Fit and Strong! Plus Comparative Effectiveness Trial

NCT03180008

Trial protocol and analysis plan

7/22/2016

SIGNIFICANCE (All revisions are in bold and *italics*.)

Osteoarthritis (OA) is the most common condition affecting older adults and the principal cause of disability among them (Hootman et al., 2009). Previously, we demonstrated that lower extremity *(LE) joint impairment caused by OA is the route through which disability develops* (Dunlop, Hughes et al., 1998). *Importantly, LE symptomatology related to OA can be caused or exacerbated by obesity***.** Longitudinal data show that a 5.1 kg weight loss over 10 years decreased the odds of developing knee OA by more than 50% (Felson et al., 1992). Obesity also exacerbates OA pain and disability (Hartz et al., 1986). Cross-sectional data from population-based studies show strong associations between moderate overweight and self-reported OA of the hip or knee (OR = 1.7), chronic LE pain (OR = 1.6) and mobility disability (OR = 1.7) (Tukker, Visscher, and Picavet, 2009) as well as associations between foot OA, obesity, and impaired functional performance on chair stand and 8-foot walk times (Golightly et al., 2011).

The prevalence of obesity (BMI ≥ 30) among older adults has increased rapidly in the U.S. For example, the prevalence of obesity among people aged 60-69 increased 56% between 1992 and 2002 (Villareal et al., 2005). By 2007-8, 37.1% of men and 48.1% of women 60 or older were obese.(Flegal et al., 2010) ***Despite this increase, a recent meta-analysis reports a lack of high quality evidence to support the efficacy of weight loss programs in older adults (Witham and Avenell, 2010). Nationally, obesity prevalence in 2009 was 54% higher among adults with arthritis than among those without the condition, and the number of states with prevalence > 30% increased from 38 in 2003 to 48 (Hootman et al., 2011a). Recent CDC data indicate that arthritis affects 35.6% of persons with obesity. Importantly, persons who were obese and had arthritis were 44% more likely to be physically inactive compared to persons who were obese without arthritis (Hootman et al., 2011b).***

The relationship between obesity and LE OA in part explains recent rapid increases in hip and knee replacement surgery in the U.S. In 2004, 225,900 hip and 431,485 knee replacements were performed, representing increases of 37% and 53%, respectively, since 2000 (Kim, 2008). Hospital costs for these procedures in 2004 were $11billion and nearly 600,000 hip and 1.4 million knee replacements are projected to be performed in 2015 (Wilson et al., 2008). ***Finally, simulations of the impact of obesity and knee OA on morbidity and mortality of older Americans estimate that total losses of per-person quality-adjusted life years range from 1.9 in non-obese persons with OA to 3.5 for persons affected by both conditions, resulting in 86.0 million quality-adjusted life-years lost to obesity, knee OA, or both, with disproportionately high losses seen among Hispanic and black women. Reversing obesity levels to those seen 10 years ago would avert 111,206 total knee replacements (Losina et al. 2011).*** Together, this body of evidence indicates an urgent need for the testing and rapid translation of evidence-based public health interventions that can reverse or mitigate obesity among older adults with OA.

Completed Work. Fit and Strong! is an evidence-based physical activity (PA)/behavior-change program that effectively addresses symptoms experienced by older adults with LE OA (Hughes et al., 2004; Hughes et al., 2006). Previous research has shown that older adults with OA have strength and aerobic deficits compared to age matched controls (Fisher et al., 1991; Minor et al., 1989). The pain and stiffness older adults with OA experience in weight bearing LE joints leads to and/or exacerbates sedentary behavior in this population. Sedentary behavior, in turn, leads to muscle wasting and decreased aerobic capacity. Fit and Strong! was designed to address and reverse these deficits. Fit and Strong! is a group- and facility-based program that meets 90 minutes, 3 times per week for 8 weeks (24 sessions total). The first 60 minutes focus on multiple-component exercise including flexibility/balance, aerobics, and LE strengthening using exercise bands and adjustable ankle cuff weights. Instructors progressively challenge participants' balance during exercise. The remaining 30 minutes are devoted to group problem solving and education using a Social Cognitive Theory (SCT)-based curriculum that facilitates arthritis symptom management and promotes self-efficacy (SE) for exercise and adherence to exercise over time. In Week 6, participants meet with instructors to *negotiate* an *individualized* PA maintenance plan with the goal of maintaining 20 minutes of flexibility, aerobic, and strength exercise 3 or more times per week.

Efficacy. We tested the *efficacy* of Fit and Strong! in an RCT with 215 individuals with OA (Hughes et al., 2004; Hughes et al., 2006). Relative to controls, treatment participants improved significantly in SE for exercise, exercise participation, and LE stiffness after 8 weeks. At 6 months, participants retained the original gains and had significant benefits vs. controls in SE for exercise adherence, LE pain, and SE for arthritis pain management. At 12 months, significant effects were maintained on SE for exercise and exercise participation,

accompanied by marginally significant reductions in LE stiffness and pain. Effect sizes were *0.798 and 0.713* for SE for exercise at 6 and 12 months, respectively, and *0.905 and 0.669* for exercise participation in the treatment group.

The exercise component of Fit and Strong! was originally designed and taught by licensed physical therapists but is now taught by certified exercise instructors (CEIs) to expand its reach (Glasgow, Vogt, and Boles, 1999). At 2 and 6 months participants under both instruction modes improved significantly over baseline with respect to LE pain, stiffness, physical function, LE strength (timed-stand), and aerobic capacity (6 minute distance walk) (Seymour, Hughes et al., 2009). Participants rated both types of instruction highly, attendance was identical, and n*o adverse health effects were reported.*

Effectiveness. Our recent effectiveness trial (N=486) compared two ways of reinforcing maintenance of PA after the 8 week program ends. We compared maintenance outcomes for participants with a customary Fit and Strong! negotiated maintenance plan to participants who were mainstreamed to an existing PA program at the same facility. We examined the effectiveness of both approaches with and without tapered telephone reinforcement (TR) (NIA R01 AG23424). Findings showed that persons in the *negotiated TR group* showed the greatest amount of PA maintenance at 18 months, followed by the *customary negotiated follow-up* group (Hughes et al., 2010). *Across all four study arms, we found significantly increased maintenance of PA at 18 months as well as significantly improved LE stiffness, pain, and function; LE strength (sit-stand); 6-minute distance walk; and anxiety and depression (Hughes et al., 2010).* ***The impact on gait speed is notable given recent findings that gait speed, along with age and sex, is a strong predictor of survival (Studenski et al., 2011).***

Translation. We are currently funded by CDC (R18 DP001140) to translate Fit and Strong! in collaboration with Area Agencies on Aging in Illinois and North Carolina. Both CDC and AoA have recommended Fit and Strong! as an evidence-based program that all states should promote. We also provide the program in Florida in collaboration with the Health Foundation of South Florida and the Florida Department of Elder Affairs. Single group pre-post findings from a reduced set of outcomes obtained on the first 272 participants in this effort show a continued statistically significant impact on LE pain and stiffness, energy/fatigue, and SE for exercise at two months accompanied by a *marginally significant impact on BMI*, demonstrating consistent benefits of the program on important outcomes. However, *the current program does not explicitly address the relationship between weight and presence/exacerbation of LE OA symptomatology, nor does it address changes in diet for sustained weight loss over time.*

To date, two studies have shown that combining PA with weight loss is more effective than either approach alone in improving the functioning of older adults. Rejeski et al. (2011) found that a combined PA/reduced caloric intake intervention with older adults with cardiovascular disease achieved an 8% weight loss at 6 months that was maintained at 18 months, accompanied by improved mobility. Using a similar approach with a general population of older adults, Villareal and colleagues found a 9% decrease in weight at 12 months that was accompanied by a 21% increase on the physical performance test (Villareal et al., 2011). Importantly, to date, <u>only one study</u> (ADAPT) has tested the impact of combined PA/weight reduction on older adults with OA. The ADAPT trial randomly assigned 316 sedentary persons 60 years of age and older with knee OA and BMI > 28 kg/m^2 to one of four 18-month interventions: dietary weight loss, exercise, dietary weight loss + exercise, or control (Messier et al., 2004). The <u>ADAPT *PA intervention* was very similar to Fit and Strong!</u>, using a 24-week intensive *facility-based program* that met 3 times per week for 60 minutes. Exercises included flexibility, aerobics, and resistance training. At 4 months, participants transitioned to a home-based program accompanied by TR. The <u>*weight control* intervention</u> sought to achieve an average weight loss of 5% over 18 months through a 4-month intensive phase (16 weekly sessions), a 2-month transition phase (bi-weekly sessions), and a 12-month maintenance phase (monthly sessions plus TR). The intervention focused on lowering caloric intake by improving self-regulatory skills.

The combined PA/diet group showed the strongest effects, including significant improvement in LE physical function (WOMAC), 6-minute distance walk, stair-climb time, and knee pain, as well as a 5.7% weight loss. These findings indicate that *a combination of modest weight loss plus moderate exercise provides better pain and mobility outcomes for obese adults with knee OA than weight loss or PA alone* (Messier et al., 2004). In a more recent study that included a weight loss component based on meal replacement, nutrition education, and lifestyle behavior modifications, Messier and colleagues found a weight reduction of 8.7% at six months (Messier et al., 2009). However, meal replacement is probably not scalable as a public health strategy for

diverse populations (Miller et al., 2006). The importance of findings from both Messier studies is reinforced by a recent meta-analysis which demonstrated that *physical disability among overweight persons with knee OA diminishes after a moderate weight loss (5%) and indicated that this level of weight loss is achievable within 20 weeks (Christensen et al., 2007).*

INNOVATION

Despite the urgent need for interventions that target overweight/obese older adults, a recent meta-analysis found a striking lack of evidence supporting the effectiveness of weight loss interventions for this population (Witham and Avenell, 2010). Interventions that combined PA and diet had the best results with respect to weight reduction. However, of 9 studies examined, only 2 combined PA with diet. One was ADAPT (reviewed above) and the other examined outcomes only to 12 months (Villareal et al., 2008). To date, ADAPT is the only trial that has demonstrated that it is <u>possible</u> to reduce caloric intake among older adults with OA, resulting in a 5.7% weight loss. However, ADAPT was conducted in clinical settings with limited scalability. The subsequent IDEA trial achieved an 8.7% weight loss at 6 months but used a meal replacement approach that is also not scalable. Rejeski's study of patients with cardiovascular disease is the only example of a 'scalable' PA/dietary intervention for older adults of which we are aware. However, the scalability of the intervention is limited due to program length (weekly sessions for 6 months), and the use of a dietician. Thus, the need for a scalable, efficacious PA/dietary intervention for the sizeable population of older adults with LE OA remains.

Eighty-five percent of participants in our effectiveness trial were overweight or obese at baseline, and many requested more help with diet and weight management than the curriculum currently offers. We propose to address this need by examining the feasibility, efficacy, and effectiveness of an intervention that combines an evidence-based PA program (Fit and Strong!) with elements of two evidence-based dietary programs (ADAPT and ORBIT). <u>Several elements of the proposed study are highly innovative</u>: 1) <u>We will address a serious gap in the armamentarium of tools currently available to address the critical problem of obesity among older adults with LE OA</u>. We will fill this gap by incorporating an evidence-based weight management protocol into the Fit and Strong! health education curriculum using intervention content and methods from both the ADAPT and ORBIT trials. Co-PI Marian Fitzgibbon, PhD, recently completed the NCI-funded Obesity Reduction Black Intervention Trial (ORBIT) (CA105051). ORBIT tested the impact of a PA/diet intervention on obese middle-aged African American women. Using SCT and dietary change, ORBIT achieved a 5% reduction in weight at 6 months that was maintained at 18 months, very similar to the ADAPT findings (Fitzgibbon et al., 2010). 2) <u>The proposed PA/dietary intervention is scalable, and we have the experience and capacity to bring it to scale</u>. We have demonstrated consistent benefits from Fit and Strong! across time, multiple geographic sites, instructors, and populations. The combination of this program with elements of effective dietary interventions in community-based settings has substantial potential to address the lack of scalable, efficacious PA/dietary interventions for older adults with OA. Further, our 8-week Fit and Strong! program benefits LE pain, stiffness and function using the same WOMAC and 6-minute distance walk measures used by ADAPT, but <u>in half the time</u> which is important for adoption purposes (Green & Glasgow, 2006). As the NIA Midwest Roybal Center for Health Promotion and Translation, we have the capacity to bring Fit and Strong! Plus to scale quickly if it demonstrates efficacy. We have developed instructor training protocols, an interactive website that tracks attendance and participant outcomes (www.fitandstrong.org), Participant and Instructor Manuals, and standard procedures to monitor program fidelity in the field. We also have a Roybal Advisory Committee that includes representatives from several groups that are key to translation of EB programs, both locally and nationally (see Appendix A for Committee Roster). A recent review of 19 weight loss studies found that very few addressed issues of translation into real world settings and urged that future studies address how programs will be adopted and maintained with special attention to costs for participants and for program implementation (Akers, Estabrooks and Davy, 2010). 3) <u>We now test the impact of dietary change as a route to weight loss out to 24 months</u> in contrast to 18 month outcomes reported by current studies. 4) <u>We will examine health care claims data and health-related quality of life pre and post both interventions</u>. Fit and Strong! is currently being considered for inclusion in a Centers for Medicare and Medicaid Services (CMS) evaluation of appropriateness for Medicare reimbursement. The CMS data will enable us to examine impact of both programs on health care use and cost. 5) We will <u>conduct the trial in local Park Department sites. Parks and Recreation</u>

sites are located all over the country and provide a systems delivery mechanism for taking Fit and Strong! Plus to scale. For all of these reasons, we believe we have reached an ideal time to test whether the already substantial impact of Fit and Strong! can be modified to achieve even greater improvements among persons with OA by also addressing weight management needs that are so common in this population.

APPROACH

We propose to conduct a randomized controlled trial to examine the feasibility, efficacy, and comparative effectiveness of two community-based health promotion programs for older adults with OA: our evidence-based *Fit and Strong!* PA program and an enhanced program, *Fit and Strong! Plus*, that includes elements common to two existing evidence-based behavior change dietary interventions.

Proposed Study Team. The interdisciplinary team that will conduct this work is very strong. It includes Co-PIs **Susan Hughes**, DSW, Professor, School of Public Health and Co-Director, Center for Research on Health and Aging in the Institute for Health Research and Policy at the University of Illinois at Chicago ***and Marian Fitzgibbon, PhD, Professor, School of Medicine and behavioral psychologist with expertise in lifestyle and weight loss interventions. Dr. Fitzgibbon designed the weight management protocol used in the ORBIT trial and will perform the same function in this trial. Carol Braunschweig, PhD, Associate Professor Kinesiology and Nutrition, will serve as the study dietician.*** Other key investigators include Richard Campbell, PhD., Division of Biostatistics and Epidemiology, James Shaw PhD, pharmaco-economist and Assistant Professor in the School of Pharmacy, Gail Huber, PhD., Assistant Professor, School of Physical Therapy, Northwestern University, and Juan Chang, M.D., M.P.H., study rheumatologist. Finally, **Pankaja Desai**, PhD, who examined the impact of TR on mediators of PA in our effectiveness trial, will serve as Co-I and Project Manager. ***With the exceptions of Drs. Fitzgibbon and Braunschweig, all team members contributed to the development, implementation, and or evaluation of the original Fit and Strong! program and have experience providing PA interventions, including those designed for older adults. The PI has experience developing and studying dietary interventions including recent comparisons of the impact of a web-based health promotion/behavior change program to use of a health educator coach (1 R01 DP000094-01, 1 R01 DP001170-02). Behaviors examined included PA, healthy diet, stress, smoking, BMI, and waist circumference. Six- and 12-month findings showed superior outcomes for the Coach group on PA and diet (e.g. fruit and vegetable consumption and decreased percent energy from fat (Hughes et al., 2011). Drs. Fitzgibbon and Braunschweig also have extensive experience with dietary interventions, including ORBIT (CA105051), the program that will contribute to our proposed dietary component in Fit and Strong! Plus.***

Conceptual Model—***We have used Social Cognitive Theory (SCT) (Bandura , 1982; Bandura 1989) and Self Determination Theory (SDT) (Deci and Ryan 1991; Deci and Ryan 1980; Deci and Ryan, 1985) to guide model development, intervention design, and selection of study measures. SCT specifies that behavior change occurs as a result of the dynamic interaction between modifications in behavior, cognition (self-efficacy, perception of barriers), and the environment (social support), and that modeling and reinforcement can be used to encourage change. SDT is a broad-based theory of human motivation (Ryan and Deci , 2000) that is increasingly cited to explain how personal or intrinsic motivation can lead to increased physical activity and improved eating patterns (Deci and Ryan, 1985). According to SDT, an individual's increased intrinsic motivation to improve eating and activity patterns should positively relate to self-efficacy and the ability to overcome barriers and solicit support.***

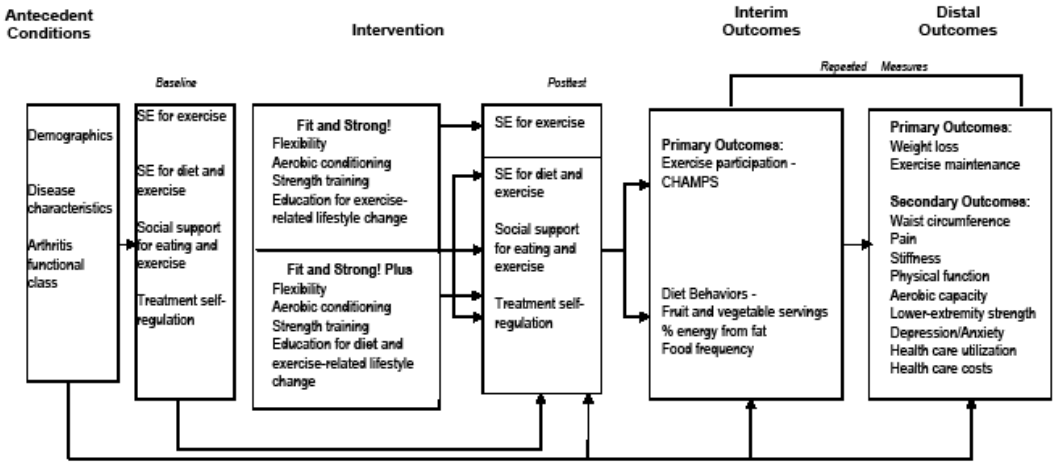

Figure 1. Conceptual Model for Proposed Fit and Strong! vs. Fit and Strong! Plus Comparison Study

Our Conceptual Model (Figure 1) shows that demographic, disease, and arthritis functional class variables are antecedents that will be controlled in multivariate analyses. These antecedent variables predispose some participants to be more responsive to both the PA and PA/diet interventions. SE/motivation for exercise and SE/motivation for dietary behaviors are expected to change as a result of exposure to treatment. They are also expected to mediate the impact of the interventions. ***Both the dietary change and PA interventions tested will use social modeling, exercise logs or food diaries, individualized goal setting, and shared group problem solving to increase mastery and goal achievement in small incremental steps to enhance self regulatory skills. We hypothesize that customary Fit and Strong! will increase SE and intrinsic motivation for exercise only; whereas Fit and Strong! Plus will increase SE and motivation for both exercise and weight loss. These mediators will impact the interim primary outcome of physical activity and dietary behaviors. These improved behaviors, in turn, are hypothesized to impact the more distal primary outcomes of exercise maintenance and weight loss along with the associated secondary outcomes shown.***

Pilot Studies—***We are currently piloting Fit and Strong Plus! with 11 older adults at the Chicago Park District Washington Park site. Results will be used to revise the intervention protocol. The revised protocol will be tested in a multi-site randomized trial with repeated measures to compare outcomes among participants in Fit and Strong! Plus to outcomes experienced by participants in the customary version of the program.***

Our 8-week pilot is now in week 4. Two instructors were trained to lead the program. Retention of participants is 90.9% (1 dropout weighed 340 lbs with a BMI of 56 and felt she was holding up the class). Average attendance is 8.5/10 sessions. Participant mean age is 68, 91% are female, 64% are African American, and 82% have hypertension. All participants have mild to moderate LE joint impairment. Mean weight at baseline was 214.4 lbs with a mean BMI of 36.3 (36.4% overweight and 63.4% obese, range 26.0-49.4). We obtained a subset of diet/weight outcomes in session 10 of 24. Findings showed a mean weight loss of 1.63 lbs, accompanied by a marginally significant decrease in percent energy from fat (P=0.064). We also debriefed participants and instructors to learn how the program was going. Participants reported dietary changes, some weight loss, and numerous improvements in function (stair climbing, flexibility, etc.). Instructors liked the Manual and loved including the new nutrition information. They believed that teaching the PA and Diet material in a single program was quite feasible (see pilot findings, Appendix B). Overall, findings were quite positive but indicate that we should use an upper end cut-point for BMI and provide BMI feedback to participants at the first class session along with information regarding ideal BMI for their gender and age, as well as "cheat sheets" summarizing diet guidelines for participants to use while food shopping. We will also allow participants to take the Manuals home at night or provide electronic copies so that they can read the health education material in advance of each session.

Design—As stated earlier, Fit and Strong! is a facility- /group-based program that lasts 8 weeks. Each class accommodates approximately *17* enrollees. We will enroll *400* persons who will be randomly assigned to participate in either Fit and Strong! or Fit and Strong! Plus (i.e.,*200* participants per group). Each intervention

will be repeated *4* times at *3* sites to achieve a final targeted baseline sample of *400* participants (i.e., 2 interventions x 3 sites x 4 replications x 17 participants = 408 participants). Outcome measures will be obtained at baseline, 2, 6, 12 and 18 months (see Figure 2, Projected Consort Flow Diagram, Appendix C).

Settings—We will partner with the Chicago Park District and Westside Health Authority (WHA) to conduct the trial. Although we require *3* sites to conduct the trial, the Park District has identified *4* sites that can participate, and WHA has identified 1 site. The Park sites include Smith Park (Northwest), Wicker Park (Northwest), Washington Park (Southeast), and Columbus Park (Southwest), and the WHA site includes their location on the westside (see more information about the sites in Appendix D). ***All sites are staffed by nationally certified exercise instructors who will be trained separately to conduct either customary Fit and Strong! or Fit and Strong! Plus. (See letters from Timothy Mitchell, CEO, Chicago Park District from Barbara Tulipane, CEO, National Recreation and Park Association, and from Morris Reed, CEO, Westside Health Authority in Section 14).***

Recruitment—Recruitment will begin in Year 1 and continue through Year *2.* Based on our experience enrolling *486* persons in our effectiveness trial*,* we will use multiple, diverse recruitment methods to screen an estimated *888* older adults in order to identify *533* (60%) who will meet all study inclusion criteria, *400* of whom will elect to participate in baseline measurement and the two interventions. The *Arthritis Foundation/Heartland Region* will assist with recruitment (see Section 14). Their database includes *7,000 older adults with OA.* Chapter staff will do direct mailings to older adults with OA *residing in zip codes served by study sites.* Staff will also publicize the study and refer older adults who call their information hotline. *Park District* sites will publicize the study in quarterly activity catalogs mailed to persons over 60 living in the same zip codes. The *UIC Department of Geriatrics* has a mailing list of 1,500 patients to whom it will send mailings based on zip codes. They also partner with the *Jesse Brown Veteran's Administration Hospital*, which provides access to an additional 4,000 people 65+ (see Section 14). Research staff will speak to groups about the study at all sites and obtain contact information from interested persons. Potential participants will be called to conduct follow up eligibility screens. Recruitment advertisements will ask interested persons to call a central registry number that will be fielded by research staff who will record contact information, screen callers for eligibility and schedule interviews for those deemed eligible. ***These procedures have been approved by the UIC IRB and were used successfully for the current Fit and Strong! Plus pilot.***

Procedures and Data Collection—We have experience training research staff for health risk reduction interventions and will use the same procedures we have used in the past. Training will take place prior to the initial interview and will cover an overview of the study, informed consent, interviewing skills, data check/editing, anthropometrics, participant contact (phone call etiquette and schedule for mailings), protocol for compensating participants, data scanning, and data packet construction. ***Prior to the pilot we developed an interviewer training manual covering all data collection procedures (see Training Manual, Appendix E).*** Project staff will obtain informed consent at the baseline interview. Participants will be paid $25 per interview for each of 5 interviews. In addition, four participants at each participating site (2 from each study group) who complete each posttest will be randomly selected to receive a $50 gift certificate to a local store of their choice. Participants will also be paid *$50 for participating in 24-month interviews*. CRHA staff will make at least 10 attempts to schedule interviews on different days of the week and at different times of the day before giving a case a final disposition. Posttest measurement *will take place at intervention sites* and will be scheduled on separate days for the two intervention groups.

Additionally, if participants complete data collection for the ancillary study (Protocol # 2013-0098) prior to their baseline/post-test interview, the height and weight data collected by the ancillary study will be used as part of the #2012-0277 study. Protocol # 2013-0098 has received approval through March 19, 2014. The study is called, "Effect of Community-based Lifestyle Interventions on Serum Biomarkers of Cancer Risk in Overweight and Obese Older Minority Adults with Osteoarthritis: A Randomized Trial". The data collection site for this protocol is the Integrative Physiology Lab in the UIC Disability, Health & Social Policy Building, at 1640 W. Roosevelt.

Randomization—After obtaining informed consent, participants will be assigned to Fit and Strong! or Fit and Strong! Plus using a randomized block design with blocks consisting of approximately ***17*** participants at each of the ***3*** sites. Within each block we will stratify by American College of Rheumatology (ACR) functional classes (I, II, or III) to achieve balance on arthritis severity by group. The random permutation of block sizes will help to minimize manipulation of an assignment.

Inclusion/Exclusion Criteria—Inclusion criteria include LE OA (hips, knees, ankles, feet, lower back), age 60+, no current participation in a regular exercise program, a calculated BMI of >=25 – 50 kg/m^{2} - (upper limit used in ORBIT) (Fitzgibbon et al., 2010) and willingness to participate in measurement and intervention procedures. The study rheumatologist will examine participants at the baseline interview to confirm presence of LE OA and determine ACR functional class. *Exclusion* criteria include severe cardiovascular disease, active thrombophlebitis, recent pulmonary embolus, an acute systemic illness, poorly controlled diabetes, other health conditions that might preclude exercise training, age <60, current participation in organized PA, uncomplicated hip or knee surgery within the previous 6 months or complicated surgery within the past year, steroid injections in either knee or hip within the previous three months, or diagnosis of rheumatoid arthritis. Participants with blood pressure readings 180/110 mm Hg or higher or 90/50 mm Hg or lower will be excluded.

Intervention Instructors—Exercise instructors delivering the programs will be certified by at least 1 of 10 possible nationally recognized certification bodies (e.g., ACSM, ACE, etc.). Certified exercise instructors (CEIs) will be trained separately to conduct either Fit and Strong! or Fit and Strong! Plus. The CEIs will lead exercise sessions, maintain participant attendance records, and negotiate participant adherence plans during week 6. They will also facilitate the group problem solving sessions (see Fit and Strong! Plus Instructor Manual in Appendix F). If both programs are offered at the same site on the same day, we will schedule one program in the morning and the other in the afternoon to minimize contact between both participants and instructors. An alternative will be to schedule one program Mon, Weds, Fri and the other Tues, Thurs, Sat. Instructors for customary Fit and Strong! will participate in *an 8-hour training protocol* that we developed and refined over multiple studies. The protocol reviews theories used to design Fit and Strong!, findings from completed research, along with detailed information and hands-on modeling of the exercise components (warm ups, flexibility, aerobic conditioning, strength training, cool down), role playing group problem solving processes, and negotiating PA contracts. Fit and Strong! Plus instructors will participate *in a 12-hour training protocol* for Fit and Strong! Plus that includes the full Fit and Strong! instructor training plus training on *diet and weight management.* The training will cover the *contribution of excess weight to disability and exacerbation of OA symptoms, the significance of a minimum 5% weight loss* for this population, components of a healthy diet, the new USDA my plate (choosemyplate.gov), food shopping on a budget, healthy meal preparation, handling situations that trigger impulse eating, tips for healthy eating at restaurants, ethnic eating, cultural aspects of eating preferences, and choosing foods at special occasions. ***Drs. Hughes and Fitzgibbon, both of whom participated in the pilot training, developed the draft protocol.*** The protocol includes role play for facilitating diet-focused group discussion/problem solving sessions and negotiating *PA and diet* adherence contracts (see Instructor Training, Appendix G).

Attendance/Retention—Participants will be notified of the dates of the classes, and those who anticipate missing more than three classes will be asked to defer to a subsequent iteration. Participants in the Fit and Strong! effectiveness trial attended *79.2% of possible sessions*. ***The ORBIT trial had 95% retention post-intervention and 92% at 18 months (Fitzgibbon et al., 2010). Attendance during the current pilot has been 85%.*** To maximize retention during the facility-based portion of the study, we take attendance and call participants who miss *any* sessions. We will call anyone who withdraws from the program to obtain reasons for dropout. ***Of 11 persons who enrolled in the current Pilot, 10 are actively engaged at 4 weeks.***

Exercise Components—Both interventions encompass identical exercise routines. All exercises are accompanied by music, and the instructors progressively challenge participants' balance.

Flexibility. Sessions begin and end with 10-minute warm ups and cool downs involving neck, trunk, and extremity range of motion exercises. Static and dynamic sitting and standing balance exercises are used and floor exercises are conducted during cool down in the latter weeks of the program.

Aerobics. Fitness walking progresses from maximum capacity at baseline to 20 minutes of sustained walking. Intensity is 40% - 60% of maximum heart rate (13 - 15 on the Borg Scale of Perceived Exertion) (Borg, 1982). Participants are taught basic low impact aerobic routines to maximize SE for enrollment in that type of program after Fit and Strong! ends if that is their choice for a maintenance PA program.

Strengthening. LE strengthening exercises use a graded, task-specific approach (sit to stand and postural stabilization). We implement resistance exercises using cuff weights and exercise bands (Fisher et al., 1991; Fiatarone et al., 1994). Resistance is progressively increased by adding weight in increments of 0.5 lbs. Since ability to rise unassisted from a chair or the floor is critical for independent functioning, strengthening exercises incorporate progressive sit-to-stand and floor-to-stand activities targeting these functions.

Physical Activity Logs. Participants log their PA (e.g., number of repetitions, sets, weight, and exertion level) in the Participant Manual at the end of each exercise session to reinforce their sense of mastery over time.

Education/Behavior Change—**This is where the two programs diverge:**

Fit and Strong!. The health education component of Fit and Strong! bolsters *SE for exercise* and *SE for exercise adherence over time and in the presence of barriers*. It also addresses SE to manage pain and other arthritis-related symptoms. The curriculum consists of 24 sessions that address OA, the use of PA to manage OA symptoms, basic elements of a balanced exercise program, exercising safely with OA, barriers to PA maintenance, and strategies to overcome common barriers.

In customary Fit and Strong!, participants meet with instructors in *week 6* to *review individual preferences for a follow-up PA maintenance plan*. The plan meets minimal criteria for *90 minutes each of flexibility, aerobic and resistance training per week after Fit and Strong! ends.* In negotiating the contract, instructors follow the Jensen and Lorish (1994) *process model for patient-practitioner collaboration*. Instead of *prescribing* a post-training regimen, instructors ask "what is the best regimen that this participant is likely to follow?", and follow up with *negotiation* and *iterative problem-solving*, including discussion of the participant's belief that the exercise will accomplish a valued goal. The emphasis is on building skills and identifying strategies that will assist participants to maintain adherence. Participants are encouraged to *supplement* exercises learned in Fit and Strong! with other PA like swimming, gardening, mall walking, etc.

Fit and Strong! Plus. In addition to the activities described above for the health education component of the customary program, Fit and Strong! Plus also addresses SE for diet behaviors and ***includes techniques to achieve a minimum 5% weight loss (see Instructor Manual, Appendix F). The goal is to increase consumption of fruits and vegetables, decrease percent energy from saturated fats, decrease consumption of sugar sweetened drinks, and reduce overall caloric consumption such that participants will achieve a minimum 5% weight loss at 6 months that will be maintained over time—the same dietary goals achieved by the ORBIT trial***. To boost SE for diet, we ask participants at baseline to *specify dietary and weight outcomes that they plan to achieve* through participation in Fit and Strong! Plus. Week 1 addresses the relationship between OA, obesity, and disability, and stresses the importance of a 5% decrease in weight. The instructor lets participants know that the remainder of the program will provide the tools that will help them achieve this goal. ***During Week 1, all participants receive The Calorie King Calorie, Fat, and Carbohydrate Counter (www.CalorieKing.com) that lists calories and fat contained in popular foods. Participants are taught how to use the book to fill out food diaries in which they record all food consumed during Week Two. Participants bring the food diaries to class where their content is discussed during classes 5, 6 and 7. The diary documents all food eaten daily, including portion size, time of day, where and with whom food was eaten, other activities while eating, and mood. Participants calculate the number of pounds that they need to lose over the next 6 months to achieve a minimum 5% weight loss. Participants who weigh <= 250 lbs. are asked to adhere to 1200-1500 calories per day and persons who weigh more than 250 lbs. are asked to adhere to 1500-1800 calories per day. All participants are urged to consume foods that contain no more than 3 grams of fat per serving. Participants are encouraged to maintain the diary on their own after Week 2 and are given diaries to maintain at graduation from the class in session 24. Weight is measured weekly on a scale that remains at the study site***. Food diaries and routine weigh-ins help participants track progress over time, increasing awareness of dietary habits and motivating participants to modify habits to meet goals.

The customary Fit and Strong! health education curriculum devotes 24 sessions to topics related to PA and arthritis. The Fit and Strong! Plus Manual condenses the PA/arthritis sessions from 14 to **7** and adds **7** *new sessions addressing specific dietary topics.* These include: Healthy Eating, Reading Labels, Grocery Shopping, Healthy Cooking, Healthy Meals, Handling Triggers, and Getting Past Barriers to Healthy Eating. ***Where possible, each diet session also includes a homework assignment that enables participants to try a technique at home and bring results back to class to share and refine***. Of the remaining 17 sessions, 9 address combined PA and diet content, 7 focus on PA alone, and 1 is devoted to the negotiated adherence contract. Thus, Fit and Strong Plus! puts *equal* emphasis on diet and PA. ***Notably, the 16 dietary/weight loss sessions in Fit and Strong! are identical to the dose used in the ADAPT trial. Table 1 in Appendix H compares content for Fit and Strong! and Fit and Strong! Plus to the ADAPT/ ORBIT trials. Table 2 in the same Appendix compares program dose.*** The PA maintenance contract has been expanded to include actions planned to maintain diet changes and weight loss. Session 17 "Healthy Meal Ideas**"** requires participants to bring a healthy recipe to share with the class and the last session asks participants to bring

healthy dishes to share. The recipes shared during session 17 are printed, bound, and returned to participants following a graduation ceremony on the last day of class. Participants also receive their manuals, ankle weights, exercise bands, and food diaries.

Participants in Fit and Strong! Plus meet with the instructor during week 6 to develop a negotiated PA plus weight management maintenance contract. The instructor uses the same process model as in Fit and Strong! to arrive at a realistic diet/weight loss maintenance plan. The review includes strategies to 1) include more fruits and vegetables daily, 2) decrease consumption of fat, 3) decrease sugar sweetened beverages, and 4) decrease overall caloric consumption by dealing with triggers, selecting healthy snacks, making shopping plans, etc. The review can include referral to community programs like Weight Watchers if participants express a preference for ongoing structured group-based reinforcement. In cases of both Fit and Strong! and Fit and Strong! Plus our goal is to enroll participants who are at high risk of mobility disability, help them adopt healthy behaviors over 8 weeks, and then help them to develop personalized maintenance strategies that have substantial probability of long–term adherence.

Maintenance boosters—Maintenance of behavior will be reinforced in both groups during months 3 through ***24*** using tapered TR. Using methods tested in our effectiveness trial (Hughes et al., 2010), we will recruit 2 Master's of Public Health student research assistants (RAs) well versed in health education techniques. One student will work with customary Fit and Strong! participants, and the other will work with Fit and Strong! Plus participants using scripted protocols. RAs will be trained separately. A two-week training program will include 1) reading materials related to successful PA or PA and weight loss maintenance interventions; 2) an overview of intervention objectives; 3) a review of each week's curriculum; and 4) role playing dealing with frustrations and barriers inherent in achieving physical activity or physical activity / weight loss maintenance. The Project Manager will meet with RAs bi-weekly to debrief calls, provide feedback and guidance, and revise the protocols as needed. To monitor call quality, she and the study PIs will listen to a sample of calls made by each RA periodically. All participants will receive one call during months 4, 8, and 15. Newsletters will be mailed each quarter to study participants. The newsletter will reinforce materials learned in class about physical activity and diet related topics.

TR for Customary Fit and Strong!. The RA will review participants' original or amended contract, participation in exercise since the last call, barriers experienced, motivation for exercise, exercise efficacy, and recent symptoms (pain, stiffness). Adverse events will be documented and reported to the PIs. The RA will tailor call content to problems identified by participants and will support participants' long-term maintenance of regular exercise. If participants are in maintenance, calls will focus on helping them to stay motivated and will support SE for exercise. If participants are experiencing difficulties, calls will address barriers and ways to *reactivate* participation. The RA will review benefits of PA and provide information regarding local exercise programs. Based on prior work, we expect each call to take 15 minutes**.**

TR for Fit and Strong! Plus. In addition to the activities described above, the diet/PA calls to Fit and Strong! Plus participants will also address weight management and weight loss goals, success, challenges, and barriers. The RA will ask for self-reported weight and discuss progress toward weight loss goals. If participants are in maintenance, calls will reinforce this success in the same manner described above. If participants report difficulty, calls will explore the circumstances of relapse and engage participants in strategizing ways to get back on track, and provide information about local programs. These calls will be longer than calls for customary Fit and Strong! participants because they will address both PA and weight loss goals. Drs. Braunschweig and Fitzgibbon will collaborate on developing the training protocol for the Fit and Strong! Plus RA, participate in training, and review a subset of calls.

We realize that the translation of TR to real world settings is problematic, but believe it is important to use this methodology in the trial. If Fit and Strong! Plus is successful, we believe it will be possible to refer participants to existing web-based diet and PA messages (i.e., everydayhealth.com) rather than TR. We will explore participant Internet access during the trial and will also explore the production of a booster DVD in study out years.

Table 3: Proposed Study Measures

A. Screening Measures

10-item Short Portable Mental Status Questionnaire (Kahn et al., 1960)	• Screens for moderate-to-severe cognitive impairment • Good reliability and validity (Kane and Kane, 1981) • Ineligible if answer more than three items incorrectly
Physical examination of joints and muscles by study rheumatologist	• Determines clinical presence of OA in LE joints • Rates functional significance using ACR arthritis functional class (Hochberg et al.., American College of Rheumatology, 1992)
History of falls	• Self-reported number of falls in last 2 years (Mobility and aging survey developed and used by the Centers for Disease Control and Prevention Healthy Aging Network).
B. Dependent Measures: Assessed at baseline, 2, 6, 12 and 18 months	
Primary Proximal Outcomes	
National Cancer Institute (NCI) Percent Energy from Fat Screener (Thompson et al., 1998)	• Assesses usual daily intake from fat over previous 12 months • Correlates strongly with true dietary intake (Thompson et al., 2007)
NCI Fruit and Vegetable Screener (Thompson et al., 2000)	• Obtains fruit and vegetable intake during a typical day • Correlates strongly with true dietary intake (Thompson, 2002)
Block Brief Food Frequency Questionnaire (FFQ) (Block et al., 1990)	• Assesses 6-month changes in energy intake, % energy from fat, saturated fat, grams of fiber, servings of fruit and vegetables based on 70 food items • Reliability and validity demonstrated in a wide range of age, gender, income and ethnic groups including low-income women (Coates et al., 1991; Block et al., 1992; Lanza et al., 2001; French et al., 2000)
Primary Distal Outcomes	
Weight and BMI	• Weight measured without shoes using same calibrated Tanita BWB-800 digital scale • Height measured without shoes to calculate BMI using Seca 214 portable stadiometer
4-position Balance Stand	• These 4-positions are the most sensitive balance stands taken from the Berg balance scale, a valid and reliable measure of balance in older adults.
Timed Up and Go Test (TUG)	• Measures the amount of time it takes to stand up from a seated position, walk 3 meters, turn around, walk 3 meters back to the chair, and sit down. Validity and reliability of the instrument have been demonstrated in populations of older adults with and without physical impairments (Steffen et al., 2002; van Hedel, Wirz, & Dietz, 2005)
Physical Activity Scale for the Elderly (PASE)	• Measures self-reported occupational, household, and leisure activities for individuals 65 years of age and older • Can be administered by telephone, mail, or in person • PASE scores are calculated from weights and frequency values for each of the types of activities
Waist Circumference	• Assesses body composition change due to exercise • Measured using Gulick 150 centimeter anthropometric tape
Western Ontario and McMasters University Osteoarthritis Index (WOMAC) (Bellamy et al., 1989)	• Measures LE function using pain, stiffness, and physical function subscales • Cronbach's αs of 0.81, 0.74, and 0.95, respectively (Hughes et al., 2010) • Will enable us to compare our findings to ADAPT trial
Functional Lower Extremity Muscle Strength (Guralnik et al.,1995)	• Functionally assesses LE muscle strength and endurance • Measures time to complete five full stands from sitting position • Correlates well with age and with knee flexor and extensor muscle strength (Csuka and McCarty, 1985)
6-minute Walk Test (Guyatt, et al., 1985)	• Measures functional exercise capacity reliably; correlates moderately to strongly with treadmill or bicycle ergometer tests • Number of feet walked in 6 minutes measured by Rolatape Measure Master • ***Used in ADAPT and recommended by Whitham and Avenell (2010) for future diet trials with older adults***
Arthritis Impact Measurement Scales for elderly respondents (GeriAIMS) (Hughes et al., 1991)	• Measures arthritis-specific symptoms of depression, anxiety, and combined depression/anxiety • Cronbach's αs of 0.73 for depression, 0.72 for anxiety, and 0.82 for combined depression/anxiety (Hughes et al., 2010)
California Older Adult Stroop Test (COAST) (Pachana, Thompson, Marcopulos, & Yoash-Gantz, 2004)	• Modeled from the traditional Stroop test, the California Older Adult Stroop Test (COAST) was developed specifically for use in a geriatric population and requires participants to distinguish between words and colors.
Speed of Processing, Selective Attention, and Divided Attention (UFOV Test) (Edwards, Vance, Wadley, Cissell, Roenker, & Ball, 2005).	• These three domains are measured using the valid and reliable computer-based Useful Field of View (UFOV) test. Participants' speed of processing and visual attention abilities are measured through three increasingly difficult tasks of stimulus detection, divided attention, and selective attention

Task Switching (Connections Test) (Salthouse et al, 2000)	• Modeled from the classic Trail Making Test, the purpose of the Connections Test is to draw a line connecting an alternating sequence of letters and numbers randomly placed on a page. Time taken to complete this task is measured
Working Memory (Digit Span) (Cooper, Sagar, Jorda, Harvey, & Sullivan, 1991; Wilson, 2002)	• Digit Span forward and backward (Weschler, 1987) and digit ordering
Attention **(SDMT)**	• Symbol digit modalities test (Smith, 1982) and digit symbol substitution (Wechsler Adult Intelligence Scale—Revised. Psychological Corporation; San Antonio, TX: 1981) will be used to measure working memory, visuomotor coordination, and selective attention are important factors that determine the final score.
California Verbal Learning Test (CVLT)	• Test-retest reliability of CVLT in healthy adults are supported (Woods, Delis, Scott, Kramer, Holdnack, 2006) • Measures total learning, delayed recall, intrusion errors, and recognition performance (Lacritz, Cullum, Weiner, & Rosenberg, 2001)
Blood Pressure	• Blood pressure will be assessed using the NHANES protocol.
C. Independent Variables	
Demographic variables	• Age, race/ethnicity, sex, income, marital status, living arrangements, employment status, type of health insurance coverage, and education
Chronic Conditions	• ***Witham and Avenell (2010) recommend that future diet trials with older adults assess presence of co-morbid conditions*** • Will use index of co-morbid conditions used in GeriAIMS study (Hughes et al., 1991) • Inquires about presence of 14 separate conditions and measures extent to which each condition interferes with activities

Exploratory Variables—The following measures will explore longitudinal risk of seeking total joint replacement, health care utilization, health care costs, and quality of life and technology usage in this population prior to and following participation.

Readiness for Joint Replacement Surgery. We will create a measure that will assess 1) degree of interest in total hip and knee replacement surgery and 2) intent to use either procedure in the next 6 months. We will monitor movement on that measure over time.

Health Care Utilization. Participants will complete the Health Care Utilization Measure (Lorig et al., 1996). to report number of physician and ER visits, hospital stays, hospital days, surgeries, outpatient tests and procedures, and medications used. We will obtain permission from participants to use their Social Security numbers to request healthcare utilization data from the Centers for Medicare and Medicaid. We will obtain data encompassing hospital and outpatient use, conditions, and prescription drug use. Specifically, we will request the MedPAR ss/Is/snf, Beneficiary Summary File, the Beneficiary Annual Summary file, and the corresponding crosswalk files for calendar years ***2011-2016***. Calendar year data will be converted to ***36***-month periods that correspond to ***12*** months prior to and ***-18*** months following baseline for each participant. Drs. Hughes and Shaw have prior experience analyzing these data (Hughes et al., 2000; Hughes et al., 2003).

Health-Related Quality of Life. The EQ-5D assesses 5 dimensions of health-related quality-of-life: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (EuroQoL, 1990). Respondents rate each dimension on 3 levels: no problems, some problems, extreme problems. The EQ-5D can be used to translate scores into Quality-Adjusted Life Years (QALYs) for cost analyses. ***Witham and Avenell (2010) also recommend the inclusion of these measures in future diet trials with older adults.***

Technology Usage: Participants will complete questions regarding technology use during the baseline outcomes assessment. We are trying to assess if they have internet access and if they utilize it to search for health or medical information online. We will obtain this information from the participants during their baseline outcome assessments. We would like to provide health-related website links for their reference during the program and maintenance period. In addition, it will allow us to create future projects related to health information and technology use.

Blood Pressure: Blood pressure will be assessed using the NHANES protocol. Readings will be obtained at baseline, 2, 6, 12, and 18 month follow-up visits. Participants with blood pressure over 180/110 mm Hg or below 90/50 mm Hg will be asked to contact their physician immediately after the reading and ask for instructions for care. If the participant's physician cannot be reached then an ambulance will be called for the participant. Participants with readings in these ranges will not be eligible to participate in the study.

Mediators—We will measure variables related to self-efficacy, social support, intrinsic motivation, and barriers to weight loss as outlined in Table 4 at all timepoints.

Table 4. Proposed Study Mediators

Self-Efficacy for Diet & Exercise	• 12 items assess exercise SE • 20 items assess eating SE (Sallis et al., 1988; Watters, Satia, and Galanko, 2007).
Social Support for Eating & Exercise	• Respondents rate frequency of comments from friends/family on respondent's efforts to change dietary or exercise habits. • Measure has good internal consistency with Black populations (Sallis et al., 1987; Ammerman et al. 2002).
Treatment Self-Regulation Questionnaire	• assesses autonomous/intrinsic motivation and controlled/extrinsic motivation for weight loss (Ryan and Deci, 2000; Fuemmeler et al., 2006).

Process Measures

Attrition from Measurement. We will maximize retention by providing *cash incentives and lotteries for each posttest*. ***We will conduct posttest measurement at study sites located in participant neighborhoods and will offer to do posttests over the phone or in participants' homes if necessary. We will identify a core set of primary and secondary outcomes that interviewers can prioritize.*** We will document all attrition from measurement using a brief instrument that addresses maintenance of exercise, weight, and reasons for refusal, ***and we will maximize the utility of available data using analytic techniques described in the analysis section***. ***Dr. Fitzgibbon has extensive experience retaining participants in weight loss trials and has retained more than 90% at 18 months (Fitzgibbon et al, 2010***)

Process Evaluation. Process evaluation allows investigators to assess intervention implementation (Campbell et al. 2007; Glasgow et al. 2001). The RE-AIM framework uses five dimensions (reach, efficacy or effectiveness, adoption, implementation, and maintenance), (Glasgow, Vogt, and Boles, 1999) to evaluate the implementation of interventions (Glasgow et al., 2001). Measures that we will use are shown in Table 5.

Table 5. RE-AIM Process Evaluation Framework for Fit and Strong and Fit and Strong Plus

Reach (participation) • # of participants completing Fit and Strong! sessions • # of participants completing Fit and Strong! Plus sessions • Age, education, race/ethnicity of participants • % of eligibles in site catchment area (census data)	**Implementation (dose and fidelity)** • Attendance • Instructor attrition • Site visit evaluations in Week 4 using systematic checklist • Instructor listserv and hotline staffed by PIs and dietician • Participant/Instructor program evaluations (Appendix I)
Efficacy Changes at 2 and 6 months in mediators, dietary, weight loss, and OA symptom change outcomes	**Maintenance** • Maintenance of change at 12 and 18 months in mediators, dietary, weight loss, and OA symptom change outcomes Follow-up interviews with participants, instructors and Park District managers to assess sustainability
Adoption • Perceived barriers to implementing Fit and Strong Plus • # of participants in Fit and Strong Plus using weight loss maintenance strategies (e.g., self-monitoring, problem solving, stimulus control, regular physical activity) – subset of questions in Diet TR calls	

Data Management—All survey forms will be designed using REDCap. Project staff will enter data into REDCap during data collection, and data will be automatically uploaded for processing. Data will be stored in univariate form. We will use using Stata's "reshape" command to reformat to multivariate form if necessary. We will run standard checks for outliers, duplicates, and other errors common to complex data entry and processing. All missing data will be flagged, and we will develop routines for imputations of missing data where the proportion of missing data is small. More complex imputation strategies will be developed if warranted. All data files will be password protected, and hard copies of questionnaires will be stored in locked cabinets in the research office.

Data Analysis—The basic trial design consists of one between-participant effect (customary Fit and Strong! vs. Fit and Strong! Plus) and one within participant effect (time) variable. Although the structure of the study is factorial, data analysis will be based on the general linear mixed model in a regression format (this approach is

more flexible than traditional ANOVA). Because the same persons will be measured repeatedly, the conventional regression assumption regarding independence of error terms is untenable. There are two ways to deal with this problem: generalized estimating equations (GEE) and random effect models. GEE is simpler but requires more power and a stronger set of assumptions regarding missing data. Random effect models can be used to analyze longitudinal data and permit a more sophisticated approach to analyses than GEE at the cost of some additional complexity. The basic model for data analysis is

$$Y_{it} = \beta_0 + \beta_1 Plus_i + \beta_2 Time_{it} + \beta_3 Plus_i * Time_{it} + \beta_4 ARA_i + u_i + e_{it}$$

where Y_{it} represents a particular outcome variable for person *i* at time *t*, *Plus* is a dummy variable for the Fit and Strong! Plus effect, relative to customary Fit and Strong!, *Plus*Time* represents the interaction with time, ARA is a covariate, u_i is the random effect for person *i* and e_{it} is a person-time specific error term. The Plus*Time interaction tells us whether the rate of change with respect to time is greater (or less) in the Plus condition compared to customary Fit and Strong!. As shown, the model is for a continuous outcome, but it can be estimated for a wide variety of outcome variables (e.g., logistic regression and ordered logistic regression models). Time can be represented in multiple ways in addition to the simple linear effect shown here. By including the square of time we can test whether the effects of time are non-linear, and by including properly coded dummy variables for discrete time, we can test more specific hypotheses regarding non-linear effects. A crucial assumption of such models is that the person-specific error term, u_i, is uncorrelated with the remaining variables, which is plausible given the randomized design. The model, as written, assumes an "exchangeable" correlation matrix among the errors. However that assumption can be relaxed by using simple auto-regressive or Toeplitz (banded) correlation structures. All analyses will be done using Stata.

Analyses of secondary outcomes will examine the magnitude of between and within group differences at all time points to determine whether the addition of a diet component to Fit and Strong! benefits these outcomes (as expected) or is neutral or harmful with respect to certain outcomes. Exploratory analyses will evaluate movement on the new readiness for total joint replacement measure, and will examine patterns and trends in healthcare utilization, healthcare cost, and quality of life between and within the two study groups.

Missing Data. Because we use longitudinal covariates to control on items like pain, in many cases missing data can be treated as "ignorable," meaning that dropout will be missing at random (MAR) conditional on covariates and prior state. However, we will use "pattern mixture models" (Little,1993; Hedeker and Gibbons, 1997) to explore the sensitivity of estimates to missing data assumptions. Specifically, we will include the observation pattern for each case in the model via dummy variables, interact those dummies with design variables, and compute a weighted average of the effects for the design variables based on the missing data problems. This method will allow us to assess what the effects of the design variables would have been, had all participants remained in the study.

Power Analysis. Based on prior work (Hughes et al., 2010), we used software developed by Hedeker et al. (1999) to obtain sample size estimates. Assuming a 2-tailed test, a relatively small effect size of .2 (based on a five percent end point difference in mean weight and a linear pattern of change over time), 5% attrition at each time point, and a cross time correlation for weight of .9, we find that we need a sample size of approximately 300 subjects to detect an effect size of .2 (a 5% reduction in weight) at the end of the study with power = .9. In general, power estimates of this kind are not strongly affected by assumptions regarding attrition. However, we will enroll ***400*** subjects in order to maximize power.

Timeline. The timeline outlining all activities associated with the project is shown in Appendix C. It demonstrates that we will be able to achieve all of the tasks described within the ***5***-years of the study.

Methodological Considerations. The proposed study has many strengths, including a large sample of high-risk older adults, an innovative integration of evidence-based weight loss approaches with Fit and Strong!, and potential for broad dissemination. However, as with any study, the design has some constraints (Table 6).

Table 6. Design Considerations

Design Decisions	Rationale for Decision
1. Fit and Strong! plus is shorter than interventions in the literature.	Our goal is to incorporate common elements from longer interventions into one that is translatable. We include experts in weight loss intervention trials (Dr. Fitzgibbon) and dietary assessment (Dr Braunschweig) in this effort. Fit and Strong! Plus *has the same number of diet sessions (16) as the ADAPT diet/PA arm* but in a format that is scalable.

2. We propose to recruit ***400*** older adults.	To meet this goal, we will use multiple strategies that succeeded in our prior work. We will set and closely monitor recruitment benchmarks and search for new community partners in this effort if needed.
3. We plan to follow participants for 24 months.	Our team has a 90% retention rate at 18 months. We will set retention targets and closely monitor success in meeting them. We will provide participant incentives and a lottery/cash voucher at each posttest, and we will conduct posttests at intervention sites in participants' neighborhoods.
4. Interventions are delivered by multiple instructors at multiple sites.	Our team has experience conducting training and conducting treatment fidelity checks for intervention trials. We have an established protocol to monitor fidelity and will extend this expertise to the new Fit and Strong! Plus intervention. A multi-instructor, multi-site approach will provide a more realistic assessment of feasibility for moving to scale.
5. Unanticipated consequences.	We have condensed the PA content of customary Fit and Strong! to reduce redundancy and allow space for new diet/weight loss content. We believe it unlikely that the changes will reduce the impact on PA maintenance and outcomes previously seen in Fit and Strong! trials. However, we will monitor this issue closely through fidelity checks and also use two-tailed tests to examine unexpected consequences of these changes.

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