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

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UTHealth
The University of Texas
Health Science Center at Houston

CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Strength on Wheels

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

Principal Investigator: Jessica Lee, MD, Assistant Professor, Division of Geriatric and Palliative Medicine, UTHealth

Study Contact: Jessica Lee, MD, 713-500-5457

The purpose of this study is to evaluate the effects of a home-based nutrition and exercise program on frailty status and nutritional biomarkers in homebound older adults. If you choose to participate in this study, you will be asked to participate in a home meal delivery service administered by Interfaith Ministries of Greater Houston Meals on Wheels (MOWGH), with the possible addition of a home-based exercise program. Participants will be randomized to either the treatment group (meals + exercise) or the control group (meals only). The total amount of time you will be in this study is 12 weeks.

There are potential risks involved with this study that are described in this document. Some known risks include pain or bruising from a blood draw, fatigue or mild joint or muscle pain from low-impact exercises, and psychological distress if personal health information is not held confidentially. There may be potential benefits to you such as better nutrition from the meal deliveries and increased strength from exercises. The only alternative to participating in this research study, is not to take part in the study.

Participation in this research study is voluntary. You may choose not to take part in this research study or may choose to leave the research study at any time. Your decision will not affect the clinical care you receive at the University of Texas Health Science Center at Houston (UTHealth), Memorial Hermann Healthcare System, or Harris Health System.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?
The purpose of this study is to see how well a home-based exercise program in addition to regular meal deliveries works at treating people with frailty. This study will test the safety of the home-based exercise program.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the study has ended, website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?
You are being asked to take part in this research study because you are frail or prefrail, are age 60 years or older, and are enrolled in the UTHealth-Harris Health House Call Program. This study is being

conducted at Harris Health. About 10 people will take part in the study in this county including approximately 10 people in the Harris Health System.

What will happen if I take part in this study?
This study will look at whether a home-based exercise program added to a home meal delivery service administered by Interfaith Ministries of Greater Houston Meals on Wheels (MOWGH), will improve frailty and nutritional status in homebound older adults.

The study will involve 4 home visits, every 4 weeks, over a period of 12 weeks. The visits will be conducted by the PI and will involve collecting medical and social history as well as physical and laboratory measurements.

- Screening Visit – After you sign the consent form, you will be screened at your home by the PI, who will conduct a brief social and medical history to obtain information on current chronic conditions as well as medications.

  A physical exam will be conducted similar to a routine physical exam performed by your primary care doctor, including vital signs of blood pressure, heart rate, respiratory rate and body temperature, height and weight.

  Frailty will be measured using the Fried Frailty Phenotype components of unintentional weight loss, weakness, poor endurance, slowness and low physical activity.

  Grip strength: We will measure your grip strength using a handheld digital instrument called a dynamometer.

  Walking speed: We will measure the time it takes you to walk 15 feet.

  Questionnaires: We will use the Mini-Cog test to measure your memory. We will use a modified form of the Center for Epidemiological Studies – Depression (CES-D) scale to measure your exhaustion level. We will also use the Minnesota Leisure Time Activities Questionnaire (MLTAQ) to measure your level of physical activity.

  You will then have your blood drawn (about 1 tablespoon) from a vein in your arm once for complete blood count (CBC), blood chemistry with liver function tests (CMP), and vitamin levels.

- Home Visits 2, 3, 4 – The frailty measures will be repeated every 4 weeks and at the end of the study (12 weeks) there will be another blood draw for CBC, CMP, and vitamin levels. The total amount of blood withdrawn during your participation will be about 2 tablespoons.

- 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.

If you agree to take part in this study you will be randomized (similar to flipping a coin) to receive meals alone or meals plus an exercise program. It is not known whether exercise program will be of additional benefit. For this reason, some study participants must receive only meals. This will allow a careful comparison to study the benefits and side effects of the exercise program. There is a 50% chance you will receive the meals+exercise program and a 50% chance that you will receive meals only.

- Meals Only (Control) – If you are in this group, the meal delivery drivers will ask you a short set of questions about your physical activity and any potential injuries during the 5 days a week they are delivering meals. The study coordinator will also call weekly to ask general questions about your physical activity and you will be asked to track your own weekly exercise and physical activity as well as your monthly progress using a provided log. You will also be asked to wear a fitness device on your wrist for the duration of the study, which will monitor your heart rate, activity level, and sleep habits.

- Meals+Exercise (Treatment) – If you are in this group, you will receive an exercise kit on the first visit along with a weekly set of three exercises which will be given to you by the meal delivery driver. You 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 meal delivery drivers will then ask the same daily questions about physical activity and any potential injuries, the study coordinator will call weekly to answer any questions about the exercises, and you will be asked to track your own weekly exercise and physical activity as well as your monthly progress on a standardized log. You will also be asked to wear a fitness device on your wrist for the duration of the study, which will monitor your heart rate, activity level, and sleep habits.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects. A patient study calendar below shows how often these tests will be done.

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

You will have about 1 tbsp of blood drawn from a vein in your arm twice, once at the beginning of the study and once at the end of the study. The total amount of blood withdrawn during your participation will be about 2 tbsp.

How long will you be in the study?
If you agree to take part, your participation will last for 12 weeks and will involve 4 visits to your home.

What choices do you have other than this study?
The only alternative is not to take part in this study.

What are the risks of taking part in this study?
There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

If you choose to take part in this study, there is a risk that the nutrition and exercise program may not be as good as another kind of nutrition and exercise program in treating your condition.

There is also a risk that you could have side effects from the exercise. These side effects may be worse and may be different than you would get with the usual treatment.

Some of the most and least common side effects that the study doctors know about are:

- The risks associated with the **Physical and functional performance assessment** (completed during history and physical examination) include those which are:
  Less Likely and Some May Be Serious:
  - Mild psychological distress
  - Fall risk
  - A member of the research team will be by your side during the walking test to help protect against the fall risk.

- The risks associated with the **Exercise program** include those which are:
  Less Likely and Some May Be Serious:
  - Fatigue
  - Mild joint or muscle pain
  - Fall risk

- The risks associated with the **Questionnaire data collection** include those which are:

Less Likely and Not Serious:

- Mild psychological distress
- Fatigue when answering questions
- You do not have to answer any questions you do not want to answer.

- Risks and side effects related to the **Blood sampling (with needle)** include those which are:
  Likely and Not Serious:
  - Bruising at the site of the blood draw
  - Discomfort
  - Clotting and bleeding from the site of the blood draw

  Less Likely and Not Serious:
  - May feel faint, dizzy, or lightheaded
  - Frequent donation of blood can result in low iron (may cause iron deficiency anemia)
  - Infection may occur

- There is a possible risk of breach of **confidentiality.**

There may be some risks that the study doctors do not yet know about.

What are the benefits to taking part in this study?
There is some evidence in people with frailty that healthy nutrition and exercise can prevent further muscle and weight loss. However, we do not know if this will happen in everyone with frailty. This study may help the study doctors learn things that may help other people in the future.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Jessica Lee at 713-500-5457.

Your doctor can stop the study at any time. Your doctor may stop your participation in the study if your condition worsens, the study is stopped, the exercise and meals are no longer available, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

What happens if you are injured during the study?
If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they

are to the general community. You should report any such injury to Jessica Lee, 713-500-5457. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?
The study will pay for the special tests and examinations that are required by this study and not otherwise part of your standard medical care.
If you receive a bill that you believe is related to your taking part in this research study, please contact Jessica Lee at 713-500-5457 with any questions.

You will not be paid for taking part in this study, however you will receive free meals delivered to your home.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth, Memorial Hermann Healthcare System, or Harris Health System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to frailty. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

Personal identifiers such as your name and medical record number will be removed from the information and samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth and/or Memorial Hermann Health System and/or Harris Health System
- Interfaith Ministries of Greater Houston Meals on Wheels

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann Health System or Harris Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Jessica Lee in writing at 6431 Fannin Street, MSB 5.118, Houston, TX 77030.

This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact the PI Jessica Lee at 713-500-5457, as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at (713) 500-7943.

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date	Time
Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time