UNIVERSITY OF PENNSYLVANIA
RESEARCH PARTICIPANT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title:	Evaluating a Clinic-based Multimodal Outpatient Rehabilitation Program to Improve the Functioning of Persons Suffering from Post-acute Sequelae of SARS-CoV-2 infection (PASC): A Randomized Controlled
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Research Study Summary for Potential Participants

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The research study is being conducted to develop and test a patient-centered outpatient rehabilitation intervention to improve the functioning and quality of life of individuals experiencing post-acute sequelae SARS-CoV-2 infection (PASC) also known as “Long Covid”.

If you agree to join the study, you will be randomized to one of two groups**: the Supervised Rehabilitation Program** or the **Self-guided Program.**

- Both groups will receive a comprehensive in-person assessment at study entry (baseline) and at program completion.
- **Supervised Rehabilitation Program group:** The program will consist of 12 one-hour sessions over a six-week time period. Progression through the rehabilitation program will be personalized and designed based on impairments identified during the comprehensive baseline assessment and previous sessions.
- **Self-guided Program group**: In addition to results of their baseline assessment, participants will receive the latest WHO Guide information about “Support for Rehabilitation Self-Management after COVID-19 Related Illness” along with education is its use. This guide consists of ways to manage: breathlessness,

difficulty with voice, eating, drinking and swallowing; problems with attention, memory and thinking clearly; limitations in activities of daily living, managing stress and mood dysfunction and advice for when to contact healthcare professionals.
- Both groups will complete an online follow-up survey at 90 days following study entry.

We anticipate the intervention will improve health-related quality of life, physical functioning, cognitive functioning, and endurance relative to their pre-intervention levels. The risks to this intervention are minimal but may include fatigue, musculoskeletal injury, over-exertion, and post-exertional symptoms. However, these are minimized by using trained physical therapists that are experienced in working with this population and will be closely monitoring participants and the effects of interventions.

Please note that there are other factors to consider before agreeing to participate such as additional procedures, use of your personal information, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in this research study because you have been identified as an individual that has tested positive for COVID-19 and has experienced persistent symptoms following infection for over 12 weeks. This is consistent with having a condition known as post-acute sequelae SARS-CoV-2 infection (PASC) or “Long Covid”.

Your doctor may be an investigator in this research study. You do not have to participate in any research study offered by your doctor. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. You may also decide to discuss the study with your family, friends, or family doctor. Being in a research study is different from being a patient. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study.

If you decide to participate, you will be asked to sign this form and will receive a copy for your records.

What is the purpose of this research study?

The purpose of this research study is to compare the effectiveness of a clinic-based, supervised rehabilitation program to that of a self-guided program for persons with PASC or “Long Covid” symptoms.

How long will I be in the study?

Participants will be involved in either the clinic-based, supervised rehabilitation program or the self-guided program for a six-week period, followed by an online follow-up survey 90 days post-entry into the trial.

What am I being asked to do?

All participants will receive a comprehensive baseline assessment by a physical therapist. You will then be randomized to one of two treatment protocols

- Supervised Rehabilitation Program: Participants will undergo 12 one-hour sessions over the course of six weeks. The program will consist of breathing exercises, individualized physical activity (as tolerated) including stretching and strengthening, and cognitive therapy. Depending on the area of impairment, individualized restorative treatments will be offered. Finally, subjects will be educated on healthy diet/hydration, pacing and energy conservation, sleep/sleep hygiene and identification/avoidance of symptom triggers.
- Self-guided Program: Participants will receive the results of their in-person baseline assessment as well as the latest WHO Guide information on Support for Rehabilitation Self-Management after COVID-19 Related Illness and education about its use. This guide consists of ways to manage breathlessness, difficulty with voice, eating, drinking and swallowing; problems with attention, memory and thinking clearly; limitations in activities of daily living, managing stress and mood dysfunction and advice for when to contact healthcare professionals. Participants in this group will also receive a phone call from the study team about 3 weeks from study entry to ascertain their use and perceptions of usefulness of the WHO Guide.
- Regardless of the group you are randomly assigned to, you will receive a comprehensive in-person assessment at the time of program completion (at 6 weeks from study entry for the self-guided program group and at 6 weeks from the first therapy visit among those randomized to the supervised rehabilitation program).
- Regardless of the group you are randomly assigned to, you will also be asked to complete an online follow-up survey 90 days after entering the trial.
- Regardless of the group you are randomly assigned to, upon completing the protocol, you will receive a list of COVID Recovery clinics in the area in which to seek care if symptoms persist.

What are the possible risks or discomforts?

The risks of participating in the clinical trial are minimal. You will be gently encouraged to progress in the program. You will be carefully monitored for signs of overexertion during the treatment and if any occurred following the treatment (at subsequent study visits). All participants will be educated on healthy diet/hydration, pacing and energy conservation, sleep/sleep hygiene and identification/avoidance of symptom triggers.

Risks will be minimized by ensuring all procedures in the trial are carried out by licensed therapists that are experienced in working with patients with PASC.

Participants may experience different results depending on which group they are randomized to. If participants are injured during the study they should inform the therapist treating them immediately.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

This research is designed to benefit society by gaining new knowledge. You may gain a reduction of symptoms, improvement in physical performance, and better cognition. However, you may not get any benefit from being in this research study

What other choices do I have if I do not participate?

You may discuss alternative treatments with your physician if you do not wish to participate.

Will I be paid for being in this study?

Regardless of the group you are randomly assigned to, you will receive $50 at the time of initial (baseline) in-person assessment, $75 at the time of the in-person program completion assessment, and $75 upon completing the 90-day online survey as reimbursement for your time, for a total payment of $200.
The payment is made through a ClinCard which is a reloadable prepaid card. There are no fees to use this card for store or online purchases. Fess may be incurred through the following:

- Not using the card or having funds added to it for more than 6 months will incur a $3 fee. Every time the card is used or funds are added, this 6 month period is reset.
- ATM withdrawls
- Requesting a paper statement, instead you can check your balance online or call customer service.
- Requesting a replacement card through Customer Service. Instead, your study site can replace your card at no charge.
- Requesting a check through Customer Service to remove funds from the card.

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

There are no costs to you for participating in this study. The therapy sessions and the self-guided program will be provided to you free of charge..

What happens if I am injured from being in the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician, the study Sponsor, or other oversight entitites without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor, the study Principal Investigator, or other oversight entity has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. You may do this by contacting the investigator noted on page one of this form. Withdrawal will not interfere with your future care.

How will my personal information be protected during the study?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records.

The confidentiality of your information will be protected in the following way during the study:

Only Penn Medicine providers involved in the study and the study team will have access to your records. In compliance with HIPAA, individual participant confidentiality will be assured through the use of ID codes. These ID numbers will not contain any personal identifiers (e.g., medical record numbers, date of birth). None of the analyses will permit individual identification. Data with be stored on computers which are password protected and are on Penn's private LAN network.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Will information about this study be available to the public?

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

What may happen to my information collected on this study?

Your information will be de-identified prior to storage. De-identified means that all identifiers have been removed. Your data will only be used for the purposes of this study and will not be shared with researchers outside of the study team. If you change your mind, we will not be able to destroy or withdraw your information that was collected and stored because all identifiers would have already been removed.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by using only password protected and are on Penn's private LAN network.

Will I receive the results of research testing that may be relevant to my health?

Many of tests done in research studies are only for research and have no clear impact on your healthcare. Research results for this study will not be returned to you because they would not be relevant to your healthcare.

What information about me may be collected, used or shared with others?

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- Name, address, telephone number, date of birth
- Social Security number
- Sex assigned at birth, gender
- Personal and family medical history
- Results from physical examinations, tests or procedures

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

It cannot be guaranteed that no one outside of the Penn Medicine will receive your personal information. The Principal Investigator may give your private medical information to the study sponsor and to their business partners so they can do their parts of the study. However, the information will be de-identified so that the reviewer will not have your name or contact information.

Study related information may be accessed and/or copied by other reviews. These reviewers may include the Good Shepherd Research Committee, Office for Human Research Protections in the US Department of Health and Human Services (DHHS), FDA, third party payers, authorized representatives of the National Institutes of Health, and the study sponsor. Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

<u>Oversight organizations</u>

- The U. S. Office of Human Research Protections (OHRP)
- The NIH
- The study data and safety monitoring board

Once your personal health information is disclosed to others outside Penn Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

However, Penn Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Participant HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document, you are permitting Penn Medicine to use and disclose personal health information collected about you for research purposes as described above.

Who can I call with questions, complaints or if I'm concerned about my rights as a research participant?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research participant, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the IRB at the number on page one of this form.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your protected health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that protected health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

_____	_____	_____
Name of Participant **[print]**	Signature of Participant	Date
_____	_____	_____
Name of Person Obtaining Consent **[print]**	Signature	Date