Strength on Wheels: A meal delivery and exercise intervention for homebound older adults

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Protocol Title:	Strength on Wheels: A meal delivery and exercise intervention for homebound older adults
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Population:	10 participants (5 controls, 5 exercise intervention), males and females age 60 and older who are enrolled in the UTHealth-Harris Health House Call Program
Number of Sites:	UTHealth-Harris Health House Call Program
Study Duration:	1 year
Subject Duration:	12 weeks per subject

General Information

Our specific aim is to implement a home-based exercise program, administered through Interfaith Ministries of Greater Houston Meals on Wheels (MOWGH), and evaluate its effects on frailty status and nutritional markers in homebound older adults. We hypothesize that a 12-week home-based exercise program (treatment), administered by a meal delivery service, will improve overall frailty status in frail/prefrail homebound participants, when compared to the meals-only (control) group. Because the meal delivery service for this study would be enhanced (3 meals a day) over regular MOW meal deliveries (1 meal a day), we hypothesize that for all participants, enhanced meal deliveries will improve blood markers of nutritional status and musculoskeletal health over baseline.

Background Information

Increasing numbers of community-dwelling older adults have functional impairments and are unable to leave their homes independently. In a 2011 study of the U.S. population over 65 years of age, 5.6% of them were completely homebound or went out only once a week or less in the past month and another 15% required complete assistance to leave their home or had difficulty leaving without help[1]. Despite these concerns, nearly 90% of older adults stated in a 2014 U.S. Census Bureau survey that they wanted to remain in their communities, preferably in their homes, for as long as possible[2]. Given older adults' overwhelming preference for staying functionally independent at home as they age, it is imperative that we identify risk factors and potential interventions which will help older adults successfully live at home.

Frailty is a geriatric syndrome which is highly correlated with functional decline and chronic disease, leading to disability and increased mortality. There are multiple causes and contributors to frailty and recently there has been a focus on the loss of resiliency that frail older adults have in response to physical, cognitive, or psychosocial stressors[3]. Homebound older adults often have a similar loss of resilience but frailty has not been formally evaluated in homebound older adults, despite multiple validated frailty screening tests such as the Fried Frailty Phenotype (FFP). The FFP defines frailty as having 3 or more characteristics of unintentional weight loss, fatigue, decreased physical activity, weakness, and slowness[4].

Those who have 1 or 2 characteristics are considered prefrail, while those who have no characteristics are robust.

We now have preliminary data that in a group of 20 homebound older adults who are part of the UTHealth-Harris Health House Call Program (HCP), 12 are frail (60%), 8 are prefrail (40%), and none are robust by FFP measures. When compared to previously established prevalence rates of frailty (10%) and prefrailty (45%) in community-dwelling older adults[3,4], homebound patients are clearly more frail and thus have a greater need for intervention.

We propose a pilot study to evaluate the effects of a multifactorial nutrition and exercise intervention on frailty status and nutritional biomarkers in homebound older adults.

Objectives

The primary objective will be to assess overall frailty status by FFP in the control and intervention group at 12 weeks. Secondary objectives will be to compare the serum levels of nutritional markers (plasma vitamin C, serum folate and vitamin B12, vitamin 25-OHD, methylmalonic acid (MMA), and homocysteine (HCy)) at baseline and 12 weeks in all participants.

Study Procedures

a. Research Setting

Dr. Lee is the Medical Director of the HCP with access to over 350 home-based primary care patients. The patients in the HCP are 52% female and 48% male with a large percentage of non-insured patients (43%). In addition, HCP patients are very diverse: 41% Hispanic/Latinos, 40% Black/African Americans, and 10% White/Caucasians. Thus, this population is ideal for studying a multi-racial and ethnic, as well as underserved, population.

b. Patient Recruitment Procedures

i. Eligibility – Adults age 60 and older will be recruited from the HCP. Prospective participants will be called or interviewed in-person to see if they would be interested in participating in the study. The participants do not have to be previously enrolled in MOW and if they are already receiving MOW they can still participate because the study meal deliveries are enhanced (3 meals a day vs 1 meal a day).

ii. Inclusion Criteria – The participants will be 60 years or older, enrolled in the HCP, frail or prefrail by FFP, and medically stable.

iii. Exclusion Criteria – The participants will be excluded if they are robust by FFP, have Mini-Cog score <3 and/or are unable to follow instructions, have a pre-diagnosed terminal illness, are unable to ambulate, and/or are unable to use their upper extremities.

c. Study Design

i. Screening Visit – All consented participants, will initially be screened by Dr. Lee, a medically licensed geriatrician, who will conduct a brief social and medical history to obtain information on current chronic conditions as well as medications. Demographic data such as age, race, gender, monthly income, education, marital status and living situation will also be collected. Frailty will be measured using the FFP components of unintentional weight loss, weakness, poor endurance, slowness and low physical activity[3]. Height and weight will be measured and weight loss will be considered any unintentional weight loss of >5% body weight over the last year or body mass index (BMI) less than 18.5 kg/m^2. Weakness is defined as a grip strength in the lowest 20% of the population, adjusted for gender and BMI. Poor endurance is measured by self-reported exhaustion from the Center for Epidemiological Studies – Depression (CES-D) scale. Slowness will be based on time to walk 15 feet and is defined as the slowest 20% of the population, adjusting for gender and standing height. Low physical activity level is calculated from a weighted score of kilocalories expended per week based on self-report of the

Minnesota Leisure Time Activities Questionnaire (MLTAQ) and the lowest quintile is used for each gender. Those with no characteristics will be categorized as robust, those with one or two characteristics will be categorized as prefrail, and those with three or more characteristics will be considered frail. Participants who qualify by the inclusion/exclusion criteria will then have their blood drawn (~10cc) for complete blood count (CBC), comprehensive metabolic panel (CMP), plasma vitamin C, serum folate and vitamin B12, vitamin 25-OHD, methylmalonic acid (MMA), and homocysteine (HCy). This visit will take about 2 hours

ii. Randomization Strategy – Because we are looking for pilot feasibility data, we will recruit 10 participants into 2 groups of 5: meals alone (control) and meals+exercise (treatment). Due to the small sample size, blocked randomization will be used to ensure equal sample sizes in the study arms.

d. Intervention Strategy

i. Daily Meal Delivery – All participants will receive 12 weeks of an enhanced MOW meal delivery. MOWGH will in-person deliver 3 meals per day (1 shelf-stable, 1 hot, and 1 frozen) during the weekdays (Monday through Friday) with 6 frozen meals at the end of the week to cover the weekends. The meals have been created with the input of a registered dietician and meet the Dietary Reference Intakes for older adults set forth by the Food and Nutrition Board of the Institute of Medicine.

ii. Meals Only (Control) – The meal delivery drivers will be trained to ask a short set of questions about the participants' physical activity and any potential injuries during the 5 days a week they are delivering meals. The participants will be asked to track their own weekly exercise and physical activity[5] as well as their monthly progress[6] using a provided log. The daily questions from the drivers and the use of the standardized log will be the same as those in the treatment arm to minimize differences in the social aspects of the two arms. All participants will also be asked to wear a fitness activity tracker which will monitor heart rate, activity level, and sleep habits for the duration of the study.

iii. Meals+Exercise (Treatment) – For patients who are randomized to the treatment group, they will receive an exercise kit on the first visit by the meal delivery driver with 2 tennis balls, 2 1-pound hand weights, and one towel. Every week, the meal delivery driver will give them 3 exercises from the National Institute on Aging's Go4Life Workout-to-Go book, 1 exercise from each of 3 categories: strength/endurance, balance, and flexibility[7]. They will be asked to do the 3 exercises every day. The exercises are low-intensity and all can be done in the home, either standing, walking, or with a chair. The exercises include hand grip, wall push-up, overhead arm raise, back leg raise, side leg raise, toe stand, stand on one foot, heel-to-toe walk, balance walk, and ankles, back, thigh, shoulder/upper arm stretches. The participants will repeat the exercises in different combinations over the course of 12 weeks so that the strength/endurance exercises will be repeated twice, the balance exercises will be repeated 4 times, and the flexibility exercises will be repeated 3 times. Similar to the control group, the meal delivery drivers will ask the same daily questions about physical activity and any potential injuries and the participants will be asked to track their own weekly exercise and physical activity[6] as well as their monthly progress[7] on a standardized log. All participants will also be asked to wear a fitness activity tracker which will monitor heart rate, activity level, and sleep habits for the duration of the study.

iv. Home Visits – Every 4 weeks during the 12-week study period, the participants will undergo FFP measurements and safety checks to monitor for any adverse events. At 12 weeks, they will have their blood drawn (~10cc) again for nutritional biomarkers: CBC, CMP, plasma vitamin C, serum folate and vitamin B12, vitamin 25-OHD, MMA, HCy. These visits will take about 2 hours.

v. Compliance and Retention – Compliance for the exercise program will be tracked through the driver questions and weekly/monthly progress logs. Meals compliance will be checkedthrough counting meal trays to ensure the participants are appropriately consuming their meals. Detailed records of the reasons for all refusals or failures to complete the study will be filed and analyzed to help describe the study's outcomes in reference to compliance issues and to help understand selection bias. Participants will have the opportunity to enroll in the regular MOW program after their participation in the study, if they were not in it before.

e. Data Collection

i. Study Participants' Timeline –

Procedure	Home Visit 1 (Screening)	Home Visit 2	Home Visit 3	Home Visit 4
Mini-Cog	X			
Medical History	X			
Physical Exam	X			
Vital Signs, Weight, Height	X	X	X	X
Grip Strength	X	X	X	X
Walking Speed	X	X	X	X
CES-D and MLTAQ Questionnaires	X	X	X	X
Complete Blood Count	X			X
Blood Chemistry with Liver Function	X			X
Vitamin Blood Levels	X			X
Weekly Exercise Log		X	X	X
Monthly Progress Log		X	X	X
Wearable Fitness Device		X	X	X

f. Sources of Material – Research material obtained from the patients will consist of blood samples, questionnaires, measurements of frailty including height, weight, grip strength, and walking speed, and information from the wearable fitness device (heart rate, activity level, sleep habits). All research material will be used explicitly for the purpose of research. Participants will be assigned unique identification numbers for purposes of data collection. Participant names and addresses that are linked to the unique research identification number will be placed in a separate password-protected electronic file until it is apparent that this information is no longer needed. At that time, it will be destroyed and deleted from all files and databases. All data will be stored and archived on a double password-secured computer and in Microsoft Excel or Microsoft Word format.

Data and Safety Monitoring

a. Potential Risks

i. Phlebotomy – Blood draw is performed by taking blood from a vein in the forearm or antecubital fossa. This may cause pain during insertion of the needle or slight bruising afterward. This risk is minimized by the use of disposable single use needles, trained personnel, and application of pressure after the blood draw. In addition, the blood tests will be

coordinated such that if the participant needs to have blood drawn for other reasons, the tests will be done together

ii. Frailty Testing – Frailty testing involves squeezing a grip strength apparatus to assess hand grip strength, and ambulating 15 feet at normal gait speed. These procedures entail minimal risk. Patients who may be unsteady during ambulation will be escorted by the researcher if needed.

iii. Exercises – There is generally minimal risk involved in the low-impact exercises, mainly fatigue and possibly mild joint or muscle pain. The exercises are designed for older adults and may be modified if participants have an unsteady gait/balance. There will be close monitoring of their physical activity by the MOW drivers and the study team.

iv. Questionnaires, Health History and Physical Examination – This information is routinely collected in the process of medical care of patients. There are not any significant physical risks from these procedures. As with all medical information, there is always the risk of psychological distress if personal health information is not held confidential within the wishes of the participant. In order to minimize this risk, electronic medical records are held in HIPAA- 2 compliant password-protected databases, and written information is stored in locked files or file-rooms when not attended by study personnel. Medical information is provided to treating sources consistent with HIPAA guidelines.

v. Adequacy of Protection Against Risks – To maximize participant comfort, the PI who is a licensed geriatrician will perform the blood draws and complete the questionnaires and physical assessments while at the participant's home. She will monitor for any untoward side effects and contraindications and will initiate emergency procedures should an untoward effect occur, or if she finds the client ill or otherwise incapacitated. Should a serious medical emergency occur, the research team will call 911. For any incidental laboratory or questionnaire findings, the primary care physician for the participant will be notified.

b. Data and Safety Monitoring Plan

i. Adverse Events (AEs) and Serious Adverse Events (SAEs) Collection and Reporting – AEs and SAEs will be brought to the immediate attention of the PI. All AEs are collected on an Adverse Event Form. All AEs experienced by the participant during the home visit will be recorded. The AE form contains a column to indicate whether the event is serious. Thus, SAEs are a subset of the reported AEs. Routine reporting of AEs will be performed monthly. All SAEs will be reported within 24 hours of the study's knowledge of the SAE to the IRB, the PI, and the Data and Safety Monitoring Board (DSMB). An expedited report of an SAE will be submitted by telephone, fax, or email to the IRB within 24 hours of the event being reported to the PI. The PI will be responsible for ensuring participants' safety on a daily basis.

ii. Content of Data and Safety Monitoring Report – The content of the data and safety monitoring report will include: Report Summary; Protocol Synopsis (Project Organizational Chart, Personnel, Brief Statement of Purpose of Trial, Projected Timetable and Schedule); Narrative/Trial Summary (Study Status, Action Items, Resolution of Action Items, Summary of Protocol Changes); Recruitment and Participant Status figures and tables; and Safety Assessments for All Participants tables and listings of adverse events and serious adverse events.

c. Data and Safety Monitoring Board – Since we are conducting a clinical trial, a data safety and monitoring board will be formed to provide additional, independent oversight of data to ensure participants in the study are protected and to ensure their interests are not made secondary to the interest of the scientific investigation. The committee will include an outside Geriatrician and Exercise Physiologist.

i. Frequency of Meetings – The DSMB will meet at least twice during the year-long study and will be available for more frequent meetings as necessary. Members will review outcome, toxicity, and efficacy data of enrolled patients.
ii. Conflict of Interest – The DSMB nominees will be interviewed to ascertain any potential conflict of interest for members.
iii. Protection of Confidentiality – Data reviewed by the DSMB will be de-identified and will not contain any personal identifiers.
iv. Monitoring Activities – Specifically the committee will perform the following: a) review the research protocol and plans for data and safety monitoring; b) review major modifications to the study proposed by the PI prior to implementation, c) evaluate study progress, including data quality, recruitment rates, retention rates, outcome and adverse experience data, d) communicate information and recommendations to appropriated persons at UTHealth IRB, e) make recommendations to terminate the trial if needed because of safety concerns, and f) protect the confidentiality of trial data.

Statistics

a. **Sample Size and Power Calculation** – Because this is a pilot study with limited funding, we did not perform a formal power calculation and instead plan to recruit 10 participants, 5 for the intervention arm and 5 for the control arm. This sample size is not designed to definitely test the intervention but to provide information about feasibility of implementation and generalizability to develop a more in-depth power analysis for future studies. We will assess for differential attrition and if detected, will control for imbalances. We also plan to conduct an intention-to-treat analysis to account for all participants whether they adhere to the protocol or not.
b. **Analysis –** Chi-square test or Fisher's exact test will be use to compare the frequencies of robust, prefrail, or frail categories at baseline, 4 weeks, 8 weeks, and 12 weeks between control and treatment groups, one by one. If sample size allows, ordinal logistic regression analysis will be used for further comparison, adjusting for the age and gender. The differences between the nutritional markers at baseline and 12 weeks will be expressed in a paired t-test with significance level, $p = 0.05$.

Ethics

IRB approval will be sought from CPHS as well as Harris Health (under UT System Reciprocity Agreement). For the consent process, the participants will have a home visit from the research team to obtain written and verbal informed consent to participate. The key parts of the consent will be read aloud to every participant, while they review the hard copy, explaining the purpose and components of the study while emphasizing that 1) this is a study to characterize frailty and potential resiliency biomarkers, as well as evaluate an exercise intervention administered through a meal delivery program in homebound older adults, 2) that all participants will receive meal deliveries but will be randomized to the exercise or no exercise program, 3) participation is voluntary and has no impact on their regularly scheduled home visits with their primary care clinician, 4) the risks and benefits, and 5) that all information will be kept confidential. Each participant is required, before signing, to repeat back the above points and must be able to consent on their own, though they can live with family members who assist with caregiving.

Data handling and record keeping

Confidentiality will be maintained in a number of ways. Participants will be assigned a study identification number at the time the field team visits. All study documentation regarding that

participant will be indexed to the identification number. Names will not be used. All files will be kept in a locked cabinet, accessible only to study personnel.

Publication Plan

This study will be registered and results information will be submitted to ClinicalTrials.gov prior to recruitment of participants. The informed consent documents will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov. UTHealth CPHS/IRB have policies for ensuring that clinical trials registration and results reporting occur appropriately. Otherwise, results will be shared through presentations at meeting and conferences, manuscript publications, and dissemination to social service agencies and policy-making bodies.

References

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