Title: Predictors of Recovery and the App-Facilitated Tele-Rehabilitation (AFTER) Program for COVID Survivors

NCT04663945

Version Date: 04.23.2022 IRB Approval Date: 05.05.2022

Principal Investigator: Jennifer Stevens-Lapsley MPT, PhD
COMIRB No: 20-2415
Version Date: 04.23.2021
Study Title: Predictors of Recovery and the App-Facilitated Tele-Rehabilitation (AFTER) Program for COVID Survivors

---

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about physical rehabilitation after a hospitalization for COVID-19.

You are being asked to be in this research study because you were diagnosed with and hospitalized for COVID-19.

Other people in this study

Up to 150 people from your area will participate in the study.

Up to 150 people around the country will be in the study.

What happens if I join this study?

If you join the study, you will be randomized into one of two groups. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care.

If you are randomized to Group 1, you will participate in 12 individual telerehabilitation visits which will last approximately 1 hour each. You will also participate in home exercise sessions. If you are randomized to Group 2, you will be contacted by a study team member 1 time per week for 12 weeks. You will also receive general recommendations for exercise after week 12 testing session.

All participants in both Group 1 and Group 2 will complete 4 testing sessions (one at baseline, one at 6 weeks, one at 12 weeks, and one at 26 weeks) in which you complete physical function tests and answer questionnaires either via phone/video call, via the internet, or via an application referred to as the Platform. You will be asked to wear a Fitbit to track your daily steps. We will provide a tablet for you to use to access the Platform and the Fitbit to use to track your steps. You will be given the option to set up your Fitbit account with an email address that we provide to you or with your own email. If you use the email address that we provide we will have access to other information that the Fitbit can collect, such as biometrics, sleep, stress, etc.; however, we will not collect this data and will not use this data in the research. We will only collect your step counts for this research.

We may also provide a pulse oximeter, a blood pressure cuff, and other items to facilitate testing sessions (i.e., a rope to measure a specific distance, and a stand for you to hold the tablet) during the study.

Group 1 will also be provided exercise equipment (e.g., resistance tubing and/or weights) to use during the study. We may drop off the equipment at your home or provide your name and address to Amazon so that the exercise equipment can be shipped directly to you.

Optional Procedures:

We may ask to audio and/or video record some telerehabilitation sessions so that we can check the researcher's consistency in the sessions. You are free to choose to allow these recording or not to allow them.

Audio record: ☐ Yes ☐ No Initials _____

Video record: ☐ Yes ☐ No Initials _____

Your participation in this study will last 26 weeks.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include muscle soreness, fatigue, shortness of breath, and minor strains with exercise. Falling is an uncommon occurrence during the exercise program and the physical function assessment.
Breach of confidentiality is a rare risk.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

You will be assigned to a study treatment by chance, and the study treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about physical rehabilitation after hospitalization for COVID-19.

This study is not designed to treat any illness or to improve your health.

Are there alternative treatments?

There may be other ways of treating your COVID-19 physical rehabilitation. These other ways include in-person rehabilitation. You could also choose to get no treatment at all.

You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored by the National Institute on Aging.

Will I be paid for being in the study?

You will not be paid to be in the study; however, if you complete all four testing sessions you will be allowed to keep the tablet and the Fitbit you used during the study. If you leave the study early, or if we have to take you out of the study, you will be asked to return the tablet and Fitbit. You may also keep the weights, resistance bands, pulse oximeter, blood pressure cuff, and stand provided to you if you complete the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

Certificate of Confidentiality

This study has been issued a Certificate of Confidentiality from the federal government to help protect your privacy. The Certificate prohibits the researchers from disclosing your name, or any identifiable information, document or biospecimen from the research, with the exceptions listed below. A certificate provides protections against disclosing research information in federal, state, or local civil, criminal, administrative, legislative, or other proceedings. These protections apply only to your research records. The protections do not apply to your medical records.

The researchers may disclose your name or identifiable information, document or biospecimen, under the following circumstances:

- **To those connected with the research,**
- **If required by Federal, State or local laws,**
- **If necessary for your medical treatment, with your consent,**
- **For other scientific research conducted in compliance with Federal regulations,**
- **To comply with mandated reporting, such as a possible threat to harm yourself or others, reports of child abuse, and required communicable disease reporting, or**
- **Under other circumstances with your consent.**

A Certificate of Confidentiality does not protect information you or a member of your family voluntarily release.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call Dr. Jennifer Stevens-Lapsley immediately. Her phone number is [redacted]

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Jennifer Stevens-Lapsley. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Stevens-Lapsley at [redacted]. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Stevens-Lapsley with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303.724.1055.

A description of this clinical trial will be available on http://www.Clinical Trials.gov. 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.

Who will see my research information?

The University of Colorado Denver | Anschutz Medical Campus (the University) and its affiliated health systems have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- University of Colorado Denver | Anschutz Medical Campus
- University of Colorado Health

We cannot do this study without your permission to see, use, and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the University and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Jennifer Stevens-Lapsley, MPT, PhD
UCD Physical Therapy Program
Mail Stop C244
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- The Institutional Review Board that is responsible for overseeing this research
- The study doctor and the rest of the study team.
- The National Institute on Aging, who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Blue Marble Rehab Inc, dba Blue Marble Health, the Platform company

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make *all or some* **of the following health information about you collected in this study available to:** Blue Marble Rehab Inc, dba Blue Marble Health

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory studies
- Research Visit and Research Test records

What happens to Data that are collected in this study?

Scientists at the University and the health systems involved in this study work to find the causes and cures of disease. The data collected from you during this study are important to this study and to future research. If you join this study:

- The data given by you to the investigators for this research no longer belong to you.

- Both the investigators and any sponsor of this research may study your data collected from you.
- If data are in a form that identifies you, the University or the health systems involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

HIPAA Authorization for Optional Additional Study Procedures

In this form, you were given the option to agree to additional, optional research procedures. You must also give us your permission, under HIPAA rules, to use and disclose the information collected from these optional procedures, as described above.

If you decline to give us permission to use and disclose your information, you cannot take part in these optional procedures, but you can still participate in the main study. Please initial next to your choice:

_____ I give permission for my information, from the optional procedures I have agreed to above, to be used and disclosed as described in this section.

_____ I do not give permission for my information for any optional procedures to be used and disclosed; I understand that I will not participate in any optional procedures.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use, and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name:_____