Evaluating the Impact of Focused Muscle Contraction Therapy in Retired American Professional Football Players

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Version: 8

Date: 03/24/21

1.0 Project Summary/Abstract

This study will investigate the effects of an exercise intervention on retired American professional football (APF) players. A total of 20 retired APF players (≥ 18 years of age), who suffer from chronic pain, will be enrolled. The study duration for each participants will be 18 months. Enrolled participants will perform a 18 months exercise intervention which involves 90 exercise rehabilitation training visits. In addition, participants will also be tested on various measures of health and function both at baseline (prior to intervention), at 6 months, 12 months, and 18 months (post intervention). All testing and result interpretation will be performed by trained research personnel indicated on the Appendix P. Participants are not UIC participants; however study testing visits will occur at the University of Illinois at Chicago Disability Health and Social Policy Building (UIC-DHSP), located at 1640 W. Roosevelt Road in Suites 158, 190, and 195, Chicago, IL 0608. All exercise intervention training visits will occur at Gh Fitlab, located at 1730 N Western Ave., Chicago, IL 60647.

2.0 Background/Scientific Rationale

The World Health Organization estimates that one in five individuals world-wide live with chronic pain[1]. For individuals who suffer traumatic injury, over 60% report persistence of moderately severe, injury-related pain, in more than one body region, for several years after injury[2-4]. For APF players, the injury rate is nearly 100% and is associated with long-term physical and cognitive disabilities[5]. Participants who suffer with chronic pain experience difficulties sleeping, fatigue, depression, and demonstrate the lowest quality of life, the lowest of any medical condition [6,7].

Opioids have been the traditional treatment of both acute and chronic pain in the APF[5]. In a study of retired APF players, opioid use was three times the rate of the general population[8]. Randomized clinical trials have demonstrated little evidence of long-term efficacy with opioids; in treatment of chronic low back pain, for example, pain relief is short term and leads to relief in less than 30% of those affected[9]. Opioid use is associated with several unwanted side effects which appear as early as two weeks after treatment and can include addiction, drug tolerance, overdose related mortality, myocardial infarction, and depression, and for these reasons, is not an acceptable treatment[10,11]. In an extensive review of treatment strategies including anti-depressants, anti-consultants, topical agents, injection therapy, physical therapy, and psychological approaches, none are known to provide more than 30% reduction in pain or improvement in function[12]. Similarly, a Cochrane review on

exercise therapies for the treatment of chronic pain have also demonstrated 30% or less efficacy in the treatment of chronic pain[13].

It is generally believed that chronic pain changes the structure of the brain[14]. Participants with chronic pain demonstrate brain atrophy with decreased cortical gray matter in the bilateral dorsolateral prefrontal cortex, thalamus, brainstem, primary somatosensory cortex (S1), and posterior parietal cortex[15-17]. The duration of pain and its intensity can predict regional atrophy in the dorsolateral prefrontal cortex of the brain[15]. Eliminating chronic pain is associated with restoration of brain anatomy and function. For example, following surgical or regional anesthetic block and loss of chronic pain symptoms, participants demonstrated reversal of abnormal brain anatomy and function[18]. However, only a small subset of participants can be treated in this fashion for durable relief of chronic pain; for the majority participants with injury-related, multiple site chronic pain, these are not treatment options.

Areas of the brain in which anatomic volume and function are decreased due to chronic pain are also involved in the successful learning of new motor tasks. Activation of the dorsolateral prefrontal cortex is initially high in learning a new motor task but appears to progressively decrease when a motor task becomes more and more "automatic"; it is believed that this change in function may be due to the delegation of responsibility to other brain structures[19, 20]. This finding may also be a contributing factor in the lack of exercise activity, usually automatic in its structure, in treating chronic pain and restoring anatomic form and function. For example, for the past 15 years, a series of well-documented studies have demonstrated increased automaticity when the focus is external to the muscle, ie, task focused[21]. Such automatic responses would imply the recruitment of lower brain structures once the task has been learned[9, 20]; these areas of the brain would not be the ones involved in chronic pain. In contrast, deliberate focus on the contraction of the muscle requires intense concentration; such focused attention is most effective if accompanied by verbal instruction[22]. Such concentration would imply the need for higher order brain function, with likely engagement of brain areas such as the dorsolateral prefrontal cortex, which is highly engaged in learning new motor tasks. It is possible that active stimulation in a focused motor task may stimulate atrophic areas of the brain, thereby restoring brain anatomy and function and, as a consequence, also extinguish the perception of chronic pain.

Focused muscle contraction can lead to increased quality of contraction and increased recruitment and activation of adjacent muscle fibers[23-25]. Following muscle activation, skeletal muscle can release growth factors in the blood stream such as brain derived growth factor and nerve growth factor [26,27]. These factors have been implicated in improved brain function. In addition, muscle activation can lead to the systemic release of other soluble factors, such as muscle specific microRNAs miR-1, -122a, and -124a, which serve as master regulators of multiple processes; these are produced by skeletal muscle and also found in the brain [28]. It is possible that in addition to direct effects on brain anatomy and function, focused muscle contraction may release mediators, which indirectly augment brain anatomy and function.

In our own studies of kidney transplant participants with multiple sites of chronic pain, a 6 month, twice- weekly regimen led to sustainable decreases in chronic pain with return to work rates of 75%, over 5 times the national rate of 14%. In a similar new study of five retired APF players, this muscle contraction program led to greater than 90% resolution of all pain. Such rates of sustainable pain relief have not been described before using any treatment modality and warrant further study.

At present, the field of pain control rests largely on devising new strategies of established treatments. Notably, no new effective therapeutics for the treatment of injury- related, chronic pain have been identified in the past decade. Further, the rate of opioid addition, depression, and escalating opioid-related suicide rates, continue to rise with no new alternative therapies. The use of focused muscle contraction therapy may serve as an important, non-pharmaceutical way of eliminating chronic pain in a durable sustained manner.

3.0 Objectives/Aims

The present study aims to analyze the effectiveness of a specific physical activity training program (aka GH Method) in retired APF players.

Hypotheses:

1. Exercise will positively affect body composition. With this hypothesis we will test whether muscle strength (dynamometer) and muscle mass (DEXA scan) changes after 6 months, 12 months, 18 months of an exercise intervention. Baseline measurement will be performed before the intervention, at 6 months, 12 months, and at the end of the study (18 months) with muscle mass measured by DEXA and strength measured again by dynamometer.
2. We expect participants will see improvements in their physical abilities after 18 months in the exercise training sessions. This will be assessed by comparing

baseline, 6 months, 12 months, and 18 months, 8 foot walk, timed sit to stand, and balance testing scores.

3. Participants enrolled in the exercise intervention will have an overall improved sense of well-being, increased independence, quality of life, and decreased depression. Participants will be asked about their overall general health, mental health and pain intensity using the PROMIS, SF 36, BDI, Fatigue Severity Index, and pain assessments.
4. APF players with chronic pain described as greater than 5 out of a 10 point scale and lasting greater than 12 months, will display alterations in brain wave function consistent with abnormal function of the bilateral dorsolateral prefrontal cortex (DLPFC) , thalamus (relays motor and sensory signals to the cortex) , brainstem, primary somatosensory cortex (S1, postcentral gyrus of the anterior parietal lobe) and posterior parietal cortex (posterior to the primary somatosensory cortex)

4.0 Eligibility

This study will enroll retired APF players, who are 18 years of age or older, and suffer from chronic pain. Participants will be recruited by referral to the PI by Dr. Arthur (Archie) Roberts at the National Football Foundation. 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 (using the screening eligibility form) and consented by authorized research staff, if eligible to participate. Please reference Section *13.1 Informed Consent* for more information on the consent process.

4.1 Inclusion Criteria

- Retired APF player (there is no minimum duration or career length required no minimum duration or career length required)
- 18 years of age and older

4.2 Exclusion Criteria

- Unable to travel to the training center
- Unable to give consent
- Unable to understand the study
- Unable to comply with the training program

4.3 Excluded or Vulnerable Populations

- This study will exclude non-English speaking participants as they would not be able to complete intensive survey requirement of the study as all surveys will be administered in the English language.

5.0 Participant Enrollment

- Participants will be recruited by referral to the PI by Dr. Roberts at the National Football Foundation. 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.
- Eligible participants will give voluntary informed consent to participate in the study.

6.0 Study Design and Procedures

The study will include 20 retired APF players participating in a 18 month exercise rehabilitation. The study will consist of 94 visits (4 study testing visits and 90 exercise visits). Participants will come in for data collection visits at baseline (prior to starting the exercise program), at 6 months, 12 months, 18 months (after ending the exercise program). Each of those visits will take about 2-3 hours. All testing done in the 4 test visits will help assess the participant'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, participants will come twice weekly, for roughly 1 hour each session, for 6 months (52 visits). From 6-12months, participants will come once a week, for roughly 1 hour each session (26 additional visits). From 12-18 months, participants will come twice a month, for roughly 1 hour sessions (12 visits). All study testing visits will occur at the UIC-DHSP, located at 1640 W. Roosevelt Road in Suites 158, 190, and 195, Chicago, IL 60608. All exercise intervention training visits will occur at Gh Fitlab, located at 1730 N Western Ave., Chicago, IL 60647.

Study Testing Visits:

Mental Health and Quality of Life Assessments

The following questionnaires will be performed at baseline, 6 months, 12 months, and 18 months **(please see protocol appendices for all questionnaires and data collection documents):**

- Measures of Pain and Disability: The transition from acute to chronic pain is associated with the fear that movement will promote significant pain or re-injury. To avoid pain, movement is avoided which leads to disuse, disability, and depression. Hence, measures of baseline pain will include two measures [29]. The Numeric Rating Scale for Pain, is a visual analog scale in which the participant selects the number which best reflects the intensity of pain; this requires 1 minute to complete. The Pain Catastrophizing Scale is a 13 item scale which takes approximately 5 minutes to complete and assesses the degree of fear, and three subscale scores assessing rumination, magnification and helplessness [30].

- The PROMIS v.1.1 - Global Health short form will be administered to all participants. The PROMIS v.1.1 - Global Health short form will assesses 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 participants. 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 participants.. 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.. BDI is a validated to measure depression in a general medical population and in chronic disease participants.
- Fatigue: The Fatigue Severity Index is one of the few assessments which allows assessment over time 30. It requires 5 minutes to complete

Body composition, strength and functional capacity

All of the following assessments will be performed at baseline, at 6 months, 12 months, and 18 months.

- BMI will be calculated. The participants 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.
- 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 participant 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 participants' 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. Participants will be asked to walk eight feet as quickly as they could. Participants 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, participants will be asked to stand up and sit down without using their arms for assistance for a total of five times without assistance. Participants unable to perform this test at all were assigned a chair stands score of 32 seconds, the 99%ile value among participants who were able to perform this test. Participants 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. Participants 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.1RM leg press strength testing: Participants 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. Participants 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)

- Participants will be assessed for their maximum weight lifted during a training session.. This data is a cumulated number of all weight lifted during all exercises and repetitions performed in a single training session (60 minutes). At baseline, a maximum weight lifted will be determined as the total of all weight lifted for all muscle groups in a single session. This total will encompass all reps done of each exercise/weight, for an overall total. (example if 5 reps of 100lbs were done in arms and 5 reps of 100 pounds were done in legs in one session, the total weight lifted for that day would be 1000 lbs).

Measures of brain anatomy and function

All of the following assessments will be performed at baseline, at 6 months, 12 months, and 18 months.

- A Quantitative Electroencephalogram (QEEG) is noninvasive, 19 sensors instrument, which produces comprehensive analysis of individual frequencies that make up the raw electroencephalograph (EEG) by measuring brain wave activities. A special cap made of stretchy material will be placed on the participant's head that have these 19 sensors. The data gathered from QEEG is utilized for the creation of topographic brain maps of color-coded simulations of the electrical activity of the cerebral cortex, which can then be compared to a normative database and used for statistical analyses[31]. QEEG will be recorded during rest (in two conditions, eyes closed and eyes open) in order to get an understanding of differences in oscillatory activation across the full spectrum of QEEG bandwidths. Neli Cohen, PhD, Director, Holistic Neuro Psychological Interventions, (HNPI) (https:// www.holisticneuropsych.com/about-us), will provide neurocognitive assessments. Dr. Cohen has treated football players with traumatic brain injuries and is extremely dedicated to the improvement in the quality of life of participants suffering with chronic pain. She will investigate brain functioning with QEEG two analyses: Spectral Analysis and LORETA. Maab Osman, Neuropsychological Technician, HNPI, will assisting Dr. Neli Cohen. The QEEG equipment will be brought to UIC-DHSP and tests will be performed on campus.

- The Integrated Visual and Auditory Scale (IVA-2) measures visual and auditory responses as a test of sustained attention[32]. Specifically, it measures

vigilance, focus, speed, prudence, consistency, stamina, comprehension, persistence and sensory /motor responses. This test is administered by computer and will be performed on campus. More information on this test can be found at *https://www.braintrain.com/iva2/* .

Employment Status

- Employment status will be assessed through participant response at baseline, at 6 months, 12 months, and 18 months.

Other measurements: Height and weight will be measured and body mass index will be calculated as weight (kg) divided by height (m) squared. Age, race, years in the APF league, number of concussions, number of fractures, surgical history, and list of pain medications will be verbally asked for as part of qualitative data collection.

Exercise Training Visits:

Exercise Training Visits (GH Method session):

- Participants will attend 2 trainings sessions a week from 0-6 months (52 visits). From 6-12 months, participants will attend 1 training session a week (26 visits). From 12-18 months, participants 2 trainings sessions a month (12 visits). Participants will complete a total of 90 exercise training visits in 18 months. Each training session will be roughly an hour. All of these visits will occur at 1730 N Western Ave. Chicago IL 60647.
- At least twice per week, GH personnel will attempt to follow-up with participants 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.

Consent Addendum (optional)

- In a separate consent addendum, enrolled participants will be asked if they would like to 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 (i.e. participant progress videos may be created, at a later date, to be shown in addition to the recruiting info sheet)
    - Presentations and/or Publications
    - Fundraising (i.e. participant progress videos may be included on a future UIC donation page regarding this research (not yet created))
    - Websites and social media

The consent addendum will be thoroughly explained to the participants, which will detail all the uses of media production. Participants will be ensured that the items included in the consent addendum are optional and will not affect their current study participation. They will be notified that they can withdraw consent at any time and any media production will be destroyed. Participants will be approached to sign the consent addendum at a study or exercise visit. Any uses for publicity or advertising for the fitness program that are not related to the research study will not be described or solicited from participants in the consent addendum. Research participants will not be asked to stage photographs, speech or video for promotional purposes as part of the research study. In addition to the consent addendum, all participants will also sign the "UIC/UI Health Reporting, Publication or Broadcast Release for patients" for release of protected health information to media, which is available online: https://today.uic.edu/resources/photo-video-policies. Any media production will be sent to UIC's Office of Public and Government Affairs and IRB review prior to release.

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

Summary of GH Study Visits:

- Participants may be asked to repeat previous weeks and/or skip a particular week depending on their energy, progress, and overall health.
- Depending on a participant'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.
- On Weeks 6, 13,18, 25, 41, and 52 participants will focus on cardio and endurance exercises. These exercises may include running in place, or using a recumbent (stationary) bike. All other weeks consist of basic strength training/resistance workouts.
- The attached exercise list 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 participants 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.

- We would like participants to follow Table 1 on page 11-12 of the protocol as closely as possible. There is a set structure for the categories and duration of exercises as part of this research. However, intensity/weight for each participant will vary depending on personal ability. Keeping the participants safe is our main priority.

Table 1

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, or on a recumbent bike). 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, or on a recumbent bike). 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, or on a recumbent bike). 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 (e.g. run in place, or on a recumbent bike). 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**

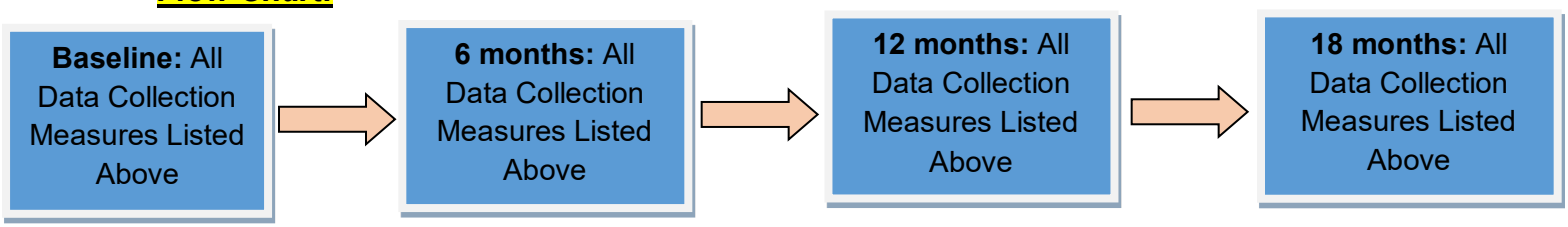
Week 40	**1 set 90 seconds focused on resistance. Medium speed.**	**Lighter**	**2 minutes**
Week 41	**Cardio Exercises. 10 exercises in a set. 2 Sets.**	**Moderate**	**3 minutes**
Week 42	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 43	**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**
Week 54	**1 Warm Up Set of 15 repetitions. 1 Heavier Set of 11 Repetitions.**	**Moderate/Heavy**	**3 minute breaks**

Week 56	**1 Warm Up Set of 15 Repetitions. 3 Sets of 6-8 repetitions (depending on exercise)**	**Moderate/Heavy**	**3 minutes**
Week 58	**1 Set of 25 - 30 Repetitions**	**Moderate**	**3 Minutes**
Week 60	**1st Set: Warm up of 12 repetitions. 2nd Set: 6 repetitions**	**Moderate/Heavy**	**3 minutes**
Week 62	**1 Set: 35 - 40 repetitions**	**Moderate/Light**	**3 minutes**
Week 64	**1 Warm Up Set: 15 repetitions 1 Heavier Set 8 - 10 repetitions**	**Moderate/Heavy**	**3 minutes**
Week 66	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 68	**1 Warm Up Set 8 reps 1 Heavy Set 8 reps. Medium speed.**	**Heavy**	**3 minutes**
Week 70	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 72	**3 Sets on each exercise of 6, 8, 12 repetitions. Lower weights each set. Medium speed.**	**Moderate**	**3 minutes**
Week 74	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 76	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**
Week 78	**1 Warm Up Set: 8 – 12 reps. 1 Heavy Set: 8 – 12 reps. Slower Speed.**	**Moderate/Heavy**	**2 minutes**

GH Method: List of Strength/Resistance Exercises

Exercise
Chest: Smith Bench Press/Incline
Glutes: Abductor
Biceps: Cable Easy Curl/Free Bar
Quads: Leg Extension
Calves: Calf Machine
Biceps: Preacher
Quads: Leg Press
Quads: Leg Extension
Abs: Decline
Back: Pull Down Behind
Hamstring: Curl Machine
Shoulders: Dumbbell Press / Smith Press
Back: Low Roll
Hamstring: Good Morning with Dumbbell/ 1 Leg Hamstring Curl
Shoulders: Side Rise with Dumbbells
Triceps: Push Down / Kick Back
Abs: Sit Ups
Triceps: Close Grip

Flow Chart:



Throughout: Exercise rehabilitation sessions (details listed above); 0-6 months: 2 days/week; 6-12 months 1hour/session, 12-18 months 2 days/month

7.0 Expected Risks/Benefits

The main risk of this research is loss of confidentiality of medical information. Consent will be obtained for all participants. Master participant 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 participants may have. The participant may also experience mild anxiety or discomfort in providing information via questionnaires, or computer program, about your their health, well-being and brain function.

Risks associated with the consent addendum:

The main risk is loss of confidentiality. Participants 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 or when completing questionnaires.

Risk associated with grip strength (Dynamometer) and 1RM tests include:
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:
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:
The participant 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.

Risk associated with a QEEG:
An QEEG has no known medical risks.

8.0 Data Collection and Management Procedures

Data collected from the participant 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 drive 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 participant name will be held in a separate file accessible only to the PI. Limited access will be given to pre-determined personnel listed in Appendix P. Master participant 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, UIC-DHSP.. Electronic original media production will

be stored on a secured hospital server, N drive. Only investigator and co-investigators will have access to study data.

9.0 Data Analysis

The coded collected data will be entered into a SAS database. Initial descriptive analysis will include calculating means, standard deviations, ranges and frequencies. ANOVA 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 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 participant 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 participant self-reporting at each visit and will be reported to the IRB when applicable per IRB policy. If participants declare that they have suicidal thoughts/intentions via the Beck's Depression Inventory questionnaire, they will be asked if they have a plan for following through with suicidal intentions. If they say yes, they will be sent to the ED. If they say they do not, the patient will be asked to follow up with their PCP to discuss potential depression.

Participants have the right to withdraw from (i.e., discontinue participation in) research at any time. If a participant decides to withdraw from all components of a research study, the investigator will discontinue all research activities involving that participant'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 participants 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 participant'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 comparing the same group's baseline, 6 month and 12 month data. These factors will be analyzed:

1. a significant difference in term of pre and post treatment perception of well-being

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

3. a significant difference in BMI

4. Changes in strength, physical performance, and QEEG patterns.

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

The coded collected data will be entered into a SAS database. Initial descriptive analysis will include calculating means, standard deviations, ranges and frequencies. ANOVA 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 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 UIC-DHSP building, located at 1640 W. Roosevelt Road. Participants will come to UIC per referral and information sheet. Participants will

be screened using the screening eligibility form, before enrolling in the study. The study will be discussed with the potential participant by designated authorized research personnel. The consent will be reviewed, and any questions will be answered. The participant will be able to decide if they would like to participate in the study. It will be reinforced that participation is completely voluntary. If they are interested and state that they can comply with the study requirements, they will sign the consent form and then proceed with physical assessments and study visits.

13.2 Subject Confidentiality

The medical and research record will be confidential to the extent permitted by law. Study participants 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 participant except:

- If necessary to protect the participant's rights and welfare (for example, if the participant 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

PAPER COLLECTION FORM:

GH APF Collection Form:
ID:
Baseline visit date:
6 month date:
12 month date:
18 month date:

Descriptive

Weight :		
Height:		
Waist Circumference:		
BMI:		
Age/DOB:		
Race:		
Employment Status:	**Full or Part Time or Retired:**	**Seeking Employment?**
School?	**Full or Part Time:**	
BP:		**Location:**
Questions to verbally ask participant during study visit?:		
Years in APF		
Number of Concussions		
Surgery HX		

Fracture Hx		
Taking pain medications?	**List medications:**	

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 = > 1
.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:

QUESTIONNAIRES (PRINT OUT ATTACHED) SEE BELOW

PROMIS:

UIC Department of Kinesiology and Nutrition
UNIVERSITY OF ILLINOIS AT CHICAGO
COLLEGE OF APPLIED HEALTH SCIENCES

Global Health and Well-being

Global Health-
PROMIS Global Health (10) SF

	Please respond to each item by marking one box per row	Excellent	Very good	Good	Fair	Poor
Global 01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 09	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
Global 06	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
Global 10	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
Global 08	How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global 07	How would you rate your pain on average?	☐ 0 No Pain ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 Worst Imaginable Pain				

Scoring:
Re-code Global07. The recoded score ranges from 1 to 5.
(0 No pain =5; 1, 2, or 3 =4; 4, 5, or 6 =3; 7, 8, or 9 =2; 10 worst pain imaginable =1)

After recoding, the
Global Physical Health score = SUM responses to G03 + G06 + G07 + G08.
Global Mental Health score = SUM G02 + G04 + G05 + Global10.

TOTALS	Raw Score	T-Score
Global Physical Health		
Global Mental Health		

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 P0610	I felt helpless	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
EDDE P2911	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 N926	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 (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

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 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

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.

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 participant begins to stand up. Count aloud each time participant arises. Stop the stopwatch when participant has straightened up completely for the fifth time. Also stop if the participant uses arms, or after 1 minute, if participant has not completed rises, and if concerned about the participant'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

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.

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

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

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
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

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

PAIN CATASTROPHIZING SCALE (COPYRIGHT 1995, 2001, 2004, 2006, 2009 MICHAEL JL SULLIVAN, PHD)

Everyone experiences painful situations at some point in their lives. Such experiences may include headaches, tooth pain, joint or muscle pain. People are often exposed to situations that may cause pain such as illness, injury, dental procedures or surgery.

We are interested in the types of thoughts and feeling that you have when you are in pain. Listed below are thirteen statements describing different thoughts and feelings that may be associated with pain. Using the scale, please indicate the degree to which you have these thoughts and feelings when you are experiencing pain.

	Not at	To a slight	To a modera	To a great	All the
I worry all the time about whether the pain will end	0	1	2	3	4
I feel I can' t go on	0	1	2	3	4
It' s terrible and I think it' s never going to get any better	0	1	2	3	4
It' s awful and I feel that it overwhelms me	0	1	2	3	4
I feel I can' t stand it anymore	0	1	2	3	4
I become afraid that the pain will get worse	0	1	2	3	4
I keep thinking of other painful events	0	1	2	3	4
I anxiously want the pain to go away	0	1	2	3	4
I can' t seem to keep it out of my mind	0	1	2	3	4

I keep thinking about how much it hurts	0	1	2	3	4
I keep thinking about how badly I want the pain to stop	0	1	2	3	4
There' s nothing I can do to reduce the intensity of the pain	0	1	2	3	4
I wonder whether something serious may happen	0	1	2	3	4

FATIGUE SEVERITY SCALE (FSS)

Date

Name

Please circle the number between 1 and 7 which you feel best fits the following statements. This refers to your usual way of life within the last week. 1 indicates "strongly disagree" and 7 indicates "strongly agree."

Read and circle a number.	Strongly Disagree → Strongly Agree						
1. My motivation is lower when I am fatigued	1	2	3	4	5	6	7
2. Exercise brings on my fatigue.	1	2	3	4	5	6	7
3. I am easily fatigued.	1	2	3	4	5	6	7
4. Fatigue interferes with my physical functioning.	1	2	3	4	5	6	7
5. Fatigue causes frequent problems for me.	1	2	3	4	5	6	7
6. My fatigue prevents sustained physical functioning.	1	2	3	4	5	6	7
7. Fatigue interferes with carrying out certain duties and responsibilities.	1	2	3	4	5	6	7
8. Fatigue is among my most disabling symptoms	1	2	3	4	5	6	7
9. Fatigue interferes with my work, family, or social life.	1	2	3	4	5	6	7

VISUAL ANALOGUE FATIGUE SCALE (VAFS)

Please mark an “X” on the number line which describes your global fatigue with 0 being worst and 10 being normal.