacity and muscular strength), and physical activity.[18] Our team has pilot tested a supportive strategy that teaches older adults with cancer how to increase engagement in valued activities by utilizing activity adaptation, environmental modification, and goal setting and action planning (preliminary data described below). **The goal of the current study is to explore the feasibility and acceptability of a rehabilitation intervention that blends these restorative and supportive strategies to reduce disability for older adults with MM.** Pilot testing of the program and solicitation of stakeholder input will allow us to prepare for future efficacy trials by identifying appropriate procedures for participant identification and recruitment, delivery of the intervention via clinic or telehealth, and identification of an adequate comparison condition.

Preliminary Studies Supporting the Scientific Premise

After conducting two descriptive studies examining disability and participation among older adult cancer survivors,[19, 20] our team developed and pilot tested an intervention, referred to as the Health Through Activity (HTA) program, to reduce disability by fostering activity engagement among older adult cancer survivors. The HTA program was patient-centered, as participants self-selected activities they wanted to engage in and were taught to create an activity prescription for themselves. The occupational therapist delivering six individualized intervention sessions guided each participant to identify potential barriers and strategies to overcome these barriers. Participants were provided education (e.g., about activity adaptation or energy management) and adaptive equipment

(e.g., pedometer, reacher) as needed to address goals. Participants were also offered the chance to practice the activity of interest with the occupational therapist or to modify the environment to make it easier. This activity prescription process was repeated at each session, after debriefing about goal attainment and effectiveness of the previous week's action plan.

In the pilot study, participants most often set goals to increase exercise (44% of goals), improve instrumental activities of daily living and/or home management tasks (14%), and increase leisure activities (24%). Regarding treatment strategies, 77% of the 61 participants chose to practice the activity with the occupational therapist, 42% requested a piece of equipment, and 11% modified the environment to increase activity engagement.[21] Participants set 63 long-term goals and met or made progress towards 49 of them (full or partial goal attainment rate of 78%; full goal attainment rate of 62%).[22] In terms of self-reported disability, the control condition (i.e., "usual care" that rarely included rehabilitation) showed no change over time whereas the HTA group demonstrated improvements over time (effects were not statistically significant as study was not powered for efficacy testing).[23]

Thirty-three of the 61 participants in the HTA pilot study were living with incurable hematological malignancies such as multiple myeloma. Exploratory subgroup analyses revealed that this group of participants experienced the greatest benefit from the HTA program. Content analysis of the intervention sessions revealed that participants with advanced/metastatic cancer more often requested education about how to improve performance in activities such as exercise, sleep, and energy management.[24] They reported strong interest in increasing activity engagement that would build strength and resilience for future treatment changes or cycles. While the participants with metastatic disease reported physical impairments of fatigue (50% of participants) and pain (42%) as barriers to activity engagement, they also reported environmental barriers (weather 58%; and environment not conducive 17%) and lack of time for activity engagement (58%).[24]

<u>Refinements of the original HTA program for the current study</u>

Considering the importance of exercise to maintaining physical function among individuals with MM, we expect that the addition of a customized exercise prescription will increase the potency of the intervention. Exercise prescription that is individualized to reduce risk of injury and accommodate/address any long-standing physical impairments is important for individuals living with MM.[18, 25-27] Therefore, we will modify the HTA intervention so that it is co-delivered by an occupational therapist and physical therapist, where the former focuses upon fostering activity engagement via activity prescription (i.e., a supportive strategy to reduce disability) and the latter focuses upon fostering exercise engagement via exercise prescriptions (a restorative strategy to reduce disability).

While the home-based pilot study provided the opportunity for environmental modification and practice of an activity within the home setting, this delivery model may reduce the scalability of the intervention. However, our pilot data suggest that the intervention has the potential to be delivered in an outpatient venue, as only three participants chose to modify their home environment. Additionally, when participants chose to practice an activity with the occupational therapist, it most often involved exercise (e.g., walking), which could occur within an outpatient setting. As such, we will explore the feasibility of providing the revised HTA intervention within the outpatient environment of the MGH Institute of Health Professions (MGH IHP) (i.e., within the IMPACT Practice Center, a pro bono therapy clinic at MGH IHP, or within MGH IHP clinical research laboratories).

Early observations of our study indicate that attending in-person study visits may be a barrier for some participants. A few eligible participants have expressed a desire to participate but have chosen not to enroll due to difficulty attending in-person study visits. Furthermore, due to the immunocompromised condition of our participants, each of the three enrolled participants have had to cancel/reschedule in-person study visits because of illness, resulting in interrupted study participation. We anticipate that this is a barrier we may regularly encounter in this population. Enrolled participants and those choosing not to enroll have voiced that telehealth study visits would be appealing. Finally, our experience delivering the revised HTA intervention to the initial study participants has revealed the potential feasibility of delivering the intervention via telehealth (except for Study Visits 1 and 6 which include physical therapy tests/examination, necessitating in-person study visits). We feel that providing participants with a telehealth option may enhance study enrollment and retention without compromising the integrity of the intervention. This would potentially improve scalability/implementation of the intervention should it prove to be efficacious. As such, we will explore the feasibility of providing an option for participants to receive the revised HTA intervention via telehealth technology

3.0 Inclusion and Exclusion Criteria

3.1. Population and Sample and Screening. The target population is up to 20 adults ≥18 years of age, diagnosed with multiple myeloma currently receiving maintenance therapy. During in-person or telephone screening, study staff will describe the study, screen for eligibility, and answer questions. Potential participants will be provided with the consent form to review. If interested in participating, the research coordinator or other study staff will use a standardized screening form to review the following inclusion and exclusion criteria.

3.2. Eligibility Criteria

Inclusion Criteria: Potential participants will be adults

- ≥18 years of age,

- Diagnosed with multiple myeloma currently receiving maintenance therapy,
- Experiencing disability as indicated by an answer of "yes" to the question "Do health problems interfere with your ability to carry out your social or day to day activities?"[28]

Exclusion Criteria: Participants will be excluded if their medical record documents or they report:

- Bone pain that is either a) new onset or increased in the past month or b) uncontrolled i.e., in the patient's estimation the bone pain "greatly interferes with daily activities"
- History of fracture in the past 12 months without fixation, or
- Any injury or medical condition that would prohibit being able to safely perform exercise as indicated by the Physical Activity Readiness Questionnaire[29] (i.e., atrial fibrillation, chest pain or angina, uncontrolled high blood pressure or hypertension, loss of balance due to dizziness in the past 12 months, or loss of consciousness in the past 12 months).
- We will also exclude individuals with moderate or worse cognitive impairment as indicated by a score of 3 or less on the Callahan six item cognitive screening tool.[30]

Rationale: We are excluding people with new onset or recent increase in bone pain as this may suggest progression of disease or acute change in bone integrity. We are excluding people with uncontrolled pain as it could be indicative of bony disease process warranting further medical attention. Additionally, it would be best to ensure that pain is being optimally managed before starting any new exercise program. We are excluding people with history of fracture without fixation as exercise with unstable bony lesions increases the risk of injury. If people are excluded for these reasons, we will suggest that they discuss this with their physician.

3.3. We will not be enrolling the following vulnerable populations: adults unable to consent, individuals who are not yet adults [infants, children, teenagers], pregnant women, prisoners.

4.0 Study-Wide Number of Subjects

We aim to recruit up to 20 participants for this study.

5.0 Study-Wide Recruitment Methods

Participants will be recruited from the Massachusetts General Hospital (MGH) Cancer Center's Center for Multiple Myeloma in Boston, Massachusetts. This Center serves a diverse population and provides comprehensive treatment for all stages of multiple myeloma. Consecutive sampling of the outpatient service will be performed to minimize bias through the inclusion of all eligible patients.[31]

Prior to initiating the trial, we will meet with the referring clinicians to review the study and the recruitment and enrollment procedures. These procedures mirror those established and successfully utilized by the Cancer Outcomes and Research Education (CORE) research program at MGH Cancer Center.

We request a partial HIPAA waiver to allow us to review the medical records of patients with multiple myeloma coming for outpatient appointments to pre-screen them for potential eligibility.

The research coordinator will review the weekly appointment schedule of referring clinicians. The research coordinator will communicate with the clinicians (i.e., the physicians and advanced practice providers who care for the patients in the outpatient setting) via email, through the electronic health record, or verbally (based on clinician preference) to notify them that the patient may be eligible for the study and inquire about concerns regarding their participation. If the clinicians voice objections to the patient enrolling in the study, the research coordinator will document the reason and not approach those individuals. If the clinicians have no objections, the research coordinator will approach patients either in person, by telephone (using the included eligibility screening script), or will send a letter by mail or Patient Gateway (using the included template). In this communication, the research coordinator will inform the patient that their clinicians have indicated they might be eligible for this study and wanted to let them know about this study. Patients who were sent a letter will be asked to reply to the research coordinator either by phone or email if interested in learning more about the study. The letter includes text indicating that the research coordinator may also follow up with a phone call to see if they would like to learn more about the study.

In person or via telephone, the research coordinator will provide the potential participant an overview of the study using the study brochure. If the person is interested in learning more, the research coordinator will proceed with the standardized screening questions (included in the initial IRB application) to determine eligibility. If the person is eligible, the research coordinator will either 1) provide a study iPad with an electronic version of the study consent form (eConsent) via REDCap (if obtaining consent in-person), or 2) send a private link to the eConsent form via REDCap (if obtaining consent over the phone), so that the potential participant can view the consent form as the research coordinator reviews it with them. A paper-based consent will remain an option as well. The research coordinator will review the consent document which details the nature of all study procedures, encouraging the person to ask questions to clarify any confusion. If the person wants to enroll, the coordinator will obtain written informed consent from the patient and provide them with a dually signed digital copy of the consent form. This process will be managed via REDCap.

The research coordinator will create a database with the names and details of all individuals contacted by the study team so that participants who decline or who are not eligible are not re-contacted. Names will be removed from the database upon completion of study recruitment.

6.0 Study Timelines

Estimated study dates:

- Pilot Start Date: 9/1/22
- End of recruitment and enrollment: 8/31/24
- Primary Analyses Complete Date: 12/31/25

Participation timeline. Participants in this study will be asked to attend 6 weekly study visits (rescheduled if requested for participant convenience). Following the final study visit, participants will be contacted by telephone for a follow up assessment and interview. Therefore, participation in this study may last between 3 and 4 months.

7.0 Study Endpoints

7.1. Primary study endpoints are the *feasibility* of recruitment and data collection activities. *Feasibility* of enrolling and retaining participants with multiple myeloma into a pilot test of the refined HTA intervention delivered from MGH IHP and via telehealth will be measured by the following rates: # screened, # found eligible, # enrolled, # intervention visits completed, and # surveys completed.

7.2. Secondary study endpoint is the *acceptability* of the Health Through Activity program. *Acceptability* of the Health Through Activity program will be assessed utilizing semi-structured interviews to solicit feedback on the utility of HTA and recommendations for modifications to the intervention.

8.0 Procedures Involved

8.1. Design. This is a single arm feasibility study of the Health Through Activity rehabilitation intervention for people living with multiple myeloma. The goal is to determine if we can feasibly deliver the program from MGH IHP (i.e., out of the IMPACT Practice Center or clinical research laboratories) and via telehealth. This feasibility study will allow us to obtain feedback from stakeholders that we will use to refine the procedures and program in future testing.

8.2. Philosophy and Treatment Procedures.

Rehabilitation is an active, collaborative pursuit in which the therapist serves as a guide as the patient engages the mind, body and spirit in an activity. The Person-Environment-Occupation (PEO) Model[32] is one OT practice model. The PEO model encourages therapists to consider the transactions between the person, environment, and valued activities and to maximize the congruence between the three elements in order to reduce disability. The PEO model suggests three potentially complementary courses of action in response to disability. When someone is unable to perform a valued activity, the individual can: (1) change

something about his or her personal skills and capabilities (e.g., improve strength through exercise), (2) change the environment in which the activity is performed (e.g., improve lighting or reduce ambient noise), or (3) change the nature of the activity itself (eliminate steps of an activity or utilize adaptive equipment). The use of these complementary approaches is determined in collaboration with the participant, as each approach has a benefit/effort ratio for an individual.

After enrolling, participants will be asked to complete baseline study surveys (described below in section 8.3) electronically using a browser-based research electronic data capture (REDCap). Participants will also schedule their first in-person study visit.

Feedback from the first three participants in our study suggest that some participants may be interested in receiving the educational workbook (described below) prior to attending Study Visit 1. Therefore, after enrolling and completing baseline surveys, participants will be offered the option to be sent an electronic (PDF) version of the workbook.

At the first in-person study visit, participants will be met individually by a licensed occupational therapist, and a licensed physical therapist, at the MGH Institute of Health Professions in the Charlestown Navy Yard. The therapists will begin Study visit 1 by providing education (using an educational workbook) regarding the importance of daily activity and exercise in the maintenance of physical, cognitive, and emotional health. After discussing ways in which cancer treatment can affect daily activities, participants will discuss their current activity level and any pre-existing exercise routine and identify priorities for intervention (described as individual activity goals in Measures). The physical therapist will then repeat the safety screening (i.e., review contraindications to exercise as per exclusion criteria, screen for current presence and severity of pain, and discuss participant concerns regarding participation in exercise) and administer the Short Physical Performance Battery (SPPB), a 2-Minute Walk Test (2MWT) and the Self-Efficacy with Exercise (SEE) Scale Questionnaire. Based on the results of the SPPB, 2MWT, and SEE Scale. The physical therapist will prescribe a customized exercise program consisting of aerobic, resistance, and balance exercises. Exercises will be based on clinical practice guidelines that foster safe exercise engagement and delineate contraindications for exercise for individuals with multiple myeloma. Individualized exercise instructions will minimize risk of injury by emphasizing postural alignment, controlled movements, utilization of proper technique, fall risk reduction, and by considering participants' individual risk factors (e.g., lytic lesion location, peripheral neuropathy).[18, 33]

In each of study visits 2-6, the therapists will lead the participant through an activity planning process to identify activity and environmental adaptations to support engagement in 1) a specific daily activity of the participant's choice and, 2) the execution of the individualized exercise prescription. An "activity

prescription" (i.e., goal and action plan) is collaboratively generated to allow the participant to complete the activity and exercise program in the coming week. The action plan is practiced with the therapist present whenever feasible and the individualized exercises are first demonstrated by the therapist with return demonstration by the participant.

The HTA Treatment Manual describes the theoretical base of the intervention and the structure of the six sessions. The six sessions ideally occur once a week (rescheduled as needed for participant convenience) and last 50 to 75 minutes. Sessions will be individually delivered. Sessions 1 and 6 will occur in-person at MGH IHP either in the IMPACT Practice Center or in the clinical research laboratories. Participants will be given the option of completing study visits 2-5 in-person at MGH IHP or virtually via telehealth technology.

8.3. Measures

Sociodemographic and Clinical Characteristics to Describe the Sample

A standardized survey will be used to collect data on participants' age, race, ethnicity, employment status, level of education, marital status, household income, living situation, gender identity, and clinical comorbidities[34]. We will also collect baseline clinical, disease, and treatment information via chart review such as: Eastern Cooperative Oncology Group (ECOG) performance status, date of initial diagnosis of multiple myeloma, chemotherapy treatment regimen, and date started on maintenance therapy.

Disability

The Late-Life Function and Disability Instrument (LLFDI). The LLFDI is a self-report assessment developed for use in community-dwelling older adults.[35, 36] The function subscale (32 items) measures limitations in specific physical tasks of daily life and the disability subscale (16 items) measures inability to participate in major life tasks. When used with adults with a mean age of 80 years (SEM = 0.4 years), the scores were moderately correlated with a short physical performance battery, gait speed, and lower extremity function.[37] One week test-retest reliability of the function subscale had an intraclass correlation coefficient (ICC) of 0.96. One week test-retest of the disability subscale demonstrated an ICC of 0.68 for frequency scores and 0.82 for limitation scores.

Activity Level

Activity Card Sort modified (ACSm).[38] The Activity Card Sort [39] was developed to measure the instrumental, leisure, and social activity levels of older adults and modified for use with cancer survivors [40]. The ACSm provides a total score and four domain scores: instrumental activities (cooking meals,

paying bills, driving), low physical demand leisure (e.g., reading, doing puzzles, using the computer), high physical demand leisure (e.g., golfing, woodworking, gardening), and social activities (e.g., eating at a restaurant, going to parties, going to a place of worship). While originally developed as a manual card sort using labeled, pictorial depictions of the 80 activities, the tool demonstrates adequate reliability without the use of the picture cards [40, 41]. Activity Card Sort scores have been positively associated with quality of life [40, 42], health, and functioning [41].

Individual Activity Targets (IAT): During the first session, the occupational therapist elicits the participant's individual activity goals. The participant rates each activity with Likert scales for three characteristics: frequency of current performance (very often, often, once in a while, almost never, never), importance of the activity (1-10), and satisfaction with the activity (1-10). These ratings were used in the pilot study and provided a simple and pragmatic tool for assessing individualized outcomes

Quality of Life and Cancer-Related Fatigue

Functional Assessment of Chronic Illness Treatment – Fatigue (FACIT-F). The FACIT-F is a 41-item questionnaire consisting of the FACT-G (28 items), which measures health-related quality of life covering four domains of well-being (physical, social/family, emotional, functional), plus 13 fatigue-specific items. The FACIT-F has robust psychometric properties with excellent test-retest reliability (ICC=0.91),[43] validity, and the ability to detect change over time among older adults with cancer.[44-46] A cut off score of 34 is diagnostic of cancer-related fatigue, based on a 0-52 total available score for the fatigue subscale.[47]

Balance, Gait Speed, and Functional Strength

Short Physical Performance Battery.[48] The Short Physical Performance Battery (SPPB) is a multidimensional tool used to assess lower extremity function and is strongly associated with self-reported disability among older adults.[48] The SPPB assesses the ability to stand for ten seconds with the feet in three different positions (i.e., balance), time to walk 3 or 4 meters (i.e., gait speed), and the time it takes to rise from a chair five times (i.e., functional strength).[48] The SPPB is highly recommended as a measure of functional mobility by the EDGE Task Force of the Academy of Oncologic Physical Therapy of the American Physical Therapy Association due to its ease of administration and scoring, excellent test-retest reliability (ICC = 0.81-0.91) and sensitivity to detect change (MCID = 0.5 points).[49, 50] Established normative data and cut-off scores will assist in identifying participants who may be at increased risk of mobility disability.[50, 51] The SPPB produces a composite score, ranging 0-12, with higher scores indicating better function.

Aerobic Capacity

2-Minute Walk Test.[52] The 2-Minute Walk Test (2MWT) is a measure of aerobic capacity that assesses walking distance covered in two minutes. Among older adults, the 2MWT has excellent test-retest reliability (ICC=0.95) and established normative data (150.4 meters) and MDC (12.2 meters).[52] The 2MWT correlates highly with the 6-Minute Walk Test (r = 0.93) and the Timed Up and Go Test (r = - 0.87),[52] while there is evidence that the 2MWT is more tolerable than the 6-Minute Walk Test among older adults.[53]

Exercise Self-Efficacy

Self-Efficacy for Exercise (SEE) scale.[54] The SEE scale consists of nine potential exercise barriers and asks the individual to rate their confidence on a 0 (not confident) – 10 (very confident) scale that they could exercise for twenty minutes, three times per week, given each barrier (maximum score of 90 indicates highest exercise self-efficacy). Among older adults, the SEE scale has been shown to have excellent internal consistency (Cronbach'sα= 0.92) and SEE scale scores significantly predict exercise activity.[54] Although the SEE scale has not been validated in samples of survivors with CRF, a validated measure of ESE in this population does not currently exist, and we feel that the nine barriers appropriately represent scenarios that our participants may regularly encounter.

Acceptability of the intervention

Satisfaction survey. We will use a 7-item survey that we developed for previous studies to assess satisfaction with: the intervention, the therapists, the number and length of sessions, the helpfulness and importance of the intervention content. These items are rated on a 5-point Likert scale with verbal descriptions. The final question asks if the participant would recommend the intervention to another person who was trying to be active while living with multiple myeloma.

Semi-structured interview. Dr. Wechsler will train the project coordinator to conduct the semi-structured interview. During these interviews, the coordinator will solicit feedback on the utility of HTA and recommendations for modifications to the intervention. While the guide serves as a starting point for the conversation, it will evolve to be responsive to the accounts being obtained both from the interviews up to that point and the account emerging in the ongoing interview. We expect the interview to last approximately 20 minutes. With participant permission, the interview will be audiorecorded and transcribed verbatim. Once the transcript has been proofread, the audiorecording will be deleted.

We will also conduct one semi-structured interview with each interventionist who delivered the HTA program. The interventionists are valuable stakeholders to provide insight into feasibility and acceptability of this program and to help the study team determine issues related to scalability, implementation, and potential modifications required for future iterations. These semi-structured interviews will be conducted individually by a research coordinator who was not involved in delivery of the intervention to minimize risk of social desirability bias. An interview guide will serve as a starting point for the conversation but will evolve as described above to be responsive to the information being gathered.

Verbal consent will be obtained from each interventionist prior to the interview, including permission to audio-record the interview. Audio-recorded interviews will be transcribed verbatim and the audiorecording will be deleted once the transcript has been proofread.

Data Collection

The table below depicts the schedule and the study staff who will administer the instruments (PC = Project Coordinator, PT = physical therapist, and OT = Occupational therapist). The project coordinator will collect the data by telephone at baseline (Time 1), after completion of the intervention (Time 2) and six weeks after completion of the intervention (Time 3). The occupational and physical therapists will collect data in person during sessions 1 and 6.

Variable	Instrument	# of items	Administered by	Time 1	Session 1	Session 6	Time 2	Time 3
Demographics and Comorbidities	Survey	29	PC	X				
Function and Disability	LLFDI	32 16	PC	X			X	X
Activity level	ACSm IAT	80 variable	PC OT	X	 X	 X	X	X
Quality of Life and fatigue	FACIT-F	40	PC	X			X	X
Exercise Self-Efficacy	SEE Scale	9	PC	X			X	X
Acceptability	Survey and Interview	7 N/A	PC				X	
Balance, gait, and strength	SPPB	N/A	PT		X	X		
Aerobic Capacity	2MWT	N/A	PT		X	X		

9.0 Data Banking*

No data will be used for anything beyond the analyses described in this protocol.

10.0 Data Management* and Confidentiality

10.1. Analysis.

Aim 1: To evaluate the feasibility of enrolling and retaining participants with multiple myeloma into a pilot test of the refined HTA intervention, delivered from MGH Institute of Health Professions (i.e., within the IMPACT Practice Center or clinical research laboratories) and via telehealth technology.

Aim 2: To evaluate the feasibility of administering the outcome assessment battery that includes patient-reported outcomes of disability, activity level, quality of life, fatigue, and exercise self-efficacy, and performance-based outcomes of balance, gait speed, and strength.

For Aims 1 and 2, we will calculate the following feasibility statistics:

- Screening rate: Number patients screened/ Number patients identified as potentially eligible
- Eligibility rate: Number patients screening positive & eligible / Number screened
- Enrollment rate: Number participants enrolled / Number screened positive & eligible
- Intervention completion rate: There are two metrics for this a) Number participants completing 6 sessions of the HTA intervention/Number of participants enrolled; and b) Number of completed sessions per participant
- Assessment completion rate: Number participants completing each of the three study assessments/Number of participants enrolled

Thresholds for assessing feasibility:

- The screening rate is influenced both by staffing efforts to reach patients and patients' willingness to engage in screening in person or by telephone. Screening rate of at least 75% will indicate feasibility.
- The eligibility rate is influenced by how many people in the clinical population are experiencing disability. Based on our pilot study, we expect this rate to be at least 35%.
- The enrollment rate is one of the most important markers of feasibility as it reflects how many patients experiencing the targeted problem choose to enroll in the study. Enrollment rate of at least 75% will indicate feasibility.
- The intervention completion rate is influenced by the level of burden of the intervention, the health status of the participants, and the perceived benefit of the intervention. In our pilot study, we had a 90% intervention completion rate when using the participants as the unit of analysis (i.e., the first metric listed above). However, in the pilot study, the therapist came to the participant's home to deliver the intervention.

For this study, we will consider it feasible if 75% of participants complete all six sessions and if the mean number of sessions is greater than or equal to 4.

- The assessment completion rate is influenced by the burden (time and cognition) involved, the perceived meaningfulness of items, and the flexibility of mode of completion (e.g., by computer, by telephone per preference). In our pilot we had a 80-90% assessment completion rate depending on study arm. For this study, an assessment completion rate of 85% will indicate feasibility.

Aim 3: To assess the acceptability of the refined HTA intervention and assessment battery and utilize stakeholder feedback to identify further modifications to enhance acceptability.

For Aim 3, we will calculate descriptive statistics on the satisfaction survey data. We will also explore the interview data. All interviews will be audio-recorded and professionally transcribed. Immediately following the interview, the coordinator will listen to the recording and take detailed field notes that will describe the content and context of the interview, ending with a summary of stakeholder opinions and recommendations. Field notes will also provide details about the evolution of the interview guide and questions and themes that seem important as the interviews unfold. Transcripts, field notes, and interventionist field notes will be imported into NVivo for qualitative analysis.

Drs. Lyons and Wechsler will independently read the transcripts and field notes. Informed by the tradition of Miles and Huberman, we will code the data, then discuss and compare our codes to create a formal codebook with operational definitions. Coding is an iterative process that involves labeling segments of data. Some codes will reflect concepts introduced by participants, and many will reflect my own areas of interest such as difficulties with the intervention, or positive experiences within the intervention. We will then look within and across coded texts to extract converging themes and reach consensus on principal themes. We will use the themes to modify the manual in consultation with the full research team.

Thresholds for assessing acceptability: In terms of the satisfaction survey, any item that generates a mean score of < 4 will trigger consideration of making a modification to the treatment manual or study procedures. We will explore the interview data to help us understand what may be driving the lower satisfaction rating and brainstorm potential modifications that could be adopted in response. Independent of the survey scores, we will also use the interview data to identify potential changes. The decision to modify the protocol for subsequent studies will be informed by both the number of people expressing the opinion and the salience or potency of the concern e.g., a recommendation to add an education topic to the patient education manual or a

misunderstanding by even one participant could lead us to edit the study materials or procedure.

10.2. Sample Size Determination. Consistent with the intent of a feasibility study [55, 56], this exploratory analysis is primarily intended to develop the intervention and evaluate the feasibility and acceptability of the refined HTA program and **is not powered to test effectiveness hypotheses**. Based upon our previous studies in developing and testing behavioral interventions [57-59], we expect that 20 participants will be feasible to recruit within a 12-month period and will give us rich data to determine the feasibility and acceptability of the intervention.

10.3. Data Storage. All participant information and study source documents will remain confidential and be accessible only to study staff. Paper copies will be kept in locked file cabinets of locked offices belonging to Dr. Lyons. Electronic files will be stored on secure institutional computers using MGH Dropbox. All study data will be maintained in the MGH version of REDCap. REDCap is a free, secure, HIPAA-compliant web-based application hosted by the MGB Research Computing, Enterprise Research Infrastructure & Services (ERIS) group.

10.4. Data Security. Participant data will be collected using MGH REDCap. All participants will be assigned an id number and only one password-protected file will link the name with the study id. Participants' responses to survey questions will remain confidential. Study staff undergo training on study procedures as well as data management to ensure data security and patient confidentiality (e.g., good practice of locking computers before stepping away from desk, not using names where outside team members could hear).

11.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

The study will be monitored to ensure that it is conducted in conformance with the monitoring plan to assess continued compliance with the protocol and recognized Good Clinical Practices (GCP).

The PI (Dr. Lyons) will verify that study records are adequately maintained, that data are reported in a satisfactory manner with respect to timeliness, adequacy, and accuracy, and that the investigative team continues to have sufficient staff and facilities to conduct the study safely and effectively.

Data Safety and Monitoring Plan

The following procedures will be followed to ensure the safety of study participants and the validity and integrity of data.

- **Range of Safety Reporting**: Drs. Lyons and Wechsler will debrief (with the interventionists and/or observing students at the IMPACT Practice Center) after every session to explore and document the session content and any safety concerns. This includes reports of Adverse Events noted by the interventionists or the research coordinator.

- **Data Repository**: The research team has established procedures for data collection and management. Dr. Wechsler will oversee all aspects of data collection for the study, and the research coordinator will have the operational responsibility of data management. Specifically, the research team will develop a study-specific data management protocol and standard operating procedures for the creation and testing of all study forms, data collection, quality control, and data extraction. All data management activities will utilize REDCap.

- **Serious Adverse Events (SAEs)**: Given that this is a rehabilitation study in a population at risk for disease progression and death due to their medical condition (unrelated to study procedures), we do not expect any SAEs to be related to the study. Thus, SAEs will not be reported to the IRB, unless they are potentially related to the study procedures. Any SAEs related to the study procedures should be entered into the Electronic Data Capture (EDC) system within three (3) business days of the site becoming aware of the event.. If a SAE is reported, the MGH research team shall immediately conduct an evaluation of the SAE and will make a determination as to whether it meets the criteria for definition and for reporting to the IRB. Any reportable SAEs will be reported to the IRB as soon as possible, but in no event later than ten (10) working days after becoming aware of the event.

- **Non-Serious AE**: The research team will review monthly summary reports of the numbers and rates of AEs by treatment group and study site. These reports will include types of events, severity, and treatment phase.

- Relationship of SAE and AEs: the research team will assess the potential relationship of AEs or SAEs to the HTA intervention and classify the causality of the event according to the following definitions
    - **Definitely Related:** An AE that has a strong causal relationship. An AE that follows a strong temporal relationship, follows a known response pattern, and cannot reasonably be explained by known characteristics of the subject's clinical state or other therapies.
    - **Probably Related:** An AE that potentially has a causal relationship. The AE has a reasonable temporal relationship and alternative etiology is less likely compared to the potential relationship to the HTA program.

- **Possibly Related:** An AE that potentially has a causal relationship. The AE has a reasonable temporal relationship to the use of the investigational mobile apps but alternative etiology is equally likely compared to the potential relationship to the HTA program.
- **Not Related:** An AE without any apparent causal relationship. The AE is due to the underlying disease state or is due to concomitant medication or therapy not related to the HTA program.
- **Unknown Relationship:** If the AE cannot be determined to have a causal relationship, it will be classified as unknown.

- **Other Safety-Related Reports**: The research team will review weekly summary reports of treatment retention and reasons for dropout.

Monitoring of Data Quality by the Research Team:
The research team (at each participating institution) will review the following items on weekly basis to ensure data quality and completeness:

- Total enrollment compared with anticipated enrollment
- Number of ineligible patients registered
- Proportion of missing participant-reported outcomes
- Proportion of other missing data
- Number of participants lost to follow-up
- Number of participants completing the study

12.0 Withdrawal of Subjects

12.1. When and How to Withdraw Subjects. Throughout the study, participants will be aware that their participation in the study is voluntary. In general, participants will be focusing on engaging in activities of their choosing with the goal setting and action planning involving detailed ways to maximize the safety of activity engagement and minimize chance of injury, e.g., risk of falling during exercise. As such, there are very few times when it would be necessary to withdraw a participant from the study. That said, there are times when exercise is contraindicated such as in the presence of unstable bony metastases, increased pain (beyond normal expected response to exercise), altered neurologic presentation (e.g., diminished reflexes, bowel/bladder changes), or myelosuppression (e.g., thrombocytopenia/anemia below thresholds for safe exercise).[18, 33, 60, 61] Should those situations occur, participants will be advised to discontinue exercise until the situation resolves. Monitoring the number of times that exercise recommendations need to be suspended will inform us as to the feasibility and acceptability of the intervention for this population. As such, participants may be advised to discontinue exercise, but will not be withdrawn from the study unless they ask to be withdrawn.

Our team continues to attempt to contact participants for each session and study assessment unless and until they ask us to stop/express the desire to withdraw. Each study contact is an extension of informed consent where participants are told what is occurring, what happens next, and that their participation is voluntary. When we are unable to reach participants by telephone for at least 30 days we send a letter conveying our attempts to reach them and ask them to contact us to continue with study activities or withdraw, as they prefer.

12.2. Data Collection and Follow-up for Withdrawn Subjects. Participants who choose to withdraw from the intervention will be asked if they are amenable to continued participation in the data collection with the research coordinator or if they wish to completely withdraw from the study. The research coordinator will inform the participant that either choice is acceptable and completely up to them.

13.0 Risks to Subjects

There are three potential risks involved in this study: (1) the risk of hurting oneself when trying to exercise or increase activity level (e.g., falling while exercising or performing home management tasks); (2) the risk of distress while talking about disability and quality of life; and (3) risk of loss of confidentiality. The level of risk is generally low and strategies to minimize risks are incorporated into the HTA treatment manual and are addressed below.

Risk of injury: The goal of the HTA intervention is to reduce disability by fostering engagement in exercise and valued activity. The intervention teaches participants to change aspects about themselves, the task, or how it is performed to engage in valued activities. Regarding the risk of injury, the HTA program includes action planning to increase the safety and success of activity engagement to minimize the chances of this risk. Furthermore, we will follow clinical practice guidelines that foster safe exercise engagement and delineate contraindications for exercise. Individualized exercise instructions will minimize risk of injury by emphasizing postural alignment, controlled movements, utilization of proper technique, fall risk reduction, and by considering participants' individual risk factors (e.g., lytic lesion location, peripheral neuropathy).[18, 33] Patient educational materials will emphasize how to recognize abnormal responses to exercise and reasons to cease exercise and seek medical attention. Bidirectional communication with the participants' medical team will ensure identification of and consensus regarding any necessary precautions or contraindications to exercise. The therapists are knowledgeable in site-specific procedures to summon emergency medical help. If a participant sustains an injury while enrolled in the study, they will be assisted and instructed to seek medical attention commensurate to their injury including but not limited to presenting to the emergency room and/or following up with their oncologist for further evaluation. For virtual study visits, participants will be provided with a virtual handout depicting each exercise and the physical therapist will provide specific exercise instructions and explicit guidance to maintain safety

within the participant's environment (e.g., clearing space to avoid tripping on clutter, standing next to a countertop to maintain balance). As with in-person study visits, exercises will be based on the results of the participant's physical examination during the in-person Study Visit 1, reducing the chance of prescribing exercises that are beyond their capacity or that will jeopardize their safety. Regarding risk of injury during a virtual study visit, therapists will adhere to IMPACT Practice Center policies regarding recognizing and responding to health emergencies during telehealth care. Therapists will confirm and document the participant's location at each visit in case emergency services need to be summoned. If an injury occurs and it is determined that emergency care is required, the therapists will call 911 or, if others are present with the participant at their location, will advise the individual present to call 911. Therapists will help provide the 911 operator with necessary information and will stay on the virtual visit until emergency medical services arrive at the participant's location.

Risk of distress: This is somewhat of a self-correcting problem because the objective of HTA is to provide a structured process to help people find ways to increase activity engagement. The interventionists are trained to validate feelings of frustration and distress while re-directing the participant to actionable ways to make immediate progress. Likewise, the research coordinators who administer the outcome assessment are also trained in listening for signals of distress (e.g., long pauses, weeping) and are trained handle distress tactfully (e.g., do not indicate verbally or non-verbally that they are uncomfortable with participant distress) and to remind the participants that they can discontinue the surveys at any time. The outcome assessments of disability, activity engagement and quality of life do not contain many emotionally charged items and we find that most participants voice an appreciation for being asked to consider these aspects of their lives as opposed to being upset by them. If a participant becomes very upset, study staff will help them find a counselor and/or provide them with mental health crisis resources available through MGB and the Massachusetts Department of Mental Health.

Risk of privacy loss: Finally, to address a low-level risk of loss of privacy, participant confidentiality will be strictly protected. Hard copies of data will be maintained in locked files that can only be accessed by study personnel. Data forms will be identified using an identification (ID) number only. Access to the list cross-tabulating ID numbers with participant names will be kept in a password-protected data file following the RISO recommendations. All computer systems and programs will be password protected, and all electronic communications of study and other confidential information will be encrypted. Good computer security practice (shutting down computers after work hours, restricting physical access to machines, prohibition of password sharing) will be required of all study personnel. Virus protection software is installed on each study computer. The virus detection tools are used, maintained, audited and, if necessary, updated on all computers and pathways into the system. Redundant backups allow for quick restoration of data in the unlikely event that a hardware failure or security breach occurs.

14.0 Potential Benefits to Subjects

Given the evidence regarding the ability of exercise to improve strength and aerobic capacity and the mood-lifting benefits of engaging in valued activities, it is possible that participants will experience improved physical and emotional well-being as a result of their participation in the study. However, the purpose of the study is to determine if the intervention is feasible and acceptable and to prepare the intervention and the team for full-scale efficacy testing, should it be warranted, so there may not be a benefit to participants on an individual level.

15.0 Community-Based Participatory Research*

To date, this line of research is best described as "community-informed" as opposed to "community-engaged research." The intervention was initially developed by Dr. Lyons (PI) in response to feedback from hematologists and patients living with metastatic disease that more interventions are needed that help people stay active and engaged in life while living with incurable disease. By conducting semi-structured interviews, we are soliciting the input of participants to help us refine and improve the program. Prior to subsequent studies, we will seek out more input from the community to establish feasible procedures and assessments (e.g., through use of a community-engaged studio method).

16.0 Sharing of Results with Subjects*

Participants will be asked if they would like to receive a handout describing the results of the study. Individual data will not be provided to the participant nor to the referring physician.

17.0 Setting

Participants will be recruited from the MGH Cancer Center's Center for Multiple Myeloma in Boston, Massachusetts. In-person study visits will take place at the IMPACT Practice Center (IPC) or clinical research laboratories on MGH Institute of Health Professions (IHP) campus in the Charlestown Navy Yard in Boston, MA. The two buildings that house the IPC and clinical research laboratories are directly adjacent to each other and share a parking lot. The IPC is MGH IHP's pro-bono clinic. The IPC provides members of the community with interprofessional clinical services including occupational and physical therapy. **The IPC is also a vehicle for clinical education as MGH IHP students have opportunities to observe and participate in both clinical care and clinical research being conducted within the IPC. In this study, students enrolled in the occupational and physical therapy programs will be observing participants' study visits either in person or remotely by video observation rooms available within the IPC. Students will not be delivering study interventions.** The therapists will orient the students to the study and will debrief the students following each study visit.

Participants will have the option of completing study visits 2-5 virtually via telehealth technology. This option will allow participants to engage in the study from the comfort of their homes, potentially reducing a barrier to participation. This option may prove to be beneficial as therapists will be able to provide participants with explicit guidance regarding their home environment including modifications to increase safety or ability to engage in meaningful activities.

18.0 Resources Available

18.1. Dr. Wechsler is a doctorally-prepared physical therapist licensed to practice in Massachusetts. Dr. Lyons is a registered occupational therapist licensed to practice in Massachusetts. Drs. Lyons and Wechsler have dedicated FTE to complete the study activities.

Dr. Lyons has been principal investigator for supportive and rehabilitative studies for over 13 years and has written procedure manuals and trained and managed study coordinators for 19 years. Dr. Lyons is a member of the MGH Cancer Outcomes Research and Education Program (CORE). CORE has extensive experience conducting multi-site randomized clinical trials of supportive care interventions in oncology and has the necessary expertise to ensure the success of the proposed project. The CORE Program members, including co-investigator Dr. El-Jawari, have provided guidance according to clinical trial procedures that have been maximally effective here at MGH.

The study team will meet weekly to identify and problem-solve any study issues. All coordinators complete CITI training and study- specific training before initiating work on the study.

18.2 Patient population. At MGH, the clinicians treat approximately 100 patients with a new diagnosis of multiple myeloma per year and care for over 500 patients living with MM and therefore we are confident in our ability to recruit for this study.

18.3 Facilities. The IMPACT Practice Center (IPC) is managed by the IPC Manager, and follows MGB rules and guidelines for client-centered care and safety protocols. All licensed and supervising IHP faculty, staff, researchers, and students who see clients or perform research are required to complete MGB compliance and safety protocols, as well as a center orientation and attestation of the manual, which outlines the IPC standard operating procedures. The IPC is accessible with universal design. The IPC has private rooms to ensure study participant confidentiality, and also has first aid kits and AED devices should an emergency occur. The emergency policy is to first call MGB Security at 5400 before supporting any person who is experiencing an adverse event. The IPC has well-established protocols for providing telehealth using videoconferencing

technology including a detailed safety policy. Private rooms are available to maintain privacy during telehealth visits.

The clinical research laboratories at MGH IHP have private rooms to ensure participant confidentiality, and also has first aid kids and AED devices should an emergency occur. As the laboratories are housed within the same campus as the IPC, the same emergency policies exist as described above. Private rooms with videoconferencing technology are available within the clinical research laboratories. When conducting a virtual study visit from the clinical research laboratories, study staff will adhere to IPC protocols for providing telehealth including the detailed safety policy.

19.0 Prior Approvals

The study was reviewed and approved by the ENRICH committee of the MGH Institute of Health Professions. All study team members will undergo the safety training required for all faculty and students who work at the IMPACT Practice Center.

20.0 Recruitment Methods

20.1. Describe when, where, and how potential subjects will be recruited. Prior to initiating the trial, we will meet with the referring clinicians to review the study and the recruitment and enrollment procedures. These procedures mirror those established and successfully utilized by the Cancer Outcomes and Research Education (CORE) research program at MGH Cancer Center. Recruitment procedures are detailed in section 5.0.

20.2. Source of participants: Participants will be recruited from the Massachusetts General Hospital (MGH) Cancer Center's Center for Multiple Myeloma in Boston, Massachusetts. This Center serves a diverse population and provides comprehensive treatment for all stages of multiple myeloma. Consecutive sampling of the outpatient service will be performed to minimize bias through the inclusion of all eligible patients.[31]

20.3. Describe the methods that will be used to identify potential subjects. We request a partial HIPAA waiver to allow us to review the medical records of patients with multiple myeloma coming for outpatient appointments to pre-screen them for potential eligibility.

The research coordinator will review the weekly appointment schedule of referring clinicians. The research coordinator will communicate with the

clinicians (i.e., the physicians and advanced practice providers who care for the patient in the outpatient setting) via email, through the electronic health record, or verbally to notify them that the patient may be eligible for the study and inquire about concerns regarding their participation. If the clinicians voice objections to the patient enrolling in the study, the research coordinator will document the reason and not approach those individuals. If the clinicians have no objections, the research coordinator will approach patients either in clinic, by telephone, or will send a letter by mail or Patient Gateway.

In this communication, the coordinator will inform the patient that their clinicians have indicated they might be eligible and wanted to let them know about this study.

20.4. Materials that will be used to recruit subjects. We will use a study brochure to provide the initial overview of the study. This will be included in an initial contact with participants, whether that is in-person in the clinic, via mail, or via patient gateway. The brochure will be accompanied by a letter describing the study.

20.5. Amount and timing of any payments to subjects. Participants will receive a $25 gift card when they complete the baseline assessment, a $50 gift card after completing the 6-week follow-up survey and semi-structured interview, and a $25 gift card for completing the final survey. This leads to a total of $100 in gift cards if they complete the full study.

21.0 Local Number of Subjects

21.1. We expect to enroll at least 4 and up to 20 participants into this study.

21.2. We do not expect any screen failures in this study. Eligibility can be determined prior to enrollment by screening the medical record and asking self-report questions.

22.0 Provisions to Protect the Privacy Interests of Subjects

Participant confidentiality will be strictly protected. Hard copies of data will be maintained in locked files that can only be accessed by study personnel. Data forms will be identified using an identification (ID) number only. Access to the list cross-tabulating ID numbers with participant names will be kept in a password-protected data file following the RISO recommendations. All computer systems and programs will be password protected, and all electronic communications of study and other confidential information will be encrypted. Good computer security practice (shutting down computers after work hours, restricting physical access to machines, prohibition of password sharing) will be required of all study personnel. Virus protection software is installed on each study computer. The virus detection tools are used, maintained, audited and, if necessary, updated on all computers and pathways into the system. Redundant

backups allow for quick restoration of data in the unlikely event that a hardware failure or security breach occurs.

The study will be conducted in clinical research laboratories and the IMPACT Practice Center at MGH IHP and via virtual visits using confidential videoconferencing technology. The IMPACT Practice Center is a pro bono therapy clinic with the primary purpose of serving as a vehicle for clinical education. All students undergo standardized and rigorous training regarding protection of participant confidentiality, and fostering conditions of respect and therapeutic rapport. For example, the students are taught to ask preferences for how to refer to participants, to conduct evaluation and treatment in private rooms or to use screens if practicing sensitive exercises in the gym.

23.0 Compensation for Research-Related Injury

23.1. There is no compensation for research-related injury.

24.0 Economic Burden to Subjects

- Participants will have free parking when attending in-person study visits at MGH IHP. There is a free shuttle from MGH to the parking lot at MGH IHP that serves both the IMPACT Practice Center and clinical research laboratories. The cost of gas will be offset by the gift cards provided as a token of appreciation for study participation.

25.0 Consent Process

We will follow the procedures delineated in "SOP: Informed Consent Process (CON-100)." Eligible persons will be provided with an electronic informed consent (eConsent) form to review using a browser-based research electronic data capture (REDCap). A paper-based consent will remain an option as well. For eligible persons approached in-person, the eConsent form will be provided via iPad and explained, with ample time given to review and ask questions. For eligible persons contacted via letter and telephone, the eConsent form will be sent electronically. Our telephone consent procedures mirror our in-person procedures. We train our study staff to give the person ample opportunity to feel comfortable, express concerns, and ask any questions he or she might have.

Participants who decide to enroll will sign the eConsent form which is then co-signed by the consenting study staff. A PDF of the dually-signed consent is sent to the participant and an identical copy is retained by the study staff. No study activities are initiated until the signed consent form is obtained by study staff. At that time, the baseline assessment is scheduled.

Institutions will register eligible participants in the Clinical Trials Management System (CTMS) OnCore as required by DF/HCC SOP REGIST-101. When required by REGIST-101, registration must occur prior to the initiation of protocol-specific procedures or assessments.

Verbal consent will be obtained for all interventionists participating in semi-structured interviews including permission to audio-record the interview. This consent will be obtained using a verbal consent script included in the interventionist interview guide.

26.0 Process to Document Consent in Writing

Consent will be documented in writing as described above, following DF/HCC Policy CON-100: Informed Consent Process.

27.0 Drugs or Devices

Not applicable.

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