Home-Based Exercise to Treat Decreased Physical Function

in Patients With Varying Levels of Kidney Function

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A home-based exercise program will be feasible, safe, acceptable to patients, and improve frailty parameters and short physical performance battery (SPPB) scores in patients with varying levels of kidney function.

H-52019- HOME-BASED EXERCISE AS AN INTERVENTION TO TREAT DECREASED PHYSICAL FUNCTION IN PATIENTS WITH VARYING LEVELS OF KIDNEY FUNCTION

Concise and Focused Presentation

This is a research study. Participation is voluntary, and you may choose not to participate. If you choose not to participate, you will continue to receive your regular medical care and will not lose any services, benefits, or your care at Baylor College of Medicine.

The purpose of this research is to determine whether home-based exercise improves physical function and quality of life in patients with varying levels of kidney function.

You are being asked to participate in this study because you may benefit from an exercise program . You will be in this study for approximately 3 months.

At the baseline study visit, you will be asked to complete physical function testing and questionnaires to determine whether you qualify for the study. You may also be asked to complete a submaximal exercise test. This test involves walking on a treadmill (usually for less than 10 minutes) while your oxygen level is monitored using a sensor usually placed on your finger and your electrocardiogram is monitored using electrodes attached to your body with adhesive pads. If you qualify for the study, you will receive information regarding the exercise program, a set of resistance bands, and a pedal exerciser. If you are not able to transport the pedal exerciser home, we will arrange for it to be mailed to you. After you return home, you will be asked to wear an actigraph, or activity monitor, for 7 days and mail it back to us.

Prior to beginning the 8-week home-based exercise program, you will receive a phone call from a Mayo Clinic exercise physiologist and an individualized exercise prescription. During the exercise program, you will be asked to record information about your exercise on paper. You will also receive weekly phone calls from the exercise physiologist to assess your progress. After completing the exercise program, you will be asked to return for a completion study visit in which physical function testing andquestionnaires will be repeated. In addition, you will be asked questions about your satisfaction with the exercise program after completing it.

You will be asked to wear an actigraph for another 7 days after completing the exercise program and mail it back to us. You will also be asked to complete some questions via phone approximately 1 month after completing the program.

The additional measurements and procedures will take up some of your time. However, we will do our best to ensure these are scheduled at times convenient to you and do not interfere with your routine medical care.

As with any exercise, there is a small risk of injury or discomfort. However, you will be able to end an exercise session at any time if you feel discomfort or experience an injury. The exercise physiologist will also check with you weekly via phone and end your participation in the study if they feel it is necessary for your safety.

Some of the questions in our questionnaires may make you uncomfortable, but you are able to skip any questions that make you feel uncomfortable or that you do not want to answer. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

This study may not make your health better. However, you may experience benefits from exercise. In addition, this study may benefit future patients.

This research study is funded by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Background
At the baseline study visit, you will be asked to complete physical function testing, weight measurement, and questionnaires to determine whether you qualify for the study. You may also be asked to complete a submaximal exercise test. This test involves walking on a treadmill (usually for less than 10 minutes) while your oxygen level is monitored using a sensor usually placed on your finger and your electrocardiogram is monitored using electrodes attached to your body with adhesive pads. If you qualify for the study, you will receive information regarding the exercise program, a set of resistance bands, and a pedal exerciser. If you are not able to transport the pedal exerciser home, we will arrange for it to be mailed to you. After you return home, you will be asked to wear an actigraph, or activity monitor, for 7 days and mail it back to us.

Prior to beginning the 8-week home-based exercise program, you will receive a phone call from a Mayo Clinic exercise physiologist and an individualized exercise prescription. During the exercise program, you will be asked to record information about your exercise on paper. You will also receive weekly phone calls from the exercise physiologist to assess your progress. The exercise physiologist will record information about your exercise program in your electronic medical record. After completing the exercise program, you will be asked to return for a completion study visit in which physical function testing, weight measurement, and questionnaires will be repeated. In addition, you will be asked questions about your satisfaction with the exercise program after completing it.

You will be asked to wear an actigraph for another 7 days after completing the exercise program and mail it back to us. You will also be asked to complete some questions via phone approximately 1 month after completing the program.

Some of the questions in our questionnaires may make you feel uncomfortable, but you can skip any questions that make you feel uncomfortable or that you do not want to answer.

You will be instructed to stop exercising and notify 911 if you experience chest tightness, pressure, or

pain in your chest or severe shortness of breath that does not go away within 3 to 5 minutes. If you seek emergency care, you will be asked not to resume exercising for the study before speaking with a study team member. If the study team feels it is no longer safe for you continue the exercise program following discomfort, injury, or a medical emergency, you will be withdrawn from the study.

As with all research, there is a chance that confidentiality could be compromised. However, we take all precautions to minimize this risk.

Participation in this study is voluntary. You may choose not to participate in this study. If you choose not to participate in this study, you will continue to receive your regular medical care and will not compromise your care at Baylor College of Medicine.

If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in This study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

This research study is funded by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Purpose

The purpose of this research is to determine whether home-based exercise improves physical function and quality of life in patients with varying levels of kidney function.

Procedures

The research will be conducted at the following location(s):
Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and Mayo Clinic - Minnesota.

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Baylor College of Medicine and Baylor St. Luke's Medical Center (BSLMC).

You will continue to receive your regular medical care.

If you are eligible for this study, you will be asked to complete an 8-week home-based exercise program. The exercise program will include personalized endurance, strength, and flexibility training. You will be provided with a pedal exerciser and resistance bands with which you can exercise at home. You will have a baseline phone conversation with a Mayo Clinic exercise physiologist followed by an individualized exercise prescription. During the exercise program, you will be asked to record information about your exercise on paper. You will also receive weekly phone calls from an exercise physiologist who will review your progress and record information about your exercise in your electronic medical record. Additionally, you will be asked to wear an actigraph, or activity monitor, and complete physical function testing, questionnaires, before and after completing the exercise program. The physical function testing will include a hand grip strength test, a timed gait speed test, balance testing, and repeated chair stands as outlined below. The cost of the exercise program, exercise equipment, and any study-related testing will be covered by research.

If you agree to be in this study, you will also participate in 2 study visits. One visit will occur at baseline prior to beginning the exercise program, and one visit will occur after completing the exercise program. At each of the visits, you will be asked to participate in the activities described below:

Questionnaires: You will be asked to complete questionnaires including the Kidney Disease Quality of Life Short Form (KDQOL-SF), the Minnesota Leisure-time Physical Activity Questionnaire, and a few other questions related to your health and demographic characteristics. These questionnaires will be completed during your study visit and should take less than 30 minutes to complete. At the completion study visit, you will also be asked questions about your satisfaction with the exercise program. You will also be asked to complete some questions via phone or by mail 1 month after you complete the exercise program.

Grip Strength: You will be asked to complete a hand grip strength test by using a handheld device called a dynamometer. You will squeeze the device as hard as you can for 3 seconds, and the test will be repeated 3 times. For this test, you will use your dominant hand or your arm without your dialysis fistula or graft (if applicable).

Gait Speed: You will be asked to walk 15 feet at a comfortable walking pace 2 times.

Chair Stands: You will be asked to perform timed, repeated chair stands without using your arms and without assistance 5 times.

Balance Testing: Your balance will be tested in 3 different positions: side-by-side, semi-tandem, and tandem. You will be asked to hold each of these positions for approximately 10 seconds.

Actigraph: You will be asked to wear an actigraph, or activity monitor, for 7 days in a row and mail the device back to us in a prepaid envelope.

The study team will also collect information from your medical record. This will include demographic information (date of birth, age, sex, etc.) and elements of your medical history as they relate to your kidney disease. At the end of the exercise program, we will ask you to answer a set of questions by phone or mail regarding your experience during the exercise program. You will not be required to answer these questions if you are uncomfortable providing an answer or do not want to share your answers. In addition, we will ask you some questions via phone or by mail approximately 1 month after completing the exercise program.

Clinically Relevant Research Results

The results generated from this research study are not expected to have any clinical relevance to you.

Sharing and Future Research Studies with Identifiable Private Information

Information that identifies you may be removed from your identifiable private information collected as part of this research, and after such removal, your information may be used for future research studies or distributed to another investigator for future research studies without additional consent/authorization from you.

Research related health information

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you sign this document, you give permission to people who give medical care and ensure quality from Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and Mayo Clinic - Minnesota to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use or disclose (release) for this research includes:

- Information from health records such as diagnoses, progress notes, medications, lab or radiology findings, etc.
- Demographic information (name, D.O.B., age, gender, race, etc.)

The health information listed above may be used by and or disclosed (released) to researchers, their staff and their collaborators on this research project, the Institutional Review Board, Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), Mayo Clinic - Minnesota, and NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK) and their representatives.

Use or Disclosure Required by Law

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other

proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Information regarding study participation will be included in your medical records.

The Certificate of Confidentiality will not be used to prevent disclosure of child abuse, neglect, or harm to self or others. to state or local authorities.

Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and Mayo Clinic - Minnesota are required by law to protect your health information. By signing this document, you authorize Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and Mayo Clinic - Minnesota to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that the research does not involve treatment. Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and Mayo Clinic - Minnesota may not condition (withhold or refuse) treating you on whether you sign this Authorization.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers, their staff and their collaborators on this research project, the Institutional Review Board, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK) and their representatives, regulatory agencies such as the U.S. Department of Health and Human Services, Baylor College of Medicine, Baylor St. Luke's Medical Center (BSLMC), and Mayo Clinic - Minnesota 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. If you revoke this Authorization, you may no longer be allowed to participate in the research described in this Authorization.

To revoke this Authorization, you must write to: Elizabeth Lorenz, MD, Baylor College of Medicine, Alkek Building for Biomedical Research, M.S. BCM395 Houston, TX 77030, 713-798-2032.

This authorization does not have an expiration date. 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.

No publication or public presentation about the research described above will reveal your identity without another authorization from you.

Potential Risks and Discomforts

The additional measurements and procedures will take up some of your time. However, we will do our best to ensure these are scheduled at times convenient to you and do not interfere with your routine medical care.

As with any exercise, there is a small risk of injury or discomfort. However, you will be able to end an exercise session at any time if you feel discomfort or experience an injury. The exercise physiologist will also check with you weekly via phone and end your participation in the study if they feel it is necessary for your safety.

Some of the questions in our questionnaires may make you uncomfortable, but you are able to skip any questions that make you feel uncomfortable or that you do not want to answer

Research Related Health information collected at BCM and its affiliate institutes will be disclosed to Mayo Clinic Minnesota. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Study staff will update you in a timely way on any new information that may affect your decision to stay in the study. There is a small risk for the loss of confidentiality. However, the study personnel will make every effort to minimize these risks.

Potential Benefits

You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand You will receive no direct benefit from your participation in this study. However, your participation may help the investigators better understand benefits from exercise. In addition, this study may benefit future patients..

Alternatives

You may choose to not participate in this study.

Subject Withdrawal from a Study

You may decide to stop participation in this study at any time. You should tell one of the principal investigators or a member of the study team if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers at Baylor College of Medicine may stop you from participating in this study at any
time:
--If it is in your best interest,
--If you do not follow the study procedures, or
--If the study is stopped.

If you leave this research study early or are withdrawn from the study, no more information about you will be collected. However, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to participate in this research study.

Investigator Withdrawal of Subject from a Study

The investigator or sponsor may decide to stop you from taking part in this study at any time. You could be removed from the study for reasons related only to you for example, if you move to another city, or if you have a serious reaction to your study procedure or because the entire study is stopped. The sponsor, investigator, Food and Drug Administration, or Institutional Review Board may stop the study at any time.

Subject Costs and Payments

You will be given a participation stipend of $100 in the form of a ClinCard (similar to a credit card) for time and inconvenience associated with participation. Study participant's parking pass will be validated during the baseline and completion study visits.

You will be reimbursed using a ClinCard. Payments will be loaded onto the ClinCard within 2-3 business days of visit completion. You will be able to use ClinCard anywhere that accepts MasterCard to make purchases and to obtain cash. Your name, date of birth, social security number, address, phone number, and email address will be needed to set up your ClinCard. Baylor College of Medicine (BCM) and Greenphire (ClinCard Company) have entered into an agreement which requires Greenphire to protect your personal information. You may also decide to participate in the study without receiving payment if you decide that you do not want to provide the information needed to set up your ClinCard with Greenphire.

If you lose your ClinCard, BCM will replace your card free of charge the first time. If you lose it again, you will be charged a $7 fee for a replacement card from the balance on your card. Your ClinCard will have an expiration date for its use, but if it expires before you use it, you will be able to request a replacement card and BCM will provide you with a new card at no cost to you. The research study team will provide

you with handouts with more information about using the ClinCard.

Baylor College of Medicine policy states that reimbursements received by a research subject on one or more studies totaling $600 or more in a year will be reported as income to the Internal Revenue Services (IRS). In order to report it as income we will request your social security number for tax reporting purposes only. If you do not want to provide your social security number, you can still participate in this study and decline reimbursement.

Subject's Rights

Your signature on this consent form means that you have received the information about this study and that you agree to volunteer for this research study.

You will be given a copy of this signed form to keep. You are not giving up any of your rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop taking part in this study.

If you choose not to take part in the research or if you decide to stop taking part later, your benefits and services will stay the same as before this study was discussed with you. You will not lose these benefits, services, or rights.

The investigator, ELIZABETH LORENZ, and/or someone he/she appoints in his/her place will try to answer all of your questions. If you have questions or concerns at any time, or if you need to report an injury related to the research, you may speak with a member of the study staff: ELIZABETH LORENZ at (713) 798-2032 during the day and at (507) 398-9786 after hours.

Members of the Institutional Review Board for Baylor College of Medicine and Affiliated Hospitals (IRB) can also answer your questions and concerns about your rights as a research subject. The IRB office number is (713) 798-6970. Call the IRB office if you would like to speak to a person independent of the investigator and research staff for complaints about the research, if you cannot reach the research staff, or if you wish to talk to someone other than the research staff.

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Subject	Date
Investigator or Designee Obtaining Consent	Date
Witness (if applicable)	Date
Translator (if applicable)	Date