Enhancing Well-Being Through Exercise During Older Age

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“Enhancing Well-Being Through Exercise During Older Age”

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Sponsors:

The Midwest Roybal Center for Health Promotion and Translation Pilot Grant Program

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Research Protocol for “Enhancing Well-Being Through Exercise During Older Age”
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A. Specific Aims

AIM 1. Determine the feasibility of adapting Fit and Strong! to include affect and mood-related content and employing this intervention among older adults with a range of depressive symptoms.
HYPOTHESIS 1. Participants will demonstrate **(1a)** adherence to the Fit & Strong! intervention defined as attendance at two-thirds or more of the exercise sessions over a 8-week period and **(1b)** acceptability of the Fit & Strong! intervention as a way to reduce depressive symptoms and improve positive affect and reduce negative affect, defined as at least 75% of participants reporting positive subjective opinions of the protocol during debriefing session assessments.

AIM 2. Begin to determine whether Fit & Strong! is efficacious as an approach for reducing depressive symptoms and improving positive affect and reducing negative affect among older adults.
HYPOTHESIS 2. Compared to wait-list participants, intervention participants will report an improvement in positive affect and a reduction in negative affect and depressive symptoms at 9 weeks as measured by medium to large effect sizes.

AIM 3. We will explore the relationship between negative/positive affect and depressive symptoms and maintenance of physical activity between groups at baseline, and 9- weeks, in order to determine whether an improvement in positive affect and a reduction in positive affect is associated with an increase in physical activity.
HYPOTHESIS 3. Participants randomly assigned to the intervention arm will demonstrate an increase in physical activity at 9- weeks as measured by medium to large effect sizes, and this increase in positive affect/reduction in negative affect will be mediated by an increase in physical activity.

AIM 4. We will explore the relationship between physical activity and the brain between groups at baseline and 9-weeks, in order to determine whether an improvement in brain network connectivity and function is associated with an increase in physical activity.
HYPOTHESIS 4. Participants randomly assigned to the intervention arm will demonstrate an increase in physical activity and brain network connectivity and function at 9-weeks.

B. Background and Significance

Affective well-being is typically characterized as the presence of positive feelings and the absence of negative feelings over time, and have been showing to be relatively independent constructs (Lucas et al., 1996). After the age of 60, negative affect tends to remain stable, (Gross et al., 1997) but positive affect decreases (Kunzmann et al., 2000). Positive affect in late life has been positively associated with social engagement (e.g., Kunzmann, 2008), while negative affect in late life has been linked to self-reported physical health (e.g., Brief et al., 1993). Studies have demonstrated that exercise is associated with higher positive affect and lower negative affect (Dua et al., 1992; Rizk et al., 2015) In clinical samples, exercise has long been established as an

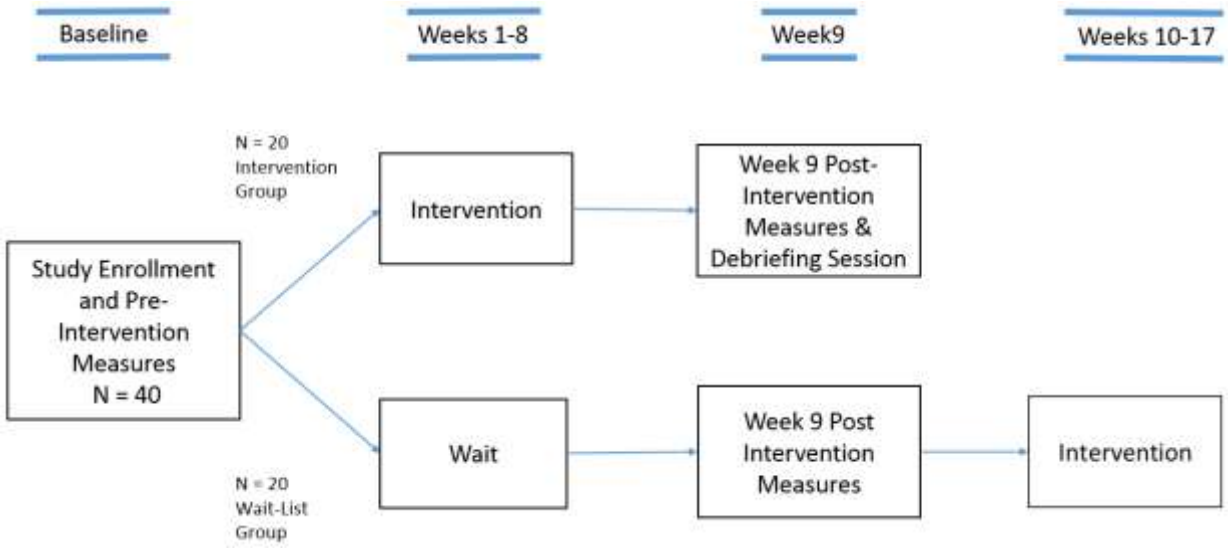
effective treatment for depression in younger [Krogh et al., 2011] and older adults [Blake et al., 2009]. Importantly, exercise also addresses vascular risk factors thought to be particularly relevant to aging (Blaha et al., 2016), in general, as well as depression in late life [Alexopoulos et al., 2006, Sheline et al., 2010]. While there have been several studies demonstrating the benefits of exercise on depression in older adults, no known study has examined the positive benefits of a structured, group exercise program on mood and well-being in an aging sample. As an ancillary aim, we will also examine the impact of a structured exercise intervention on cognitive functioning. Fit and Strong!, a physical activity / behavior change program for older adults with lower extremity osteoarthritis, has demonstrated efficacy, effectiveness, and ease of dissemination for individuals with osteoarthritis living in the community [Hughes et al., 2004, 2006, 2010]. The goal of this study is to adapt Fit & Strong! for increasing positive affect and reducing negative affect and depressive symptoms among older adults residing in the community.

C. Research Design and Methods

C.1 General study design

We will enroll 40 subjects in this study between the ages of 60 and older, from the community who score at least 1 on the Patient Health Questionnaire-8 (PHQ). Up to 20 participants will have PHQ-8 scores of 1-4, while up to one-half of participants will have PHQ scores >4. At the outset of the study, up to 20 individuals will be randomly assigned to the intervention portion of the study, while up to 20 individuals will be randomly assigned to a crossover wait-list group, who will undergo the intervention beginning at study week 10. Outcome measures will be administered to all participants before the intervention and to the intervention group after they undergo the intervention. The wait-list group will complete all of their outcome measures before they begin the intervention(see Figure 1).

Figure 1



C.2 Phone screen and Study Visits

C2.1 Pre-Study Screen:

Before being scheduled to a study visit, potential participants will undergo a phone or in-person screen where the aims and structure of the study will be explained to them. The potential participants will be allowed to ask specifics about the study and express their interest in the study. If they wish to participate in the study, they will undergo a phone screen assessing past and current medical and psychiatric history, as well as answer a six-item screener, Patient Health Questionnaire-8 and Physical Readiness Questionnaire. Participants will also be informed about compensation during the phone screen. If a participant scores 10 or higher on the PHQ, but refuses to participate in the study, we will refer them to a list of treatment facilities including UIC's Psychiatry Outpatient Program. Scores above 10 or 11 are thought to be indicative of clinical depression (see https://www.ncbi.nlm.nih.gov/pubmed/18752852 or https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2943487/) Participants who express interest and are eligible for the intervention group will also be screened with the MRI Screening document to see if they are eligible for the optional MRI component of the study.

C2.2. Study Enrollment and Pre-Intervention Measures (approximately 3 hours)
All eligible individuals will be invited to the University of Illinois at Chicago or to Oakwood Shores for their first study visit, which will last approximately two hours. First, the entire study will be described to participants and any questions that they have about the study will be answered. After the participant has signed the consent form, they will participate in an interview with a trained research assistant. Some of these questions will be of a personal nature and may make the participant feel uncomfortable. They can decline to answer any question. Next, they will complete a packet of self-report questionnaires and will undergo a neuropsychological (memory/cognitive) testing battery and mobility assessment with a trained staff person. Randomized participants of the intervention group will be invited to participate in optional MRI testing which will take place pre-intervention (Week 0) and post-intervention (Week 9).

C2.3. Exercise Intervention. Participants will be invited back to Oakwood Shores for an 8-week physical activity/behavior change intervention. The intervention will consist of the Fit and Strong! program adapted to address the impact of exercise on enhancing positive affect and reducing negative affect and depressive symptoms. Exercise classes will meet three times per week for 90 minutes per session for eight weeks. Each class is divided into 60 minutes of strength training, flexibility, and cardiovascular exercise and 30 minutes of group education/discussion, which has been adapted to include affect-oriented content. An outline of education topics for each of the 24 sessions can be found in Section C.7. Two sessions of Fit and Strong! will be delivered as part of the study; each will be limited to 20 participants. Classes will be taught by certified exercise instructors who will undergo 8-hours of training on the Fit & Strong! Program. The instructor will be trained to deliver depression specific content by a clinical psychologist Program fidelity will be monitored with the Fit and Strong! Plus Implementation Checklist and observation of the intervention by study investigators during one Fit & Strong class per 8-week session. During the intervention, participants will complete a medication adherence and group cohesion measure at baseline, 4 weeks, and 8 weeks.

C2.4. Debriefing Session: Following the intervention, a debriefing session will be held with all intervention participants. This session will be used to adapt Fit & Strong! for future study, addressing issues around affect and treatment effectiveness.

C2.5. Post-Intervention Measures. During Week 9, participants will undergo the same interview, self-report questionnaires (only those bolded in section C.6.3), mobility assessment, and

neuropsychological tests they completed during the baseline visit. Participants that were involved in the MRI testing component will also undergo the same testing for post-intervention results.

C.3 Subject Payment

All participants enrolled in the study (intervention and crossover wait list group) will be paid $20 upon completion of their baseline interview and $35 upon completion of their post-test. Participants will be paid in cash. Participants involved in the MRI testing will be paid $50 in cash upon completion of the scan pre-intervention and post-intervention ($100 total).

C.4 Entry Criteria for Studies

C.4.1 Inclusion Criteria:

Inclusion Criteria for All Participants: a) ages 60+; b) Sufficient visual and hearing capacity to follow instructions; c) a score of at least 1 on the Patient Health Questionnaire-8 (Kroenke et al., 2001); d) Six Item Screener (Callahan, 2002) score > 4; e) pass screening with the EASY scale [Cardinal et al., 1996] or have doctor's clearance to participate; e) no recent (<6 months) joint replacements; f) physically inactive (<150 minutes of exercise per week); and g) able to walk at least 20 feet (with or without the aid of a cane or walker); speak English proficiently. *In the event we need a doctor's clearance for a subject to participate, we would have the participant sign a release of information for us to contact their doctor and then we would contact the doctor via pager/phone and get verbal permission to allow them to participate in an exercise study. They would then sign a form to document their authorization.

C.4.2 Exclusion Criteria:

a) Non-proficient in English; b)0 on the Patient Health Questionnaire-8 (Kroenke et al., 2001); cb) Six Item Screener < 5 (Callahan, 2005); c) fail screening with the EASY scale and does not have doctor's clearance to participate; d) joint replacement in last 6 months; e) 150+ minutes of exercise per week; g) unable to walk at least 20 feet; f) severe medical illness (i.e., metastatic cancer, brain tumors, unstable cardiac, hepatic, or renal disease, myocardial infarction or stroke) within the 3 months preceding the study; g) Other brain/neurological disorders (i.e., dementia or delirium according to DSM-IV criteria, history of severe head trauma, Parkinson's disease or Parkinson's plus syndromes, multiple sclerosis, epilepsy); h) Conditions often associated with depression (i.e., endocrinopathies other than diabetes, lymphoma, and pancreatic cancer).

Potential participants for the optional MRI study will be excluded for the following: a) cardiac pacemaker or defibrillator: b) metal parts in head, spinal cord, eyes, or chest: d) past operation or radiation therapy with skull or brain: e) aneurysm clips: f) dentures that have been surgically implanted with magnets, braces: g) claustrophobia: h) heart valve replacement: i) history of work with metal resulting in an injury: j) eye injury with metal: k) history of strokes/seizures: l) participants in the waitlist group.

C.5 Recruitment and Attrition Considerations

C.5.1 Recruitment:

Recruitment will take place at the University of Illinois at Chicago campus, Oakwood Shores, clinics, churches, parks, free online community resources including Craigslist, and surrounding community areas. Recruitment will occur through advertisements about the study to individuals through printed brochures, flyers, news papers ads and announcements about the study. This will be followed by a telephone call where potential subjects can opt to go through the telephone or in-person screening process. The Resident Service Coordinator at Oakwood Shores will aid in the distribution of recruitment material and collection of names and numbers of potential

participants. The Resident Service Coordinator will not be responsible for conducting screenings or the collection of participant data, so will not be listed as authorized research personnel.

C.5.2 Attrition and Study Non-Completers/ Issue of Dropouts:
We estimate that 33% of subjects will not complete the protocol. While it would be optimal to have higher completion rate, this rate appears to represent the nature of the population. Subjects will also be financially compensated for each visit. Subjects will receive $55 on via check delivered through the mail.. This payment will be in the form of a check and will be mailed to the participants' desired address. The following strategies for subject retention will be used: phone reminders/confirmation of visits, and established contact with the study coordinator. We will provide participants with a document that includes a list of scheduled appointments on the back. Based on these strategies, we anticipate that drop-out will be minimized to 33% of the sample.

C.6 Assessment of Subjects

C.6.1 Screening Measures (35 minutes)
Screening Form: This questionnaire asks respondents questions about medical and psychiatric history, related to the inclusion/exclusion criteria for this study. The screening form will be utilized prior to subject enrollment, either in person or over the phone, to determine if someone would be a good fit for participation in the study. (15 minutes)

MRI Screening Form: This questionnaire asks respondents questions about their medical history and willingness to participate in the MRI testing. The MRI screening will be given either over the phone, at the time of the general study screening, or in-person during the baseline visit (5 minutes).

Exercise Assessment and Screening for You (Resnick, 2008) A self-report questionnaire assessing conditions that might prohibit someone from safely engaging in physical activity (2 minutes).

Six-Item Screener: (Callahan et al., 2002) A brief screen for cognitive impairment and dementia that includes three orientation items (year, month, day of the week) and delayed recall of three items. When a cut-off score of ≤1 error is used for diagnosing dementia, sensitivity is reported as 100.0 for community-dwelling elders. (2 minutes)

Patient Health Questionnaire (PHQ-8): A self-report questionnaire assessing symptoms of depression and appropriate for use when a clinician is not involved in the assessment.

C.6.2 Clinical Interview (Approximately 15 minutes)
World Health Organization Disability Assessment Scale (WHO-DAS-II; World Health Organization, 2000). A clinician-administered measure of functioning in six-domains (15 minutes).

C.6.3. Self-Report Questionnaires (approximately 50 minutes)

The composite list of questionnaires includes the following outcomes: health and disability status, depression and affect, physical activity, sleep and fatigue, falls, history, and balance confidence, stress and social/emotional well-being, mobility, and cognitive functioning.

Physical Activity Scale for the Elderly (PASE) [Washburn et al., 1993]. A measure of weekly physical activity (5 minutes).

Western Ontario and McMasters University Osteoarthritis Index [Bellamy et al., 1989]. Set of standardized questionnaires used to collect data on arthritis-specific symptoms using 24 parameters (5 minutes)

Self-Efficacy for Exercise Scale [Resnick and Jenkins, 2000]. A self-report questionnaire developed for older adults addressing expectations around self-efficacy regarding the ability to continue engaging in exercise in the face of hurdles to exercise (3 minutes).

Chronic Conditions: GERI-AIMS: Checklist of chronic medical conditions (3 minutes)

Cardiovascular Risk Factors Questionnaire: Adapted from the Guidelines of the American College of Sports Medicine, ACSM (2000), A brief screening to determine subjects cardiovascular risk factors (5 minutes).

The Established Populations for the Epidemiologic Study of the Elderly (EPESE) Questionnaire: A Likert-type scale for rating of ability to complete basic and instrumental activities of daily living. (5 minutes)

Apathy Evaluation Scale-Self Report: (Marin et al., 1991). 18-item scale asking respondents to rate symptoms of apathy on a 4-point Likert scale. (3 minutes)

Snaith-Hamilton Pleasure Scale: 14-items rated on a 4-point Likert scale reflecting experience of pleasure over the last two weeks. (3 minutes)

Activities-Specific Balance Confidence Scale (ABC; Powell et al., 1995) The ABC is a self-administered measure of balance self-efficacy. Participants indicate their level of self-confidence on a scale of 0 (no confidence)-100 (completely confident) in maintaining balance for 16 different activities performed during a typical day. Internal consistency was .96 among community-dwelling elders, with 2-week test-retest correlation coefficient of 0.92. (5 minutes)

Emotional Well Being Scale: Asks respondents to rate on a 5-point Likert scale the extent to which they experienced 6 positive emotions in the last 30 days. (2 minutes)

Life Satisfaction Survey: 5-item scale that asks respondents to list the extent to which they agree (using a 7-point Likert scale) with statements related to life satisfaction. (2 minutes)

Perceived Stress Scale: 10-items rated on a 5-point Likert scale reflecting the perception of stress in the last 30 days. (3 minutes)

The Stages of Change Questionnaire: A 4-item scale assessing physical activity. (1 minutes)

Social Provisions: A 24-item scale assessing current social behaviors. (5 minutes)

C.6.4: Mobility Measures (19 minutes)

Timed Up and Go: (Shumway et al., 2000).

Measures, in seconds, the time taken by an individual to stand up from a standard arm chair (approximate seat height of 46 cm, arm height 65 cm), walk a distance of 3 meters (approximately 10 feet), turn, walk back to the chair, and sit down (2 minutes).

Grip Strength Test: (Gershon et al., 2013): Participants are required to go through a test that assesses upper extremity strength with the use of a dynamometer (3 minutes).

Standing Balance Test: Gershon et al., 2013). This measure enables the detection of a participants' postural sway by an iPad attached to a gait belt (7 minutes).

4 Meter Walk Gait Speed Test: Gershon et al., 2013). Participants walk down an open hallway at normal pace while being timed (3 minutes).

9-Hole Pegboard Dexterity Test: (Gershon et al., 2013). Participants are asked to place pegs into a pegboard and remove them in a timely manner to assess fine motor dexterity (4 minutes).

C.6.5: Neuropsychological Testing Measures (Approximately 40 minutes)

Montreal Cognitive Assessment (MoCA): A timed screening assessment used to assess attention and concentration, executive functions, memory, language, visuo-constructional skills, conceptual thinking, calculations and orientation (10 minutes).

Picture Sequence Memory Test: Gershon et al., 2013). A measure requiring the subject to recreate the picture sequence presented on the screen before them (7 minutes).

Flanker Inhibitory Control and Attention Test: Gershon et al., 2013). Participants are required to focus on an arrow (stimuli) while preventing their focus from the stimuli flanking it (3 minutes).

List Sorting Working Memory Test: Gershon et al., 2013). This measure consists of the task of sorting out the images of foods and animals displayed on the screen from smallest to largest (7 minutes).

Dimensional Change Card Sort Test: Gershon et al., 2013). A measure requiring participants to match a series of bivalent test pictures to the target pictures according to suggested dimensions (4 minutes).

Pattern Comparison Processing Speed Test: Gershon et al., 2013). Participants are required to compare two side-by- side pictures to determine if they are identical (3 minutes).

Auditory Verbal Learning Test: Gershon et al., 2013). Measure testing immediate recall. Participants are presented with an audio recording of unrelated words and asked to recall as many as possible (3 minutes).

Oral Symbol Digit Test: Gershon et al., 2013). Measures the speed of processing. Participants are presented with a screen of symbols associated with certain numbers and then asked which number goes with the symbol (3 minutes).

C.6.6: Multimodal Neuroimaging Testing (Approximately 90 minutes)

Subjects participating in the optional MRI component of the study will attend two 90 minute sessions at the UIC Advanced Imaging Center. Participants will be asked to lie still on a padded table and be placed inside of the MRI machine. During each session, the MRI

machine will produce imaging of each participant's brain. Participants will be allowed to request earplugs to wear during the procedure, as the machine is quite noisy. In the case that a participant should start to feel claustrophobic, the MRI testing will be stopped immediately. The total time each participant will be asked to stay inside the machine should be no more than an hour. MRI testing will take place at baseline before the exercise intervention and after the intervention (week 9). A taxi will be provided to and from the imaging center for participants that need it. Participants will be paid $50 at each session ($100 total).

C 6.7. Data Analysis/Interpretation*:* Participation rates and program acceptability ratings will be quantified. Changes in depressive symptoms and positive and negative affect will be analyzed using a repeated measures ANOVA model. Between-group analyses will be conducted to determine whether significant changes occur in the outcomes between baseline, 9- and 18-weeks to examine maintenance effects over time. A mixed-effects model will be used to determine whether intervention participants significantly increased their participation in physical activity between baseline and 9- and 18-weeks. Within-group analyses will also be conducted to determine whether participants improved in depressive symptoms, positive and negative affect, and physical activity between baseline, immediately following Fit & Strong! participation, and 2 months post-Fit & Strong! participation. Finally, the Baron and Kenny Causal Steps approach [Baron and Kenny, 1986] will be used to determine whether change in physical activity between baseline and immediately post Fit & Strong! mediates the decrease in depressive and positive and negative affect. A process evaluation will be conducted to measure aspects of program implementation including fidelity, intervention dose received, participant attrition, and program acceptability ratings. [Washburn et al., 1993; Miller et al., 1992; Bellamy, 1989; Hughes et al., 1991; Resnick and Jenkins, 2000]See Appendix C. [Maust et al., 2013; van Loon et al., 2013]

C 6.8. Data and Safety Monitoring Plan
Weekly meetings of the research staff of this study will be conducted that will include review of accrual, consenting procedures, protocol adherence, adverse events, and quality control of all data obtained from the study in the previous week. All changes in protocol design will be reviewed by the IRB at the University of Illinois at Chicago before such changes in protocol design will take place. All AEs occurring during the course of the study will be reported to the PI. All AEs will be evaluated, medically treated or referred to medical treatment, and followed until satisfactorily resolved. If deemed necessary by a physician, a subject may be withdrawn from the study. AEs will be evaluated for serious adverse event (SAE) as appropriate. The initial report will be followed by a complete SAE report and sent to the IRB. If a subject from the study or the PI discontinues a subject's participation due to a SAE, the subject will receive follow-up medical care as necessary. Follow-up care will continue until the subject no longer requires medical care as necessary. Follow up care will continue until the subject no longer requires hospitalization, the condition is stabilized with no future change expected, the problem is determined to be unrelated to the study, or the subject dies. The outcome of SAEs will be reported to the IRB.

C.7: Fit & Strong Intervention
C.7.1: Fit & Strong Session Outline (See Table 1, after citations)

C.7.2 Program Fidelity. Program fidelity will be monitored with the Fit and Strong! Plus Implementation Checklist and observation of the intervention by study investigators during one Fit & Strong class per 8-week session.
Table 1

D. Protection of Human Subjects

D.1 Risks to the Subjects

D.1.1 Human Subjects Involvement and Characteristics

We will enroll 40 subjects in this study age 60 and over, all of whom are from the community for participation in an adapted version of the Fit & Strong program. Inclusion and exclusion criteria are described in the Research Design and Methods section.

D.1.2 Sources of Material

The research material obtained from the human participants will consist of data in the form of diagnostic evaluations and interviews administered by a trained clinician or trained research staff, standardized neuropsychological test results, experimenter-administered task responses, and self-report questionnaire responses. These data will be used strictly for research purposes.

D.1.3 Reporting Adverse Events (AEs)

Bi-weekly meetings of the research staff of this study will be conducted that will include review of accrual, consenting procedures, protocol adherence, adverse events, and quality control of all data obtained from the study in the previous weeks. All changes in protocol design will be reviewed by the IRB at University of Illinois at Chicago before such changes in protocol design take place. All AEs occurring during the course of the study will be reported to the PI. All AEs will be evaluated, medically treated or referred to medical treatment, and followed until resolved satisfactorily. If deemed necessary by a physician, a participant may be withdrawn from the study. AEs will be evaluated for serious adverse event (SAE) criteria (defined by the FDA). If an SAE should occur, it will be reported to the R&D and IRB as appropriate. The outcome of SAEs will be reported to the R&D and IRB.

D.1.4 Training in Fair, Responsible, and Ethical Conduct of Research

The PI and the research team have undergone training in fair and ethical conduct of research in general and on human subjects at the University of Illinois at Chicago. All personnel also up to date on this IRB training. The PI and the research team have taken HIPAA training mandated by the University of Illinois at Chicago.

D.1.5 Potential Risks

The structured diagnostic interviews (and questionnaires) are time consuming and may be boring to some individuals. These are, however, necessary in order to categorize subjects for study. In addition, questions about alcohol/drug use, interpersonal relationships, and questions related to history of suicidal and/or homicidal behavior may be considered sensitive by some subjects. The collection of such data poses a potential risk of loss of confidentiality around sensitive information such as psychiatric status, history of substance abuse, etc. Interviews will be conducted by trained staff to conduct assessments who will maintain confidentiality and all data from interviews and questionnaires will be numbered so as to conceal the identity of the subject.

If a truly unanticipated result and compelling reason to attempt to inform subjects becomes evident - either for an individual or for a group, we will submit a request to the University of Illinois IRB to send a letter to ALL subjects enrolled in the study stating that information may be available with a phone number and have a trained person available to answer questions. However, we don't anticipate any such results. Decisions regarding when something is of importance will be made by the study investigators in consultation with a genetic counselor. Study participants will not be responsible for the costs of genetic counseling incurred because of this study.

As with any exercise program, there is always a risk of injury or overexertion. There is a possible risk of physical injury such as risks associated with falls, including muscle or bone injury. A trained professional will lead the class in order to decrease the likelihood of this occurring. Also, we encourage all participants to monitor their own safety and inform the instructor if they have any concerns. Participants may have pain in their joints and sore muscles due to exercising. We do not expect anyone to feel severe pain, and any pain should go away in a few days. The class leader will encourage anyone feeling any pain to take a break or stop participating that day or to engage in a type of exercise that is less strenuous. Participants will also learn ways to exercise safely so that they do not experience any pain or stiffness, and they will learn how to treat pain safely at home.

MRI scans:
The MRI scans are performed with a powerful magnet, without using x-ray radiation or radioactive material. A specially designed computer converts information from the MRI scan into a visible image. The magnetism of the machine attracts certain metals, which could put participants at risk. Therefore, participants with pacemakers, infusion pumps, metallic-backed transdermal patches, metallic shrapnel, or any other metal in their body, will be excluded from the study. Participants may feel somewhat closed in (claustrophobic) during the MRI procedures. Also, the MRI scans will get quite noisy, and this may cause participants some discomfort, which can be aided through the provision of earplugs. Participants will be told of the potential discomfort of the scan and given a screening form to ensure they meet the physical requirements to participate.

D.2. Adequacy of Protection against Risk

D.2.1 Suicidal Risk

The clinician, Dr. Olu Ajilore MD, PhD; Associate Professor; Associate Director, Residency Training and Education; Co-Director, Adult/Neuroscience Research Track; Department of Psychiatry, or research staff may remove a subject from the study if the clinical team thinks that the subject is at imminent suicidal risk, which, while not specifically assessed, may come up during the course of the study, given that individuals with significant depressive symptoms will be enrolled in the study. If the patient is deemed to have specific suicidal ideation during any of the visits, the PI and clinician will be immediately notified, and an appropriate clinical decision for emergent psychiatric evaluation will be made, including an evaluation of the need for hospitalization.. If the potential participant brings up suicidal ideation during the phone screen, they will be referred to the suicide prevention hotline.

D.2.1 Informed Consent

In most cases, potential subjects will learn basic information about the study during a telephone or in-person screening, and an informed consent will be mailed to those who are eligible for/interested in the study. At the time of initial contact with the study coordinator, subjects will be given detailed information about the study and the informed consent form will be reviewed and signed. Written consent from the participant will be obtained before the diagnostic interview begins. A copy of the document will be given to the study participant and the original informed consent document will be kept in a locked cabinet in the principal investigator's laboratory, separate from all other study materials. Other study materials (e.g., assessment measures) will be coded by an anonymous identification number. This identification number will be linked to the subject's name in an electronic database that can be accessed only by double password authentication. Participants will also be presented with an Informed Consent Addendum form addressing the MRI inclusion to the research study. They will be asked if they are willing to participate and will be informed of the additional compensation upon completion of each MRI

session. Participants will also be informed that refusal to participate in the MRI testing will have no effect on their participation in the research study.

D.3 Protections Against Risk

D.3.1 Protection Against Risk of Psychological and Social Discomfort

In order to increase the participant's comfort before, during, and after the study visits, the following steps will be taken:

1) The clinical interview will be conducted by the PI or a well-trained clinician study team member in a private exam room.
2) Neuropsychological testing will be conducted by a trained research assistant/study coordinator. The PI will be available at all times during the study visits, and the research assistant will be instructed to contact the PI if any problems arise.
3) If it is found, during the course of the study visit, that the person is in danger of harming themselves or someone else, we are legally mandated to alert the proper authorities in order to prevent the participant or another person from being harmed. Subjects will be informed of this at the initiation of the research study, and a statement about this will be included in the informed consent document.
43) The door to study rooms will be kept closed, with a "do not disturb-testing in progress" sign posted on the door.
4) Subjects will be given breaks as needed, and they may discontinue their participation at any time without loss of compensation.

D.3.2 Protection Against Risk of Breach of Confidentiality

Participants will be identified by number on all data collected during the course of their participation except the original signed informed consent document. Their name will be connected with their subject ID number in one password protected database, accessible only by study team members. Data will need to be linked in order to link information obtained during subsequent visits. Informed consent forms will be stored separately from the remainder of the data, and these will not be linked in any way. Informed consent forms and hard copies of the data will be stored in a locked filing cabinet at UIC. Digital data will be stored on a password protected document. When the results of the research are published or discussed in conferences, no information will be included that would reveal the subjects identity.

MR images will be stored on secure machines within the UIC Advanced Imaging Center. The MR images will only be accessible to authorized study staff via a login/password.

D.3.3 Protection Against Risk of Injury, Overexertion, and Pain Associated with and Exercise

1) A trained professional will lead the class in order to decrease the likelihood of injury or overexertion occurring. Also, we encourage all participants to monitor their own safety and inform the instructor if they have any concerns.

2) . The class leader will encourage anyone feeling any pain to take a break or stop participating that day or to engage in a type of exercise that is less strenuous. Participants will also learn ways to exercise safely so that they do not experience any pain or stiffness, and they will learn how to treat pain safely at home.

D.4 Potential Benefits of the Proposed Research to the Subjects and Others

Participants may or may not benefit from increased physical activity.

The risks to subjects are no greater than minimal, and every effort will be made to abate these risks while maintaining data quality. Thus, the potential benefit to participants and the population at large to be gained by the proposed study outweighs the potential for injury or discomfort.

D.5 Importance of Knowledge to be Gained

The knowledge to be gained about the potential efficacy of exercise as a treatment for depressive symptoms among older adults is of great importance to the general population and general healthcare. The risks to subjects posed during the course of the study are minimal, and every effort will be made to reduce these risks while maintaining data quality. Thus, the importance of knowledge to be gained by the proposed study outweighs the potential for injury or discomfort.

D.6 Inclusion of Women and Minorities

Both women and minorities will be included in the study, and given the demographics of veterans in the UIC community, we expect that at least 50% of our research volunteers with be ethnic minorities, and at least 50% of our volunteers will be women. Volunteers will not be excluded on the basis of gender or minority/ethnic/racial status.

Citations

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		Topic	Topic
1	1	Welcome to Fit & Strong!	Welcome to Fit & Strong!
	2	Getting Started	Getting Started
	3	What to Wear & Foot Care	What to Wear & Foot Care
2	4	Osteoarthritis	Depression
	5	Managing Osteoarthritis through Exercise	Managing Depression through Exercise
	6	Pain & Osteoarthritis	Warm Ups
3	7	Warm Ups	Pain & Depression
	8	Stretching	Stretching
	9	Aerobic Exercise	Aerobic Exercise
4	10	Walking	Fall Prevention
	11	Strengthening	Walking
	12	Resistance Training to Improve or Maintain Strength	Strengthening
5	13	Cool-Down Exercises	Exercise as an Energy Booster
	14	Posture & Bone Health	Resistance Training to Improve or Maintain Strength
	15	Fall Prevention	Cool-Down Exercises
6	16	Negotiated Adherence Contract	Negotiated Adherence Contract
	17	Other Ways to Do Exercises	Other Ways to Do Exercises
	18	Lifestyle Changes	Lifestyle Changes
7	19	Exercise: A World of Options	Exercise: A World of Options
	20	Getting Past Barriers	Getting Past Barriers
	21	Diet & Exercise	Diet & Exercise
8	22	Stress Management	Stress Management

		Topic	Topic
	23	Maintaining an Active Lifestyle	Maintaining an Active Lifestyle
	24	Putting it All Together	Putting it All Together