Randomized Case-Control Trial evaluating the impact of targeted physical activity on clinically debilitated dialysis patients.

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Study Location(s): UIC Disability Health and Social Policy Building (DHSP) located at 1640 W. Roosevelt Road & and the UIC Outpatient Clinic, located at 1855 W Taylor, Specialty Care Building (SCB), located at 1009 S Wood St, Chicago, IL 60612, and GhFitlab 1527 Waukegan Rd, Glenview, IL 60025.

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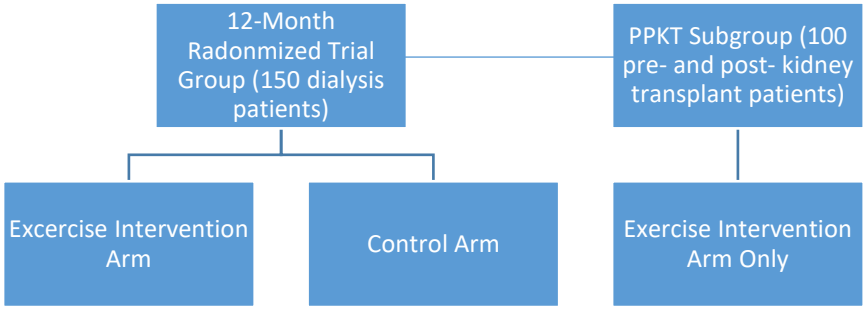
1.0 Project Summary/Abstract

This randomized case control trial will investigate the effects of an exercise intervention on clinically debilitated dialysis/kidney disease patients. The 12-Month Randomized Trial Group will include a total of 150 patients from UI Health (≥ 18 years of age), who are on dialysis, or have chronic kidney disease stage 4 (CKD 4 = GFR between 15 and 29), or have chronic kidney disease stage 5 (CKD 5 = GFR below 15) and are considered clinically debilitated by their direct healthcare professional will be enrolled. Randomization will be a 2:1 ratio (100 intervention, 50 control). The intervention arm will perform a 12-month exercise intervention which involves two days a week of personalized exercise rehabilitation. The control arm will receive no exercise intervention. Both arms of patients will be tested on various measures of health and function both at baseline (prior to intervention) at 6 months, and at 12 months (post intervention). This study will also investigate the effects of an exercise intervention on a subgroup of pre- and post- kidney transplant patients (PPKT Subgroup). This subgroup will include a total of 100 patients (≥ 18 years of age), who are on dialysis, or have CKD stage 4 or 5, and are considered clinically debilitated by their direct healthcare professional will be enrolled, or post- renal (kidney) transplant. This subgroup will perform 36 visits of exercise intervention which involves two days a week of personalized exercise rehabilitation. We will also utilize validated surveys and assessment tools to assess health issue management and depression severity. A study total of 250 patients are included in this protocol (Table A.). All testing and result interpretation will be performed by trained research personnel that are IRB approved.

Table A.



2.0 Background/Scientific Rationale

While it is well known exercise is beneficial for the general population, it is especially important for patients undergoing dialysis to help control many side effects of the treatment (1). Despite this being true, the physical activity levels in this population tend to be low (2). There are several reasons for the low physical activity levels in this

population, including both physical inability die to increased fatigue as well as negative perceptions of exercise and potential barriers (3). Patients undergoing dialysis have a high prevalence of muscle atrophy, lower functional capacity, as well as a high risk of cardiovascular complications (1). As chronic kidney disease progresses, skeletal muscle dysfunction progresses as well, leading to potential mobility limitations, loss of independence, and the vulnerability for disease complications (4). Reduced physical capacity, which partners with a reduced cardiovascular capacity, has been identified as an independent risk factor of mortality in this population (5). Furthermore, when a patient presents with high levels of frailty before kidney transplantation, about 1 in 6 patients, research has shown lower rates of preemptive transplantation, older recipient age, higher rates of delayed graft function, and longer length of stay hospital stays (6). In addition, after renal transplantation, obesity and metabolic syndrome are prominent risk factors for post-transplantation diabetes mellitus, chronic graft dysfunction, graft loss, and patient death in kidney transplant recipients (7).

Exercise has been shown to be beneficial in dialysis and kidney transplant patients by improving functional capacity, quality of life, and strength levels. (2,4,8). It is important to remember when prescribing exercise to dialysis patients, that they may have several limitations and have already experienced deficits as a result of the disease (8). Because of this it is important to have a personalized exercise program for this population that is safe and effective to reduce the side effects of chronic kidney disease and dialysis treatment.

3.0 Objectives/Aims

The present study aims to analyze the effectiveness of a specific physical activity training program (aka GH Method) in clinically debilitated dialysis/kidney disease//post kidney transplant patients.

Hypotheses:

12-Month Randomized Trial Group-

Exercise will positively affect body composition. With this hypothesis we will test whether muscle strength (dynamometer) and muscle mass (DEXA scan) changes after 12 months of an exercise intervention. Baseline measurement will be performed before the intervention and at the end of the study (12 months) with muscle mass measured by DEXA

1. We expect patients will see improvements in their physical abilities after 12 months in the exercise training sessions. This will be assessed by comparing baseline and 12 month 8 foot walk, timed sit to stand, and balance testing scores.
2. Patients enrolled in the exercise intervention will have an overall improved sense of well-being, increased independence, quality of life, and decreased depression. Patients will be asked about their overall general health, mental health and pain intensity using the PROMIS, SF 36, BDI, and ADL questionnaires.
3. Through the optional arm muscle biopsy, we expect to see how targeted exercise may change muscle development measuring expression of mature microRNAs using total RNA extraction.

PPKT Subgroup-

1. We expect pre- and post- kidney transplant patients will see improvements in their physical abilities and strength. This will be assessed monthly using the Pre-Transplant Frailty Assessment (Frailty Score).
2. We also expect patients to have a better management of their healthcare issues and a better understanding of current behavioral health, specifically their depression levels using the validated Patient Activation Measure (PAM) Survey and Patient Health Questionnaire-9 (PHQ-9).

4.0 Eligibility

The 12-Month Randomized Trial Group will enroll patients who are 18 years of age or older, are on dialysis, or have CKD stage 4 or 5 and are considered clinically debilitated by their healthcare professional.

Patients will be recruited from their pre-transplant clinic directly, using patient completion story video and screened by either the primary investigator, a co-investigator, or another member of the research staff and/or via recruitment flyer and phone screening script. Subjects can also be recruited by referral by Dr. Lorenzo Gallon at the Northwestern Medicine. He will provide potential participants with an information sheet that will provide a brief summary of the research study and who to contact, if interested. They will then be screened and consented by authorized research staff, if eligible to participate. Subjects will bring a copy of their medical records.

The PPKT Subgroup will include new patients that are not enrolled in the 12-Month Randomized Trial Group, who are pre- and post- kidney transplant (≥ 18 years of age), on dialysis, or have CKD stage 4 or 5, or post kidney transplant. Patients will be recruited from their pre- or post- transplant clinic, or when the patient is referred for evaluation. The patient will be screened by either the primary investigator, a co-investigator, or another member of the research staff. Interested patients will be consented to participate by authorized staff.

Inclusion Criteria

- Clinically debilitated patients, currently on dialysis, or have CKD 4 (GFR between 15 and 29), or have CKD 5 (GFR below 15), or post- kidney transplant (for PPKT Subgroup only) as stated by patient's health care professional.
- Adequate cognitive ability to complete the questionnaires, give consent for the study and follow the physical and diet instructions
- 18 years of age and older

6.0 Exclusion Criteria

- cardiac/pulmonary disease that contraindicate the physical training
- any contraindication to exercise testing per the American Heart Association
- unable to comply with the training program

6.0 Excluded or Vulnerable Populations

- No vulnerable population will be enrolled in this study. This includes pregnant women, minors, decisionally impaired, and prisoners.
- The 12-Month Randomized Trial Group and PPKT Subgroup will include Spanish speakers and will exclude other non-English speaking subjects as they would not be able to complete intensive survey requirement of the study as all surveys will be administered in the English or Spanish language.

5.0 Subject Enrollment

- Subjects will be screened by investigator or co-investigator using electronic medical record and enrolled if subject meets inclusion criteria.
- Subjects may be recruited at the University of Illinois at Chicago pre or post transplant clinic (for PPKT Subgroup only).
- For the 12-Month Randomized Trial, subjects may also be recruited using patient completion story videos seen on social media, gh website, or UIC donation website.
- For the 12-Month Randomized Trial, subjects may also be recruited via recruitment flyer and telephone screening phone script.
- For the 12-Month Randomized Trial, subjects can also be recruited by referral by Dr. Lorenzo Gallon at the Northwestern Medicine. He will provide potential participants with an information sheet that will provide a brief summary of the research study and who to contact, if interested.
- Only new patients, who are not enrolled in the 12-Month Randomized Trial, will be included in the PPKT Subgroup.
- All screening failures will be recorded in a password protected excel spreadsheet.

- Eligible patients will give voluntary informed consent to participate in the study.

6.0 Study Design and Procedures

The 12-Month Randomized Trial Group
This group will include 150 patients on dialysis, or have CKD 4 or 5, randomized to either the exercise intervention arm, which involves patients participating in a 12 month exercise rehabilitation intervention, or to the control arm, which is no intervention. Randomization will be a 2:1 ratio (100 intervention, 50 control). The intervention arm will consist of a total of 99 visits (3 study testing visits and 96 exercise visits). The intervention arm will receive a targeted exercise intervention for 12 months. Patients will come in for data collection visits at baseline (prior to starting the exercise program), 6 months, and 12 months. Each of those visits will take about 2-3 hours. All testing done in the 3 test visits will help assess the patient's cardiovascular and functional responses and/or changes to the exercise intervention as indicated in the Objectives/Aims Section. The next section contains a list of the tests that will be performed at each visit. After the initial baseline visit, patients will come twice weekly, for roughly 1 hour each session, for 12 months (96 visits total). The control arm will only complete the 3 data collection visits. All visits will occur at the UIC Disability Health and Social Policy Building (DHSP) located at 1640 W. Roosevelt Road in Suites 158, 190, and 195. Additionally, patients in the control arm of this study will be offered compensation for participating in this study and parking vouchers for study visits.

PPKT Subgroup
This group will include 100 pre- and post- kidney transplant patients. Participation is 36 visits of exercise rehabilitation intervention twice a week, for roughly 1 hour. At their initial (baseline), 8th, 12th, 16th, 24th, 32nd, and 36th visit additional time of roughly 30 minutes-1 hour will be added for patients to also complete survey/assessments. We will also need to review medical history, lab/surgical/pathology reports in the EMR. All visits will occur at the Specialty Care Building, Transplant Rehab Gym, Suite 1006, 1009 S. Wood St., Chicago, IL 60612, or UIC Disability Health and Social Policy Building (DHSP) located at 1640 W. Roosevelt Road in Suites 158, 190, and 195, GhFitlab, located at 1527 Waukegan Rd, Glenview, IL 60025.

<u>The 12-Month Randomized Trial Group:</u>

Both Intervention and Control Study Testing Visits:

Mental Health and Quality of Life Assessments

The following questionnaires will be performed at baseline, at 6 & 12 months:

- The PROMIS v.1.2 - Global Health short form will be administered to all patients. The PROMIS v.1.2 - Global Health short form will assess health in

general (i.e. overall health). The PROMIS Global Health short form is a 10-item instrument representing multiple domains (physical function, fatigue, pain, emotional distress, social health) as well as perceptions of general health that cut across domains. Global items allow respondents to weigh together different aspects of health to arrive at a “bottom-line” indicator of their health. Similar global health items have been found predictive of future health care utilization and mortality.

- PROMIS 29 Profile v2.0 will be administered to all patients at the time of enrollment, at 6 months, and at 12 months. The PROMIS 29 Prolife v2.0 is a short form containing four items from seven PROMIS domains (Depression, Anxiety, Physical Function, Pain Interference, Fatigue, Sleep Disturbance, and Ability to Participate in Social Roles and Activities) along with a single item on Pain Intensity.
- SF 36 will be administered to all patients at the time of enrollment, at 6 months, and at 12 months. The SF-36 has eight scaled scores; the scores are weighted sums of the questions in each section. Scores range from 0 - 100 Lower scores = more disability, higher scores = less disability Sections: • Vitality • Physical functioning • Bodily pain • General health perceptions • Physical role functioning • Emotional role functioning • Social role functioning • Mental health
- The Beck’s Depression Inventory (BDI) will be administered to all patients at the time of enrollment, at 6 months, and at 12 months. BDI is a validated to measure depression in a general medical population and in chronic disease patients.
- The Katz Index of Independence in Activities of Daily Living (ADL) will be administered to all patients at the time of enrollment, at 6 months, and at 12 months. The Katz ADL is the most appropriate instrument to assess functional status as a measurement of the patient’s ability to perform activities of daily living independently. Clinicians typically use the tool to detect problems in performing activities of daily living and to plan care accordingly. The Index ranks adequacy of performance in the six functions of bathing, dressing, toileting, transferring, continence, and feeding. Clients are scored yes/no for independence in each of the six functions. A score of 6 indicates full function, 4 indicates moderate impairment, and 2 or less indicates severe functional impairment.
- The patients will be asked to rate their average pain level from dialysis related cramping scores on a scale of 0-10 (0 no pain, 10 max pain). They will also be asked how often they have these cramps, the location of them, and regular duration.
- Patients will be asked to disclose the number of hospital visits they have had in the last 6 months. This will be collected at baseline, 6 months and 12 months.

Body composition, strength and functional capacity

All of the following assessments will be performed at baseline, 6 months, and 12 months

- BMI will be calculated. The patients will be DEXA scanned to provide the data about lean/fat tissue in specific body regions. Waist circumference as well as blood pressure will be measured for general health markers All of the following assessments will be performed at baseline, 63 months, and 12 6 months
- Waist Circumference: Waist circumference will be measured for general health markers. Measurements will be taken at the narrowest part of the torso (above the umbilicus and below xiphoid process) in the standing position using a tape measure.
- Blood Pressure: Blood pressure will be measured in the seated position in a dimly lit room after resting for five minutes. Resting blood pressure will be measured in the brachial artery using a digital sphygmomanometer according to the guidelines of the American Heart Association. Blood pressure will be measured twice, one minute apart, and the average of the two values will use as resting blood pressure.
- DEXA Scan: We will determine percent body fat via a whole body scan by dual energy x-ray absorptiometry (GE, IDXA, Madison, Wi), which will be operated and calibrated using the manufacturer's stated guidelines. The duration of the scan will be less than 10 min and the subject will be exposed to a radiation dose of □0.3 mrem based upon the manufacturer's specifications and calculations from Standford Dosiometry, LLC RADAR Medical Procedure Radiation Dose Calculator. This amount of research protocol radiation exposure is minimal given the estimated effective equivalent dose is below the 100 mrem per year, a limit set by the Nuclear Regulatory Commission for "general public" exposure.
- Grip strength in kilogram (kg), average of three trials. This will be measured in each subjects' dominant hand using a hand dynamometer. Contractions will be performed in the seated position with the dominant arm at a 90 degree angle.
- Gait speed in meters/second. Subjects will be asked to walk eight feet as quickly as they could. Patients unable to walk at all (i.e., wheelchair bound) were assigned a gait speed of 0.01 meters/second.
- Timed repeated chair stands. Starting from a seated position, subjects will be asked to stand up and sit down without using their arms for assistance for a total of five times without assistance. Patients unable to perform this test at all were assigned a chair stands score of 32 seconds, the 99%ile value among

patients who were able to perform this test. Patients will also be asked to continue performing sit to stands until they feel they are unable to do anymore. This number will be collected as their maximum sit to stand score.

- Short Physical Performance Battery. It comprises a summary of three separate measures (maximum of 4 points for each component): gait speed, balance, and timed repeated chair stands. This test requires the assessment of walking speed (time to walk 3 meters), a balance test (standing in 3 different positions for 10 seconds each-tandem, semi tandem, and side by side), and the time it takes to sit and stand 5 times in a chair (see above). Scoring is based on a scale of 0-12, lower numbers representing worse performance. Patients who cannot complete the test will receive a predetermined score or "0" that represents "not able". The Short Physical Performance Battery takes approximately 2–3 minutes to complete in the outpatient clinic setting. 1RM leg press strength testing: Patients will perform a warm-up set of 10 repetitions of a leg press at estimated 50% of 1RM, followed by a set of 5 repetitions at estimated 70% of 1RM, and a set of 3 repetitions at estimated 80% of 1RM. Subjects then incrementally increased the weight after each successful 1RM attempt, defined as controlling the movement through the entire concentric and eccentric motions. 1RM was determined to be the most weight lifted one time after three consecutive failures of an increased weight (Protocol approved in study #2017-1016)

- Patients in the exercise arm will be assessed for their maximum weight lifted during a training session at baseline, 6 months, and 12 months. This data is a cumulated number of all weight lifted during all exercises and repetitions performed in a single training session (60 minutes).
- Brachial FMD will be used to assess macrovascular endothelial function. This method involves the measurement of vascular reactivity of the brachial artery using non-invasive ultrasound technique. While the subject rests in the supine position, an 11 MHz probe will be used to determine brachial artery diameter above the antecubital fossa in the non-dominant arm. In addition, continuous wave Doppler will be used to determine brachial artery blood flow velocity. Brachial artery diameter and blood flow velocity will be measured under the following conditions: 1) At rest, 2) During reactive hyperemia produced by a five minute interruption of flow with a blood pressure cuff inflated >50mmHg above systolic pressure, 3) For three minutes after reactive hyperemia (30-second intervals for the first minute and 1-minute intervals thereafter).

- Assessment of vascular stiffness using peripheral tonometery and ultrasound imaging

- Upon entering the lab, participants will be required to rest quietly in the supine position in a dimly lit room for 10 minutes. Arterial size and stiffness will then be measured via ultrasonography using several different methodologies: 1) Pulse wave velocity: this test allows for a non-invasive way to measure arterial stiffness. Three disposable electrodes will be placed on the subject's torso. A pen-shaped transducer is placed over the carotid artery (side of the neck), over the femoral artery (top of the leg), over the anterior tibialis artery (inner ankle), and over the radial artery (wrist). The distance between each of these sites will be measured using a tape-measure. 2) Arterial Distensibility and function by ultrasound imaging: this test allows for non-invasive imaging of the carotid, brachial, and femoral arteries. Central blood pressure will be determined using the aforementioned pulse-wave analysis method (SphygmoCor SCOR, PWV Medical, Sydney, Australia). In brief, the pressure waveforms that are obtained at the radial artery site are subjected to a generalized transfer function to derive the corresponding central arterial waveforms

- Cardio-ankle vascular index (CAVI) and Ankle Brachial Index (ABI)
  CAVI and ABI will be assessed by pulse wave velocity analysis at the brachial and ankle arteries (VaSera VS 1500AU, Fukuda Denshi, Japan). The CAVI measurement requires the placement of ECG electrodes on both wrists, and a microphone for phonocardiography on the sternum in the second intercostal space, and 4 blood pressure cuffs. CAVI between the heart and ankle arteries is assessed using measurements oftime between heart sound II and plethysmograms taken at the brachial
  and ankle arteries. This will be done to measure the stiffness of arteries and is independent of blood pressure.
- Wrist Artery Stiffness
  A very sensitive pen-shaped microphone will be placed on the subject’s wrist (radial artery). This microphone measures how stiff the radial artery is.

- Central Artery Stiffness
  The same pen-shaped microphone used before will be placed on the subject’s neck and then the artery at the top of their thigh. We will use these measurements to measure how stiff their central arterial system (the arteries in the midsection of the body) is.

- Carotid Artery Stiffness and Compliance

We will look at the artery in the subject's neck using an ultrasound machine. This machine is similar to what doctors use to look at babies within the womb. We will place a small amount of gel on their neck to help us get a clearer picture. This gel is hypoallergenic and washes off very easily. We will place the probe on their skin, over the artery on the inside of their right neck. This probe will allow us to look at the carotid artery and see how it moves with each heart beat.

- Cardiac Ultrasound
  We will measure the subject's heart function with ultrasonography using ultrasound gel and a probe that will be placed on the chest area. It is the same probe used to visualize babies in the womb. We will measure how quickly the subject's heart contracts and relaxes.

- Near Infrared Spectrometry (NIRS)
  We will measure the presence of oxygen in the muscle by using a simple and noninvasive method called near infrared spectrometry (NIRS). NIRS non-invasively measures muscle oxygenation by measuring oxygenated, deoxygenated and total hemoglobin. It can monitor changes in muscle oxygenation and blood flow during submaximal and maximal exercise by using sensors placed on the forearm, with the signal corrected for skinfold thickness. During exercise, the extent to which skeletal muscles deoxygenate varies according to the type of muscle, type of exercise and blood flow response.

- Optional muscle biopsies
  We will offer an optional muscle biopsy to subject's in both intervention and control arms, at baseline and at 12 month post-intervention. This biopsy will be performed to measure expression of mature microRNAs using total RNA extraction, which will help evaluate how targeted exercise may change muscle development. The muscle biopsy will be performed by a surgeon approved to be on this study as research personnel. All surgeons are experienced surgeons with prior experience performing muscle biopsies. The muscle biopsy will be performed at the University of Illinois at Chicago Outpatient Clinic, with an address at 1855 W Taylor St, Chicago, IL 60612.

The patient will be asked to remove the clothes around the site of the biopsy. They will need to lie as still as possible. The skin will be disinfected and a small 2 cm incision made with a sterile #11 surgical blade will be made over the existing scar located on the bicep or forearm of the patient. The scar tissue is in reference to when the patient was on hemodialysis or had a forearm graft (prior to transplantation). The area will be

infiltrated with approximately 4 mL of lidocaine (2%) with special attention to ensure that no lidocaine is injected in the muscle. Thus, injection of lidocaine is done superficially and obliquely. After the 2 cm incision and the muscle tissue is visualized, a cut will be made. Muscle fibers are carefully dissected in their longitudinal axis away from the tendon insertion, to obtain a sample of 300 mg. This is about the size of 4-5 grains of rice. Both ends are immediately clipped and hemostasis is controlled. The bundle is fixed on a cork support at its apparent resting length. This will be completed twice for a sample total of 600 mg. After the samples have been retrieved, pressure will be applied to the incision site and then it will be cleaned. After cleaning the incision, the site will be stitched with sutures, and then bandaged with nonstick gauze and a protective dressing. This procedure will take approximately 30 minutes to complete.

Blood Markers

- All patients will be monitored for fasting plasma Glucose, serum creatinine and eGFR during the study per standard of care for dialysis patients. These records will be obtained from patient's medical records. This assessment will be performed at baseline, 6 months, and 12 months

Counseling

- All patients will be counseled regarding weight loss per standard of care which consists of a dialysis nutrition evaluation and education.

Employment Status

- Employment status will be assessed through patient response at baseline, 6 months and 12 months.

Other measurements: Height and weight will be measured and body mass index will be calculated as weight (kg) divided by height (m) squared. Employment status will be confirmed. Age and race will be asked for additional descriptive.

Intervention Arms Only: Exercise Training Visits (Including the 12-Month Randomized Trial and PPKT Subgroup):

Exercise Training Visits (GH Method session):

- Patients will attend 2 trainings sessions a week for 12 months (96 visits total) or 36 visits for the PPKT Group (about 4.5 months).The first four sessions in the 12-Month Randomized Trial (over 2 weeks) for any patient will be 75 minutes. Following the first 4 sessions, ongoing patients will be slotted into recurring 60 minute time slots for the remaining weeks for both the 12-Month Randomized Trial and the PPKT Subgroup. Additional time will be added for PPKT Subgroup surveys/assessment days. All of these visits will occur in the UIC Disability Health and Social Policy Building (DHSP) located at 1640 W. Roosevelt Road in Suites 158, 190, and 195 and/or Specialty Care Building,

Transplant Rehab Gym, 1006, 1009 S. Wood St., Chicago, IL 60612 and/or GhFitlab, located at 1527 Waukegan Rd, Glenview, IL 60025.

- For the 12-Month Randomized Trial and the PPKT Subgroup, at least twice per week, GH personnel will attempt to follow-up with patients via text message, email or a phone call to evaluate their physical recuperation and overall health and energy or to track their performance with a behavior change goal.
- The PPKT Subgroup will include 36 visits of exercise rehabilitation intervention twice a week, for roughly 1 hour. At the patient's initial (baseline), 8th, 12th, 16th, 24th, 32nd, and 36th visit additional time of roughly 30 minutes-1 hour will be added for patients to also complete survey/assessments, called the PAM Survey, PHQ-9 screening and the Frailty Score. We will also need to review medical history, lab/surgical/pathology reports in the EMR. The PAM Survey is a 13-item survey that assesses an individual's knowledge, skills and confidence integral to managing one's own health and healthcare. The PHQ-9 screening is a multipurpose instrument for screening, diagnosing, monitoring and measuring the severity of depression. The Frailty Score measures increased vulnerability to adverse health outcomes. All visits will occur at the Specialty Care Building, Transplant Rehab Gym, Suite 1006, 1009 S. Wood St., Chicago, IL 60612, and/or UIC Disability Health and Social Policy Building (DHSP) located at 1640 W. Roosevelt Road in Suites 158, 190, and 195, and/or GhFitlab, located at 1527 Waukegan Rd, Glenview, IL 60025.

Video recording (optional)

- Video recordings will be an option on the consent form for patients that are randomized into the GH exercise arm. The option to be video recorded by the GH team at the beginning and end of the patient's 12 months of training. The recordings will be used to compare the progress of the patient from the beginning and end of GH training. The video recording will be accessed only by research staff. Patients will be ensured that the video recording is optional.

Consent Addendum (optional)

- In a separate consent addendum, enrolled patients will be asked if they would like provide their written permission to allow the GH team, and research staff to take photographs, or produce videotapes, or other types of media productions that capture their name, voice and/or image, and used for, but is not limited to:
    - Medical and/or educational training
    - Study Recruitment
    - Presentations and/or Publications
    - Fundraising

- Websites and social media

Patients will be ensured that the items included in the consent addendum are optional and will not affect their current study participation. Patients will be approached to sign the consent addendum at a study or exercise visit.

Patients will be asked to complete a regimen based on the following:

Summary of GH Study Visits:

- Patients may be asked to repeat previous weeks and/or skip a particular week depending on their energy, progress, and overall health.
- Depending on a patient's individual physical need, mobility, the program may be slightly modified (number of repetitions, number of exercises, etc...) to be safe and appropriate for that individual.
- Each week comprises two different exercise days, each incorporating approximately 5-10 minute light warm-up plus stretching and then the exercises.
- Unless specified as a cardio or endurance week, all weeks consist of basic strength training/resistance workouts.
- The attached exercise list (Table B) includes all possible strength training exercises, and clients complete the appropriate exercises for that week during their two, one-hour appointments each week. Depending on a patients particular physical health (e.g. shoulder problems) certain exercises may be eliminated or modified in terms of the safe range of motion and intensity.
- These sessions can be directly supervised by the GH instructors or performed by trained personnel implementing written instructions given by the instructors.

3 Year Long-Term Follow Up (12 Month Randomized Trial Intervention and Control Arms):

Patients in both the control arm and the intervention arm will be followed for 3 years as a way to observe maintenance of exercise (if in exercise arm), employment status, and quality of life status. Patients will be called annually and asked a series of questions. The annual follow up phone script is attached.

Table B. – Complete 12 Month Training (PPKT Subgroup will stop at 18 weeks).

Week	Overview	Intensity/Weight	Breaks
Week 1	**1st Set: 30 Seconds with Only Safety Instruction** **2nd Set: 90 Seconds with More Focus on Form**	**Light**	**2 or more minutes**
Week 2	**1st Set: Holding at top and bottom of range (20 seconds each hold)** **2nd Set: 20 rep's and possible to add plus 5 depending on energy**	**Light**	**2 or more minutes**

Week 3	**1st Set: Warm-Up of 15 repetitions** **2nd Set: Resistance focused 60 seconds, possible plus 5**	**Light/Moderate**	**2 or more minutes**
Week 4	**3 Sets for every exercise. Each set is 12 repetitions with some holding for five seconds.**	**Moderate**	**30 seconds between sets. 2 minutes between exercises.**
Week 5	**1 Warm Up Set of 15 repetitions.** **1 Heavier Set of 11 Repetitions.**	**Moderate/Heavy**	**3 minute breaks**
Week 6	**Cardio Exercises (e.g. run in place). 5 different exercises are done as one round and two rounds total.**	**Light/Moderate**	**2 minutes between exercises and 4 minutes between rounds.**
Week 7	**1st Set: Warm up of 12 repetitions.** **2nd Set: 6 repetitions**	**Moderate/Heavy**	**3 minutes**
Week 8	**1 Set: 90 seconds**	**Light**	**3 minutes**
Week 9	**1 Warm Up Set of 15 Repetitions.** **3 Sets of 6-8 repetitions (depending on exercise)**	**Moderate/Heavy**	**3 minutes**
Week 10	**3 Sets of Declining Heaviness with 6 reps, 8 reps, and 10 reps**	**Moderate**	**3 minutes**
Week 11	**2 Sets Per Exercise without break between: 18 reps and 16 reps**	**Moderate/Light**	**2 minutes**
Week 12	**1 Set of 25 - 30 repetitions**	**Moderate/Light**	**2 minutes**
Week 13	**Cardio Exercises (e.g. run in place). 7 different exercises are done as one round and three rounds total.**	**Moderate**	**2 - 3minutes**
Week 14	**1 Set of 12 - 16 Repetitions**	**Moderate**	**2 minutes**
Week 15	**3 Sets of declining heaviness with 8, 10 and 12 repetitions**	**Moderate**	**3 minutes**
Week 16	**3 Exercises in Each Set and 7 sets**	**Moderate**	**3 minutes**

Week 17	**1 Set 90 Seconds**	**Moderate/Light**	**3 minutes**
Week 18	**Cardio Exercises (e.g. run in place). 3 different exercises per set. 3 Sets equal one Round. Three Rounds total**	**Light**	**2 minutes**
Week 19	**1 Warm-Up Set of 12 repetitions** **1 Set of 7 Repetitions**	**Moderate/Heavy**	**3 Minutes**
Week 20	**1 Set of 25 - 30 Repetitions**	**Moderate**	**3 Minutes**
Week 21	**1st Set: Warm up of 12 repetitions.** **2nd Set: 6 repetitions**	**Moderate/Heavy**	**3 minutes**
Week 22	**1 Set: 35 - 40 repetitions**	**Moderate/Light**	**3 minutes**
Week 23	**1 Warm Up Set: 15 repetitions** **1 Heavier Set 8 - 10 repetitions**	**Moderate/Heavy**	**3 minutes**
Week 24	**1 Set of 90 Seconds focused on resistance**	**Moderate**	**3 minutes**
Week 25	**Cardio Exercises. 10 exercises in a set. 2 Sets.**	**Moderate**	**3 minutes**
Week 26	**3 Exercises in 1 Set. 9 Sets.**	**Moderate**	**3 minutes**
Week 27	**1 Warm Up Set: 8 – 12 reps.** **1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 28	**1 Warm Up Set 8 reps** **1 Heavy Set 8 reps. Medium speed.**	**Heavy**	**3 minutes**
Week 29	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 30	**1 set 90 seconds. Medium speed.**	**Lighter**	**2 minutes**

Week 31	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 32	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 33	**1 set 90 seconds. Medium speed.**	**Lighter**	**2 minutes**
Week 34	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 35	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 36	**1 set 90 seconds. Medium speed.**	**Lighter**	**2 minutes**
Week 37	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 38	**2 Sets Per Exercise without break between: 18 reps and 16 reps**	**Moderate/Light**	**2 minutes**
Week 39	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 40	**1 set 90 seconds focused on resistance. Medium speed.**	**Lighter**	**2 minutes**
Week 41	**Cardio Exercises. 10 exercises in a set. 2 Sets.**	**Moderate**	**3 minutes**
Week 42	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 43	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**

Week 44	**1 set 90 seconds focused on resistance. Medium speed.**	**Lighter**	**2 minutes**
Week 45	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 46	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 47	**1 set 90 seconds focused on resistance. Medium speed.**	**Lighter**	**2 minutes**
Week 48	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 49	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 50	**1 set 90 seconds focused on resistance. Medium speed.**	**Lighter**	**2 minutes**
Week 51	**1 Warm Up Set 8 reps 1 Heavy Set 8 reps**	**Heavy**	**3 minutes**
Week 52	**Cardio Exercises. 10 exercises in a set. 2 Sets.**	**Moderate**	**3 minutes**

Table C.
GH Method: List of Strength/Resistance Exercises

MEN	**WOMEN**
Exercise	**Exercise**
Chest: Smith Bench Press/Incline	**Glutes: Abductor**
Glutes: Abductor	**Biceps: Cable Easy Curl / Free Bar**
Biceps: Cable Easy Curl/Free Bar	**Quads: Leg Extension**
Quads: Leg Extension	**Chest: Smith Press**
Calves: Calf Machine	**Abs: Decline**
Biceps: Preacher	**Quads: Leg Press**
Quads: Leg Press	**Back: Pull Down Behind**
Quads: Leg Extension	**Hamstring: Machine**
Abs: Decline	**Shoulders: Dumbbell Press / Smith Press**

Back: Pull Down Behind	**Triceps: Push Down / Kick Back / Rope Pull down**
Hamstring: Curl Machine	**Back: Low Roll**
Shoulders: Dumbbell Press / Smith Press	**Abs: Sit-Ups**
Back: Low Roll	**Shoulders: Side Raise with Dumbbells**
Hamstring: Good Morning with Dumbbell/ 1 Leg Hamstring Curl	**Triceps: Close Grip**
Shoulders: Side Rise with Dumbbells	**Hamstring: Good Morning with Dumbbells/1 Leg Hamstring**
Triceps: Push Down / Kick Back	**Triceps: Push Down / Kick Back**
Abs: Sit Ups	**Abs: Sit Ups**
Triceps: Close Grip	**Triceps: Close Grip**

Study Visit Flow Chart 12-Month Randomized Trial:

Throughout: Exercise rehabilitation sessions (details listed above); 2 days/week; 1 hour/session
*PPKT Subgroup does not have separate study visits. All data collected will be included in exercise visits.

7.0 Use of Patient Completion Story Videos

The inclusion of patient completion story videos and website screenshots for ghfitlab.com and UIC transplant donation page (will help support the study and may increase enrollment) will be used for, but are not limited to: recruitment, medical and/or education training, websites and social media, etc. These videos will include identifiable patient information. All patients that will be included will signed the consent addendum for the use and disclosure of protected health information for photo, video, interview, and media. IRB approval will be obtained prior to use of videos. Videos will be uploaded to Vimeo for sharing. We would like the option to share these videos on social media platforms, such as, Facebook, Instagram, LinkedIn, and also share them on the ghfitlab website and the UIC donation website. We have created a UIC website script.

8.0 Expected Risks/Benefits

The main risk of this research is loss of confidentiality of medical information for both the 12-Month Randomized Trial and the PPKT Subgroup. Consent will be obtained for all patients. Master patient code list will be kept in a separate file accessible only by the primary investigator. A member of the UI healthcare team will be available to answer any questions or discuss any concerns that patients may have. The patient may also experience mild anxiety or discomfort in providing information via questionnaires about their health and well-being. The patient may also have a potential to feel anxiety when being video recorded (if applicable).

Risks associated with the consent addendum for both the 12-Month Randomized Trial and the PPKT Subgroup:
The main risk is loss of confidentiality. Patients may also have a potential to feel anxiety when we take photographs, videotapes, or other types of media productions that capture their name, voice and/or image.

Risk associated with grip strength (Dynomometer) (12-Month Randomized Trial and the PPKT Subgroup) and 1RM tests include (12-Month Randomized Trial only):
Shortness of breath, fatigue, strains, sprains, and muscle soreness.

Risks associated with physical activity including 3 meter walk, sit to stand, and short performance battery tests includes (12-Month Randomized Trial only):
Fatigue, being out of breath, muscle soreness, heart rhythm irregularities, dizziness, loss of consciousness and even death. However, serious adverse events (side effects) are very rare and by careful screening and monitoring during the test, the risks of such events are minimized. Further risks include slips and trips possibly resulting in ankle sprains and falls. These risks will be minimized by having a research assistant within arm's reach for stability. All personnel assisting in testing are trained in CPR and emergency lab procedure.

Risks associated with radiation exposure from the DEXA scan (12-Month Randomized Trial only):
The patient will be exposed to a radiation dose of less than or equal to 0.3 mrem based upon manufacturer's specifications and pre-determined calculations. This amount of radiation exposure is minimal given the estimated effective equivalent dose is below 100 mrem per year, a limit set by the Nuclear Regulatory Commission for "general public" exposure.

Risks associated with vascular function, vascular stiffness, NIRS, and cardiac ultrasound measures (12-Month Randomized Trial only):

There are no known risks associated with the ultrasound tests used to measure artery stiffness and heart function. Because we will need to place 3 electrodes on the skin to measure heart rate during these procedures, we may need to shave the area on males where these will be placed which may cause some discomfort and/or redness. Some adhesive may remain once electrodes are removed which may cause redness. This should wear off within 1-8 hours. For the assessment of endothelial function (FMD) & NIRS, the act of inflating a blood pressure cuff around the arm for five minutes before deflation may cause some discomfort, temporary numbness, or tingling. These discomforts, however generally last for a minimal amount of time post deflation.

Risks associated with the muscle biopsy (12-Month Randomized Trial only)::
Bleeding, bruising, and infection at the procedure site. A subfascial hematoma (a pocket of blood that forms beneath the fatty layer of the skin next to the muscle) may occur. Medical conditions or use of medications or supplements that causes excessive bleeding creates a higher risk of bleeding from the procedure site. Less common risks include muscle contracture (shortening of the muscle) and nerve damage leading to loss of feeling at or around the procedure site. Arm may be tender or sore for 2 to 3 days post biopsy. It is not uncommon to have a patch of numbness around the scar which may last for a few weeks.

Risks associated with lidocaine use (12-Month Randomized Trial only):
Common side effects of lidocaine include site pain, feeling lightheaded, shaking, low blood pressure, drowsiness, confusion, weakness, blurry or double vision, and dizziness. Serious reactions such as seizures, abnormal heart beats, slow heartbeat, heart block, severe allergic reactions, respiratory arrest (ending of normal breathing), and coma (a state deep unconsciousness that lasts for a prolonged or indefinite period) have occurred.

9.0 Data Collection and Management Procedures

Data from questionnaires, demographics and laboratory data will be obtained from EPIC, the electronic medical record, as well as all other data collection points will be collected on paper forms and transferred and kept in an excel database. Data collected will be used for research purposes for future publications, presentations and posters (if applicable) in order to analyze the outcomes. Record of data will be locked and stored in an electronic data file stored on hospital H and N drive using sequential, numeric code (001, 002, 003, etc.) on a password-protected computer in a locked office . Master key linking code with patient name will be held in a separate file accessible only to the PI. Limited access will be given to IRB approved study team members. Data master list

will be locked in suite 840 South Wood Street, Suite 617 Clinical Sciences North Building Chicago, IL 60612-7316. Additional data collection excel documents are being kept at 1640 W. Roosevelt Rd, Chicago IL, 60608. Only investigator and co-investigators will have access to study data.

10.0 Data Analysis

The de-identified collected data will be entered into a SAS database. Initial descriptive analysis will include calculating means, standard deviations, ranges and frequencies. T-tests for continuous variables and Chi Square or Fischer exact tests of association for categorical variables will be used to compare results of the study between the two groups for the efficacy parameters listed above. A P value<0.05 will be considered significant.

11.0 Data and Safety Monitoring

This protocol is not a drug or device research study, and for that reason, monitoring by a Data Safety Monitoring Board is not required at this time.

All adverse events related to the physical therapy of the research will be reported promptly to the IRB. If a breach of patient privacy/confidentiality, occurs that the study PI views as greater than a minor occurrence, the IRB will be notified of such at the time of discovery and a mitigation plan will be developed in consultation with the IRB. Problems and adverse events will be identified by the investigator or co-investigator based on patient self-reporting at each visit and will be reported to the IRB when applicable per IRB policy. Patients have the right to withdraw from (i.e., discontinue participation in) research at any time. If a patient decides to withdraw from all components of a research study, the investigator will discontinue all research activities involving that patient's participation in that study.

11.1 Monitoring and Reporting AE & SAEs

The investigator will monitor participants for the occurrence of adverse events during the course of the study. The investigator will instruct subjects prior to transplantation to report any physical changes or new symptoms that they notice during the course of the study.

Physicians and health care personnel involved in the subject's medical care will be instructed to report all serious adverse events (defined above) as soon as possible to:

Enrico Benedetti, MD

Department of Surgery
University of Illinois
840 South Wood Street, Suite 402 (MC958)
Chicago, IL 60612
Tel: 312 355-1493
Email: *enrico@uic.edu*

When an SAE is considered reportable to regulatory agencies, Dr. Benedetti will prepare the initial report and forward copies the Institutional Review Board (IRB) within the appropriate timeframe delegated by the IRB. Serious events will be followed until resolved or considered stable. The following attributes must be assigned: description, date of onset and resolution (if known when reported), severity, assessment of relatedness to test therapy, and action taken.

12.0 Statistical Considerations

The efficacy of the methods will be determined by:

1. a significant difference in term of pre and post treatment perception of well-being between the arms/groups

2.a significant difference in the lean/fat body mass ratio between the arms/groups

3. a significant difference in BMI between the arm/groups

4. a significant difference between the metabolic parameters between the arms/groups

The data will be entered into an Excel spreadsheet and stored on the UIMCC hospital server. The patient data, including age, sex, race, underlying kidney disease, length of hospital stay, rejection episode, comorbidities, and medications will be coded and patient names will not be included in the datasheet.

The de-identified collected data will be entered into a SAS database. Initial descriptive analysis will include calculating means, standard deviations, ranges and frequencies. T-tests for continuous variables and Chi Square or Fischer exact tests of association for categorical variables will be used to compare results of the study between the two arms/groups for the efficacy parameters listed above. A P value<0.05 will be considered significant.

13.0 Regulatory Requirements

13.1 Informed Consent

This will occur in the surgery clinic at University of Illinois at Chicago Medical Center. Patients will be seen in clinic based on standard of care appointments

without any relation to the study. Patients may also be recruited using a patient video that they have seen on social media, ghfitlab website or UIC website. After being identified, the potential subject will be approached by one of the key personnel who is approved to consent. This person will explain the study and answers all questions. It will be reinforced that participation is completely voluntary and the subject's decision will not affect their relationship with the treating physician from the Department of Surgery.

In addition to the above, we will also consent Spanish speakers using a Spanish consent, phone script and questionnaires for the main 12-Month Randomized Trial. This will allow us to also consent Spanish patients that may not have been able to understand the English consent. Some of our Co-Investigators are native Spanish speakers and will be able to go over the Spanish documents with the patient thoroughly and will be able to answer any additional questions or comments. A Spanish speaker will also be present at all of the subjects' visits.

13.2 Subject Confidentiality

The medical and research record will be confidential to the extent permitted by law. Study subjects will be identified by a code for the research records which will be stored on a password protected computer in the principal investigators office. Personal information from research records will not be released without written permission by the subject except:

- If necessary to protect the subject's rights and welfare (for example, if the subject is injured and needs emergency care or when the UIC Institutional Review Board monitors the research or consent process)
- If required by law

14.0 REFERENCES

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APPENDICES

1. **PAPER COLLECTION FORM:**

GH Dialysis Collection Form:
Patient ID:
Baseline visit date:
6 month visit date:
12 month visit date:

Descriptive

Weight :		
Height:		
Waist Circumference:		
BMI:		
Age/DOB:		
Gender:		
Race:		
Employment Status:	**Full or Part Time or Retired:**	**Seeking Employment?**
School?	**Full or Part Time:**	
Start of Dialysis:	**Years:**	**Graft Arm:**
BP:	**HR:**	**Location:**

Assistive Device?		
Blood Thinners?		
Health History		

GH PPKT Subgroup Collection Form:
Patient ID:
Baseline visit date:
Visit # 12 date:
Visit # 24 date:
Visit #36 date:

Descriptive

Weight :		
Height:		
Waist Circumference:		
BMI:		
Age/DOB:		
Gender:		
Race:		
Employment Status:	**Full or Part Time or Retired:**	**Seeking Employment?**
School?	**Full or Part Time:**	
Creatinine:		
Glucose:		

GRF:		
Start of Dialysis:	**Years:**	**Graft Arm:**
Transplant date:		
BP:		**Location:**
Allergies:		
Pain Average	**Location:**	

PWA and PWV

Blood Pressure 1:
2:
3:

Average BP:
MP:

Central PWV Measurements: (R. Side)

1. Carotid → sternal notch: _____mm
2. Sternal notch → femoral: _____mm

(2-1) = _____mm

PWA Radial	
Aortic SBP (mmHg)	
Aortic DBP (mmHg)	
HR (bpm)	
Ejection Duration (ms)	
T_r (ms)	
Aortic Augmentation	
Aortic AIX (%)	
Aortic AIX@75 (%)	
SEVR	
ESP	
Radial Wave Reflection	
Forward Pulse Height (mmHg)	
Reflected Pulse Height (mmHg)	
Reflection Index (%)	
Forward Pressure Peak (ms)	
Reflected Pressure Peak (ms)	
Aortic Pulse Reflection (ms)	
Transmission Time (ms)	
PWA Carotid	
SBP (mmHg)	
DBP (mmHg)	
MAP	
PP	
Pulse Wave Velocity	
Central PWV±SD	

Notes:
cIMT and ET

Basic Carotid (cIMT):	
Rt. Mean-IMT (mm)	
Carotid Strain/Strain Rate (speckle tracking)	

Echo Tracking (ET):	
Arterial Stiffness	
Beta	
Ep (kPa)	
AC (%)	
Diameter	
D_Max (mm)	
D_Min (mm)	
DAT max (ms)	
DDiff (mm)	

Notes:

Cardiac Ultrasound

Page

Left Ventricular Mass (LVM)		
IVSD		
LVPW		
LVID		
Fractional Shortening		
Ejection Fraction (%)		
dP/dT		
Stroke Volume (mL)		
End Systolic Volume (mL)		
End Diastolic Volume (mL)		
Cardiac Output (mL)		
E		
A		
E/A		
	Septal	**Lateral**

S’		
E’		
A’		
E’/A’		
Baseline Diameter		
Diameter Difference (%Change)		
Blood Flow		
Deceleration Time (ms)		
Isovolumetric Relaxation Time (ms)		
Estimated End-Diastolic		
% Saturation		
Ventricular arterial coupling: Ea & El		
Electromechanical Delay		
Save as DICOM image to USB		
Strain/strain rate via speckle tracking		

Notes:

FMD
Arm:
Location:

Notes:

NIRS
Arm:
Location:

Notes:

Hand Grip Strength

Dominant hand grip strength (kg)

Hand Used:

1
2
3
Average

Sit-To-Stand

Time: _____sec (if five stands are completed)
Number of Stands Completed: 1 2 3 4 5
Chair Stand Ordinal Score: _____
0 = unable

1 = > 16.7 sec
2 = 16.6-13.7 sec
3 = 13.6-11.2 sec
4 = < 11.1 sec

Max Sit to Stand:_____

8 Foot Walk

Time: _____ sec
Gait Ordinal Score: _____

0 = could not do
1 = >5.7 sec (<0.43 m/sec)
2 = 4.1-6.5 sec (0.44-0.60 m/sec)
3 = 3.2-4.0 sec (0.61-0.77 m/sec)
4 = <3.1 sec (>0.78 m/sec

Balance:

Side by side:

Circle one number
2. Held for 10 sec
1. Held for less than 10 sec; number of seconds held _____
0. Not attempted

Semi Tandem

Circle one number
2. Held for 10 sec
1. Held for less than 10 sec; number of seconds held _____
0. Not attempted

Tandem

Circle one number
2. Held for 10 sec
1. Held for less than 10 sec; number of seconds held _____
0. Not attempted

Balance Ordinal Score: **_____**
0 = side by side 0-9 sec or unable

1 = side by side 10, <10 sec semitandem
2 = semitandem 10 sec, tandem 0-2 sec
3 = semitandem 10 sec, tandem 3-9 sec
4 = tandem 10 sec

DEXA

Percent body fat:

Percent fat-free mass:

(Print out attached)

2. **Questionnaires**

PROMIS:

Global Health PROMIS® Scale v1.2

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Global04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global09r	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.).....	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	Mostly	Moderately	A little	Not at all
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10r	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		None	Mild	Moderate	Severe	Very severe
Global08r	How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Global07r	How would you rate your pain on average?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10
		No pain										Worst pain imaginable

PROMIS 29

Physical Function						
	Please respond to each item by marking one box per row	Without any difficulty	With a little difficulty	With some difficulty	With much difficulty	Unable to do
PFA11 1	Are you able to do chores such as vacuuming or yard work?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA21 2	Are you able to go up and down stairs at a normal pace?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA23 3	Are you able to go for a walk of at least 15 minutes?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
PFA63 4	Are you able to run errands and shop?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Anxiety						
In the past 7 days		Never	Rarely	Sometimes	Often	Always
EDAN X016	I felt fearful	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDAN X408	I found it hard to focus on anything other than my anxiety	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDAN X417	My worries overwhelmed me	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDAN X638	I felt uneasy	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Depression						
In the past 7 days		Never	Rarely	Sometimes	Often	Always
EDDE P048	I felt worthless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDE P0810	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDE P2811	I felt depressed	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDE 4112	I felt hopeless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Fatigue						
During the past 7 days		Not at all	A little bit	Somewhat	Quite a bit	Very much
HI713	I feel fatigued	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
A314	I have trouble starting things because I am tired	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
In the past 7 days						
FATE XP41 15	How run down did you feel on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
FATE XP40 16	How fatigued were you on average?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Sleep Disturbance						
In the past 7 days		Very poor	Poor	Fair	Good	Very good
Sleep 20827	My sleep quality was	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
In the past 7 days		Not at all	A little bit	Somewhat	Quite a bit	Very much
Sleep 11618	My sleep was refreshing	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Sleep 2019	I had a problem with sleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Sleep 4422	I had difficulty falling asleep	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Satisfaction with Social Role						
In the past 7 days		Not at all	A little bit	Somewhat	Quite a bit	Very much
SRPS AT0721	I am satisfied with how much work I can do (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPS AT2422	I am satisfied with my ability to work (include work at home)	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPS AT4723	I am satisfied with my ability to do regular personal and household responsibilities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
SRPS AT4824	I am satisfied with my ability to perform my daily routines	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pain Interference						
In the past 7 days		Not at all	A little bit	Somewhat	Quite a bit	Very much
PAINI N825	How much did pain interfere with your day to day activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAINI N2228	How much did pain interfere with work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAINI N3127	How much did pain interfere with your ability to participate in social activities?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
PAINI N3428	How much did pain interfere with your household chores?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
Pain Intensity						
Global 0729	How would you rate your pain on average?	☐ 0 No Pain	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9			☐ 10 Worst Imaginable Pain

SF 36

Medical Outcomes Study Questionnaire Short Form 36 Health Survey

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey! For each of the following questions, please circle the number that best describes your answer.

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
2. Compared to one year ago,	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?
(Circle One Number on Each Line)

	Yes, Limited a Lot (1)	**Yes, Limited a Little (2)**	**No, Not limited at All (3)**
a. **Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports	1	2	3
b. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	1	2	3

c. Lifting or carrying groceries	1	2	3
d. Climbing **several** flights of stairs	1	2	3
e. Climbing **one** flight of stairs	1	2	3
f. Bending, kneeling, or stooping	1	2	3
g. Walking **more than a mile**	1	2	3
h. Walking **several blocks**	1	2	3
i. Walking **one block**	1	2	3
j. Bathing or dressing yourself	1	2	3

4. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?
(Circle One Number on Each Line)

	Yes (1)	**No (2)**
a. Cut down the amount of time you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Were limited in the **kind** of work or other activities	1	2
d. Had **difficulty** performing the work or other activities (for example, it took extra effort)	1	2

5. During the **past 4 weeks,** have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?
(Circle One Number on Each Line)

	Yes	**No**
a. Cut down the amount of time you spent on work or other activities	1	2
b. **Accomplished less** than you would like	1	2
c. Didn't do work or other activities as **carefully** as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	

Not at all	1
Slightly	2
Moderately	3
Quite a bit	4
Extremely	5

7. How much bodily pain have you had during the past 4 weeks?	
None	1
Very mild	2
Mild	3
Moderate	4
Severe	5
Very severe	6
8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?	
Not at all	1
A little bit	2
Moderately	3
Quite a bit	4
Extremely	5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **(Circle One Number on Each Line)**

9. How much of the time during the **past 4 weeks** . . .

	All of the Time	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
a. Did you feel full of pep?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
f. Have you felt downhearted and blue?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (Circle One Number)	
All of the time	1
Most of the time	2
Some of the time	3
A little of the time	4
None of the time	5

11. How TRUE or FALSE is each of the following statements for you. (Circle One Number on Each Line)

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
a. I seem to get sick a little easier than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

KATZ INDEX OF INDEPENDENCE IN ACTIVITIES OF DAILY LIVING

ACTIVITIES POINTS (1 OR 0)	INDEPENDENCE: (1 POINT) **NO** supervision, direction or personal assistance	DEPENDENCE: (0 POINTS) **WITH** supervision, direction, personal assistance or total care
BATHING POINTS:_____	**(1 POINT)** Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area or disabled extremity.	**(0 POINTS)** Needs help with bathing more than one part of the body, getting in or out of the tub or shower. Requires total bathing.
DRESSING POINTS:_____	**(1 POINT)** Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	**(0 POINTS)** Needs help with dressing self or needs to be completely dressed.
TOILETING POINTS:_____	**(1 POINT)** Goes to toilet, gets on and off, arranges clothes, cleans genital area without help.	**(0 POINTS)** Needs help transferring to the toilet, cleaning self or uses bedpan or commode.
TRANSFERRING POINTS:_____	**(1 POINT)** Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable.	**(0 POINTS)** Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE POINTS:_____	**(1 POINT)** Exercises complete self control over urination and defecation.	**(0 POINTS)** Is partially or totally incontinent of bowel or bladder.
FEEDING POINTS:_____	**(1 POINT)** Gets food from plate into mouth without help. Preparation of food may be done by another person.	**(0 POINTS)** Needs partial or total help with feeding or requires parenteral feeding.

TOTAL POINTS =_____6 = High (*patient independent*) 0 = Low (*patient very dependent*)

Slightly adapted from Katz, S., Down, T.D., Cash, H.R., & Grotz, R.C. (1970) Progress in the development of the index of ADL.
The Gerontologist, *10*(1), 20-30.

try this: general assessment series
Best Practices in Nursing Care to Older Adults

A series provided by The Hartford Institute for Geriatric Nursing, New York University, College of Nursing
EMAIL hartford.ign@nyu.edu HARTFORD INSTITUTE WEBSITE www.hartfordign.org
CLINICAL NURSING WEBSITE www.ConsultGeriRN.org

Short Physical Performance Battery

About: This battery assesses lower extremity function in adults.

Items: 5

Reliability:
Internal consistency of the SPPB is 0.76

Validity:
Has predictive validity, showing a gradient of risk for mortality, nursing home admission, and disability.

Scoring:
See scoring information in each section.
Scores range from 0 (worst performance) to 12 (best performance).

References:
Guralnik, J. M., Simonsick, E. M., Ferrucci, L., Glynn, R. J., Berkman, L. F., Blazer, D. G., Scherr, P. A., Wallace, R. B. (1994) A short physical performance battery assessing lower extremity function: Association with self-reported disability and prediction of mortality and nursing home admission. *Journal of Gerontology, 49,* M85-M94.

1. Repeated Chair Stands

Instructions: Do you think it is safe for you to try and stand up from a chair five times without using your arms? Please stand up straight as quickly as you can five times, without stopping in between. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I'll be timing you with a stopwatch. Are you ready? Begin

Grading: Begin stop watch when subject begins to stand up. Count aloud each time subject arises. Stop the stopwatch when subject has straightened up completely for the fifth time. Also stop if the subject uses arms, or after 1 minute, if subject has not completed rises, and if concerned about the subject's safety.. Record the number of seconds and the presence of imbalance.. Then complete ordinal scoring.

Time:_____sec (if five stands are completed)
Number of Stands Completed: 1 2 3 4 5

Chair Stand Ordinal Score: _____

0 = unable
1 = > 16.7 sec
2 = 16.6-13.7 sec
3 = 13.6-11.2 sec
4 = < 11.1 sec

2. Balance Testing

Begin with a semitandem stand (heel of one foot placed by the big toe of the other foot). Individuals unable to hold this position should try the side-by-side position. Those able to stand in the semitandem position should be tested in the full tandem position. Once you have completed time measures, complete ordinal scoring.

a. Semitandem Stand

Instructions: Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you.

Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into semitandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and lets go.

Circle one number

2. Held for 10 sec
1. Held for less than 10 sec; number of seconds held _____
0. Not attempted

b. Side-by-Side stand

Instructions: I want you to try to stand with your feet together, side by side, for about 10 sec. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and lets go.

Grading

2. Held of 10 sec
1. Held for less than 10 sec; number of seconds held_____
0. Not attempted

c. Tandem Stand

Instructions: Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for 10 sec. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and lets go.

Grading

2. Held of 10 sec
1. Held for less than 10 sec; number of seconds held_____

0. Not attempted

Balance Ordinal Score: _____

0 = side by side 0-9 sec or unable
1 = side by side 10, <10 sec semitandem
2 = semitandem 10 sec, tandem 0-2 sec
3 = semitandem 10 sec, tandem 3-9 sec
4 = tandem 10 sec

3. 8' Walk (2.44 meters)

Instructions: This is our walking course. If you use a cane or other walking aid when walking outside your home, please use it for this test. I want you to walk at your usual pace to the other end of this course (a distance of 8'). Walk all the way past the other end of the tape before you stop. I will walk with you. Are you ready?

Grading: Press the start button to start the stopwatch as the participant begins walking. Measure the time take to walk 8'. Then complete ordinal scoring.

Time:_____sec
Gait Ordinal Score: _____

0 = could not do
1 = >5.7 sec (<0.43 m/sec)
2 = 4.1-6.5 sec (0.44-0.60 m/sec)
3 = 3.2-4.0 sec (0.61-0.77 m/sec)
4 = <3.1 sec (>0.78 m/sec)

Summary Ordinal Score:_____
Range: 0 (worst performance) to 12 (best performance).

Beck's Depression Inventory

This depression inventory can be self-scored. The scoring scale is at the end of the questionnaire. 1.

0 I do not feel sad.
1 I feel sad
2 I am sad all the time and I can't snap out of it.
3 I am so sad and unhappy that I can't stand it.

2.

0 I am not particularly discouraged about the future.
1 I feel discouraged about the future.
2 I feel I have nothing to look forward to.
3 I feel the future is hopeless and that things cannot improve.

3.

0 I do not feel like a failure.
1 I feel I have failed more than the average person.
2 As I look back on my life, all I can see is a lot of failures.
3 I feel I am a complete failure as a person.

4.

0 I get as much satisfaction out of things as I used to.
1 I don't enjoy things the way I used to.
2 I don't get real satisfaction out of anything anymore.
3 I am dissatisfied or bored with everything.

5.

0 I don't feel particularly guilty
1 I feel guilty a good part of the time.
2 I feel quite guilty most of the time.
3 I feel guilty all of the time.

6.

0 I don't feel I am being punished.
1 I feel I may be punished.
2 I expect to be punished.
3 I feel I am being punished.

7.

0 I don't feel disappointed in myself.

1 I am disappointed in myself.
2 I am disgusted with myself.
3 I hate myself.

8.

0 I don't feel I am any worse than anybody else.
1 I am critical of myself for my weaknesses or mistakes.
2 I blame myself all the time for my faults.
3 I blame myself for everything bad that happens.

9.

0 I don't have any thoughts of killing myself.
1 I have thoughts of killing myself, but I would not carry them out.
2 I would like to kill myself.
3 I would kill myself if I had the chance.

10.

0 I don't cry any more than usual.
1 I cry more now than I used to.
2 I cry all the time now.
3 I used to be able to cry, but now I can't cry even though I want to.

11.

0 I am no more irritated by things than I ever was.
1 I am slightly more irritated now than usual.
2 I am quite annoyed or irritated a good deal of the time.
3 I feel irritated all the time.

12.

0 I have not lost interest in other people.
1 I am less interested in other people than I used to be.
2 I have lost most of my interest in other people.
3 I have lost all of my interest in other people.

13.

0 I make decisions about as well as I ever could.
1 I put off making decisions more than I used to.
2 I have greater difficulty in making decisions more than I used to.
3 I can't make decisions at all anymore.

14.

0 I don't feel that I look any worse than I used to.
1 I am worried that I am looking old or unattractive.

2 I feel there are permanent changes in my appearance that make me look unattractive

3 I believe that I look ugly.

15.

0 I can work about as well as before.

1 It takes an extra effort to get started at doing something.

2 I have to push myself very hard to do anything.

3 I can't do any work at all.

16.

0 I can sleep as well as usual.

1 I don't sleep as well as I used to.

2 I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.

3 I wake up several hours earlier than I used to and cannot get back to sleep.

17.

0 I don't get more tired than usual.

1 I get tired more easily than I used to.

2 I get tired from doing almost anything.

3 I am too tired to do anything.

18.

0 My appetite is no worse than usual.

1 My appetite is not as good as it used to be.

2 My appetite is much worse now.

3 I have no appetite at all anymore.

19.

0 I haven't lost much weight, if any, lately.

1 I have lost more than five pounds.

2 I have lost more than ten pounds.

3 I have lost more than fifteen pounds.

20.

0 I am no more worried about my health than usual.

1 I am worried about physical problems like aches, pains, upset stomach, or constipation.

2 I am very worried about physical problems and it's hard to think of much else.

3 I am so worried about my physical problems that I cannot think of anything else.

21.

0 I have not noticed any recent change in my interest in sex.
1 I am less interested in sex than I used to be.
2 I have almost no interest in sex.
3 I have lost interest in sex completely.

INTERPRETING THE BECK DEPRESSION INVENTORY

Now that you have completed the questionnaire, add up the score for each of the twenty-one questions by counting the number to the right of each question you marked. The highest possible total for the whole test would be sixty-three. This would mean you circled number three on all twenty-one questions. Since the lowest possible score for each question is zero, the lowest possible score for the test would be zero. This would mean you circles zero on each question.
You can evaluate your depression according to the

Table below. Total Score_____Levels of Depression

1-10_____These ups and downs are considered normal 11-16_____Mild mood disturbance

17-20_____Borderline clinical depression 21-30_____Moderate depression

31-40_____Severe depression over 40_____Extreme depression

Pre-Transplant Frailty Assessment
Assessment Date: _____

Shrinking:

Current Weight: _____	Weight 1 year ago: _____ Current BMI: _____

If patient has lost weight in the past year, ask: Was your weight loss was Intentional? **Yes** **No** **N/A**
Frailty score: 0 or 1 (Score 1 if patient's BMI </= 18.5 *or* answers "No" to intentional weight loss)

Physical Endurance/Energy
1. Do you feel full of energy (today)? **Yes** **or** **No**
2. During the last 4 weeks, however often did you rest in bed during the day? **Every day** **Every week** **Once** **Not at all**

Frailty score: 0 or 1
(Score 1 if patient answers "No" to question#1 AND *answers "every day or every week" to question #2)*

Low Physical Activity
1. How often do you engage in physical activity that is mildly energetic?
   Frequency of physical activity: **>/=3x/week** **1-2x/week 1-3x/month** **Hardly ever/Never**
   Walking slowly (i.e. shopping, walking around the office), making the bed, eating, preparing food, washing dishes, sitting at your computer
2. How often do you engage in physical activity that is moderately energetic?
   Frequency of physical activity: **>/=3x/week** **1-2x/week 1-3x/month** **Hardly ever/Never**
   Walking briskly, walking the dog, slow dancing, sweeping the floor, vacuuming, washing windows, shooting a basketball, yoga, golf, softball
3. How often do you engage in physical activity that is very energetic?
   Frequency of physical activity: **>/=3x/week** **1-2x/week 1-3x/month** **Hardly ever/Never**
   Running, swimming, shoveling, soccer, jumping rode, carrying heavy loads (I.e. bricks)

Frailty score: 0 or 1
(Score 1 if patient responds with "Hardly ever/never" for questions #2 AND *#3)*

Weakness
Hand Grip strength in Kg: Hand held dynamometer with dominant hand, *average* of 3 measures

Men	Grip Strength cutoff
BMI ≤ 24	≤ 29
BMI 24.1-26	≤ 30
BMI 26.1-28	≤ 30
BMI ≥ 28	≤ 32

Women	Grip Strength cutoff
BMI ≤ 23	≤ 17
BMI 23.1-26	≤ 17.3
BMI 26.1-29	≤ 18
BMI ≥ 29	≤ 21

Current BMI:_____

Measure 1: _____
Measure 2: _____
Measure 3: _____
Average: _____

Hand assessed: ***Right or Left***

Frailty Score (lowest 20% (by gender, BMI): **0 or 1**
(Score 1 if patient scores ≤ cut off for their gender and BMI)

Slow Walking Speed
Walking time in seconds (usual pace) over 15 feet

Men	Walking Speed cutoff
Height ≤ 173 cm	≥ 7 seconds
Height > 173 cm	≥ 6 seconds

Women	Walking Speed cutoff
Height ≤ 159 cm	> 7 seconds
Height > 159 cm	> 6 seconds

Current Height: _____
Clocked Time: _____

Frailty score (lowest 20%, stratified by gender and median standing height)**: 0 or 1**
(Score 1 if patient clocks ≥ cutoff for their gender and Height)

Comments: Cane **wheelchair** **with assistance** **other:**_____

Frailty Assessment: (*Add up the "1's" for each section to determine Frailty Assessment*) TOTAL=_____

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

Patient Health Questionnaire (PHQ-9)

Patient Name: _____ **Date:** _____

	Not at all	Several days	More than half the days	Nearly every day
1. Over the *last 2 weeks*, how often have you been bothered by any of the following problems?				
a. Little interest or pleasure in doing things	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless	☐	☐	☐	☐
c. Trouble falling/staying asleep, sleeping too much	☐	☐	☐	☐
d. Feeling tired or having little energy	☐	☐	☐	☐
e. Poor appetite or overeating	☐	☐	☐	☐
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down	☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television.	☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed. Or the opposite; being so fidgety or restless that you have been moving around a lot more than usual.	☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way.	☐	☐	☐	☐
2. If you checked off any problem on this questionnaire so far, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
	☐	☐	☐	☐

PHQ-9* Questionnaire for Depression Scoring and Interpretation Guide

For physician use only

Scoring:
Count the number (#) of boxes checked in a column. Multiply that number by the value indicated below, then add the subtotal to produce a total score. The possible range is 0-27. Use the table below to interpret the PHQ-9 score.

Not at all	(#) _____	x 0 = _____
Several days	(#) _____	x 1 = _____
More than half the days	(#) _____	x 2 = _____
Nearly every day	(#) _____	x 3 = _____

Total score: _____

Interpreting PHQ-9 Scores		**Actions Based on PH9 Score**	
		Score	**Action**
Minimal depression	0-4	< 4	The score suggests the patient may not need depression treatment
Mild depression	5-9		
Moderate depression	10-14	> 5 - 14	Physician uses clinical judgment about treatment, based on patient's duration of symptoms and functional impairment
Moderately severe depression	15-19		
Severe depression	20-27		
		> 15	Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment.

* PHQ-9 is described in more detail at the McArthur Institute on Depression & Primary Care website www.depression-primarycare.org/clinicians/toolkits/materials/forms/phq9/