Developing an Integrative, Recovery-Based, Post-Acute COVID-19 Syndrome (PACS) Psychotherapeutic Intervention

NCT05453201

February 1, 2024

Version Date: 01/08/2024	**Page: 1 of 16**
Subject Name:	**Informed Consent Date:**
Protocol #: GOO-1696919 **Principal Investigator: Marianne Goodman, M.D.**	**VAMC: James J Peters**
Title of Study: Developing an Integrative, Recovery-Based, Post-Acute COVID-19 Syndrome (PACS) Psychotherapeutic Intervention, "PACS Coping and Recovery"	

This page for research staff only

Research Staff: *Hello, my name is _____from the James J Peters VA Medical Center, a VA hospital located in the Bronx, New York. I am calling with one other staff member ____about a potential research opportunity that you may be interested in called Long-COVID Coping and Recovery. Are you interested in learning more about it?* **Wait for any response.** If *you are interested, I can go over the consent for the study with _____as the witness and you can ask us any questions that come up. Make sure you have the mailed copy of electronically sent version of the informed consent form to follow along.*

Research staff goes over every part of the consent form with the Veteran.

1. Purpose of study and how long it will last:

You are being asked to participate in a research study. This study aims to examine a new intervention for veterans with Long-COVID called "Long-COVID Coping and Recovery (LC-CR)." LC-CR is a psychotherapeutic intervention focusing on assisting veterans with Long-COVID in managing their illness, increasing mental and physical functioning, and moving towards psychological and medical recovery.

This new treatment is a group therapy intervention in 16 weekly sessions with experienced clinicians. This study is sponsored by the Rehabilitation Research and Development Service (RR&D) Small Projects in Rehabilitation Research (SPiRE).

You are being asked to participate in this study because you have had COVID-19, subsequent Long-COVID symptoms, and Long-COVID related psychological distress. If you participate in this study, you will be provided the LC-CR treatment described in the next section, and your participation in the study will last approximately 12 months. We plan to enroll 36 Veterans.

2. Description of the Study Including Procedures to be Used:

If you consent to participate in this research study, you will go through the following procedures:

- Private assessments with a member of the research staff occur to assess your current status. You will be asked questions related to your COVID-19 and Long-COVID symptoms and general mental and physical health. This assessment should take about 1.5 hours. We will then provide you with the telehealth links to join our LC-CR intervention.

- LC-CR intervention:
  - You will participate in a novel group intervention that has been designed to provide a mechanism to develop and enhance recovery from Long-COVID. LC-CR, a 16-session, 1 hour and 15 minute weekly group psychotherapy intervention, is designed to build a relevant and personally meaningful action plan to address the symptoms you might be experiencing due to Long-COVID. The treatment is designed to closely map onto primary recovery processes that promote engaging in meaningful life changes and developing coping skills during recovery.
  - The therapy is divided into 2 modules consisting of 8 sessions each: The first 8 sessions will focus on skill based, coping strategies to target more immediate symptoms and Long-COVID related issues as part of the recovery process. The second 8 sessions will focus on more long-term recovery and creating a meaningful and purposeful future.
  - The LC-CR group will be held over the telehealth program VA Video Connect (VVC) with VA WebEx as an approved backup. To ensure the privacy and safety of participants, LC-CR members are asked to join the VVC when they are in a private area without others around. Before they join their first LC-CR group, the PI will call the participant to verbally review the group telehealth agreement, which is standard clinical practice at the VA for groups conducted over VVC and will explain the risks and consequences of group telehealth sessions. This acknowledgment will be documented in participants' medical records.
  - For the purposes of further training of the facilitators, the sessions of the LC-CR will be audio recorded. To protect confidentiality, digital audio recordings will be assigned a number and will be stored in a locked filing cabinet and on a secure, password protected folder within the VA firewall prior to review. Only the members of the research team will have access to this filing cabinet and password protected

folder. Digital audio recordings of study sessions will be de-identified and transcribed to protocol. Tapes will be listened to by the adherence monitor, who will make de-identified notes and then promptly upload them as a secure computer file, transcribe the content and then erase the digital recording on the device.

Upon completion of Module 1 (first 8 sessions) and Module 2 (second 8 sessions), you will be re-assessed using the previous questionnaires to track and compare your progress from before starting treatment. In addition, upon completion of Module 2, you will be asked questions about your opinions of the LC-CR intervention.

- All study procedures take place through the James J. Peters VA Medical Center (JJPVAMC).

Optional Ecological Momentary Assessment (EMA) Protocol

This optional Ecological Momentary Assessment (EMA) study is conducted by Dr. Brittany Stevenson, a clinical psychologist and researcher at the Minneapolis VA. We want to know if a daily survey study is feasible for Veterans with Long COVID, or Post-Acute COVID-19 Syndrome (PACS). Your participation in this research study is voluntary. Your participation in this study is not tied to your VA treatment in any way. We will share your responses with the James J. Peters VA team who is conducting the clinical trial for Long COVID. You may choose not to participate or to end your participation at any time without penalty.

We are conducting this research study to see if Veterans with Long COVID find it feasible to do daily surveys. If you agree to participate, we will set up a schedule for three separate weeks to get surveys. The first week will be at the beginning of the Long COVID trial, then in the middle, and the last one will be at the end. During each of those weeks, we will send you one daily survey at the end of the day via text message or email. The surveys take approximately 3 minutes or less to each day. If you don't want to participate, your care at VA will not be affected in any way

3. Description of any Procedures that may Result in Discomfort or Inconvenience

The LC-CR is a group-based treatment, which you may find uncomfortable. You may find the content distressing and may not want to share details of your clinical condition or symptoms with other group members. If you begin to feel uncomfortable/distressed during an assessment, please reach out to a member of the study team. We will work closely with you to help you with these concerns. We will alert your primary mental health provider through CPRS of any discomfort/distress in case you need additional support.

Optional EMA Study

If you choose to participate in the EMA study, Because the daily survey questions will focus on your experiences with mental health and Long COVID symptoms, some of the questions may cause you to feel uncomfortable, ashamed, anxious, or other negative feelings. You may decline to answer any question. You may discontinue the survey or the study at any time.

There is a slight risk that your participation may result in a loss of confidentiality. This would occur if someone not associated with the study saw your data. In order to minimize that risk, we will label your data with a study ID number instead of your name on most records. All research data will be stored on encrypted VA equipment with access allowed only to research staff. We will not collect any picture or voice recordings for this study. Your EMA responses will not be reviewed in real time. If your responses demonstrate significant risk or distress upon review by the Minneapolis VA research team, they will notify the study clinicians at the Bronx VA so they may follow-up accordingly.

4. Expected Risks of Study:

You may feel bored when you complete some of the assessments, and in rare cases they may cause some emotional distress. You may also find the group intervention to be physically and/or mentally draining. In addition, you may be concerned that your privacy and confidentiality may be at risk due to the telehealth nature of the intervention.

The research team has developed a safety management plan for the emergence of mental health distress or suicide risk. To facilitate safety, we will obtain your physical address and a call-back number, to be used in case of emergency; and ensure that a separate phone line is available for calling the Veterans Crisis Line if necessary. When using VVC, the e911 feature can be used to call emergency services to your physical address if necessary. If there is any indication of mental health distress or suicide risk, co-I Dr. Emily Edwards (VA psychologist with expertise in Veteran suicide risk assessment and management), therapy facilitator Dr. Ariana Dichiara (VA psychologist with expertise in comorbid mental and physical health conditions), and PI Dr. Marianne Goodman (VA psychiatrist with expertise in clinical and research Veteran suicide risk assessment and management) will be available to evaluate.

To help prevent physical/mental strain, the treatment structure includes sessions on energy conservation and awareness of your personal physical/mental boundaries.

To ensure the privacy and confidentiality of patient information, all information will be kept strictly confidential, with access limited to the research staff at the JJPVAMC, with the possible exception of state or federal regulatory personnel. Data from assessments will be stored on a secure VA server with no identifying information. Additionally, the research team will be using the telehealth platforms VVC and/or VA WebEx to complete study procedures, which provide HIPAA-compliant secure connections to protect participant privacy.

5. Expected Benefits of the Study:

There may be no direct benefit to you from this study, but any information we get from this study will help others. The knowledge gained will help us design and implement more effective treatments for Veterans with Long-COVID. LC-CR may support recovery from Long-COVID and improve coping and functioning. Group treatment may lessen isolation in participants and increase pathways to social support.

Optional EMA Study

Some Veterans find it beneficial to reflect on their mood and symptoms when completing the surveys, but otherwise there are no direct benefits to participating in the EMA study. Your responses to the surveys will not be monitored in real time.

6. Other Treatments Available:

There is little information about treatment approaches that specifically address Long-COVID symptoms. Alternative treatments for the physical aspects of Long-COVID include medications and interventions such as physical and occupational therapy, and alternative treatments for the psychological aspects of Long-COVID include psychotherapy and psychiatric medications.

It is entirely up to you to participate in this study. If you choose not to participate, you will be assisted in finding clinical treatment if you wish. Your choice not to participate in this study will in no way compromise your access to treatment.

7. Use of Research Results:

We will let you and your primary provider know of any significant new findings made during this study which may affect your willingness to participate in this study. Your answers to the interview questions will be in the possession of the study staff.

The data will be collected and stored at the James J. Peters VA Medical Center. Hard copies of your answers will be stored in a locked filing cabinet of the research assistant, in a locked office. Electronic data will be stored and secured on the VA network and will only be available to the study staff. Your name will be removed from all results and replaced with a code.

Records will be retained according to National Archives and Records Administration, in accordance with Records Schedule RCS-10-1.

If results of this study are reported in medical journals or at meetings, you will not be identified by name, by recognizable photograph, or by any other means without your specific consent. No information by which you can be identified will be released or published unless required by law.

Optional EMA Study

The only people who will see your identifiable data are Dr. Stevenson, her research assistants, and the research team at James J. Peters VA who is conducting the Long COVID clinical trial you are participating in. We will review your responses in limited detail (i.e., we will not always look at what options you individually selected) and not in real time. When you finish our daily survey study, or if you withdraw, your data will be sent to them, unless you request that we delete it. After your data from Minneapolis have been merged with your data from Bronx VA, we will deidentify your data. This means that we will erase your name, contact info, and dates so that no one can personally identify your responses. Sometimes we might have to show your data to the US Food and Drug Administration (FDA), Office for Human Research Protections, the Government Accountability Office and other Federal agencies, the Institutional Review Board (IRB), and/or the Research and Development Committee of the Minneapolis VA Health Care System to review research records. However, they will only review deidentified records so they cannot identify you personally.

If you consent to participating in this optional EMA research study, your name and contact information (email address and phone number) will be sent to Dr. Stevenson and her research team through a VA-encrypted email. She and her team will also have access to the information you share in the EMA surveys, which includes responses about your mental health and Long COVID symptoms.

If you wish to consent to participate in the additional Ecological Momentary Assessment study, please initial here _____.

Version Date: 01/08/2024	**Page: 9 of 16**
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In order to comply with federal regulations, research records identifying you maybe reviewed by the following:

Representatives of the sponsor or sponsors CSR&D/VA Funding Agency of this study, Authorized representatives of the Bronx VAMC (e.g. Institutional Review Board, Research Compliance Officer) and VA, including the Office of Research Oversight (ORO), Federal Agencies such as the Government Accounting Office (GAO), VA Officeof Inspector General (OIG), Food and Drug Administration (FDA) [if applicable], and the Office for Human Research Protections (OHRP).

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.

Do you give the researchers permission to contact you in the future to collect additional information about you, or to discuss possible participation in another research project? Please initial your choice:

Yes_____No _____

If consenting over the phone staff members initial below: Your initials as the study team member obtaining consent on this form indicates you provided information about future contact, and you initialed Yes/No to indicate the participants' response.

Yes_____No _____

Your initials as the witness on this form indicates the study member obtaining consent provided information about future contact and you too initialed Yes/No to indicate the participants response.

Yes_____No _____

Otherwise, your de-identified information may not be used for future research without additional consent.

1. **Special Circumstances:**
   A copy of your signed informed consent form and signed HIPAA authorization for participation in the study will be recorded in the Veteran's health record.

2. **Compensation and/or Treatment in the Event of Injury:**
   The VA must provide necessary medical treatment to a research subject injured by participation in a research project approved by a VA R&D Committee and conducted under the supervision of one or more VA employees. Further information about compensation and medical treatment may be obtained from the medical administration service at this VA Medical Center.

3. **Voluntary Participation:**
   You are not required to take part in this study; your participation is entirely voluntary you can refuse to participate in this study or withdraw your participation in this study after you consent without penalty or loss of VA or other benefits to which you are entitled.

   You can refuse to participate now, or you can withdraw from the study at any time after giving your consent. This will not interfere with your regular medical treatment if you are a patient.

Optional EMA Study:

Your participation in this research is voluntary. Your decision to opt -in or -out of this optional EMA research study will in no way affect your ability to participate in the Long COVID-Coping and Recovery group psychotherapy research study. Similarly, your decision to withdraw from this optional EMA research study at any point will in no way affect your ability to continue to participate in the Long COVID-Coping and Recovery group psychotherapy research study.

4. Termination of Participation:

There are no consequences if you choose to withdraw from this study.

Optional EMA Study:

There are no consequences if you choose to withdraw from this study. Your decision to withdraw from this optional EMA research study at any point will in no way affect your ability to continue to participate in the Long COVID-Coping and Recovery group psychotherapy research study. If you withdraw from the Long COVID-Coping and Recovery group, you will be automatically withdrawing from this EMA study also.

5. Costs and Reimbursements:

As a veteran or non-veteran, you will not be charged for any treatments or procedures that are part of this study.

You will be offered financial compensation based on completion levels of the following:

Research Procedure for LC-CR	Participant Compensation
Pre-Treatment Baseline Assessment	$75
Post-Intervention Assessment (Mod 1)	$75
Post-Intervention Assessment (Mod 2)	$75
Post-Intervention qualitative interview	$75

You will also receive a $50 bonus upon completion of each therapy module (after the first 8 sessions and after the second 8 sessions). It may take up to six weeks for reimbursements to be received.

Optional EMA Study

You will compensated by the James J. Peters VA team based on the number of surveys you start on your mobile device. If you at least start every survey during all three weeks, you will receive a total of $135 as compensation for your time and effort. During each of these separate weeks (or bursts) of surveys, we compensate $4, $5, and $6 per daily survey (it increases each burst), with a bonus of $10 per burst for starting at least 5 of the 7 surveys.

6. Contact Persons

To obtain answers to questions about the research, report or seek treatment for a research-related injury, or to voice concerns or complaints about the research contact the following: Marianne Goodman MD:

- During the Day: Marianne Goodman, M.D., 718-584-9000 ext. 5188
- After Hours: Marianne Goodman, M.D., (646) 245-7071

I understand that should I wish to discuss my participation in this study with any other doctor or layperson, I can contact Mary Sano, Ph.D. ACOS/R&D Program by requesting an appointment at (718) 741-4228 hospital extension 4228, first floor in the research building, room 1F-01 If I have questions, concerns and/or complaints or to offer input.

Optional EMA Study:

If you have any questions, comments, or concerns about the research, please contact Brittany Stevenson at 612-467-3023.

RESEARCH SUBJECTS' RIGHTS: Dr. Marianne Goodman or her delegate has explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled.

Version Date: 01/08/2024	**Page: 14 of 16**
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The results of this study may be published, but my records will not be revealed unless required by law. This study has been explained to me. I have had a chance to ask questions. I voluntarily consent to participate in this study. I will receive a signed copy of this consent form.

Subject Signature Date

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page) | Signature of Person Obtaining Informed Consent | Date

Optional EMA Study

By completing the EMA surveys, you are agreeing to participate in this study.

*Only include this section if the IRB approves surrogate consent for the research study for individuals with impaired decision-making capacity.
This also includes subjects with a disability who do not have the physical capacity to sign consent.

*Subject's Legally Authorized Representative (Print Name) | Relationship to Subject

Signature of *Subject's Legally Authorized Representative | Date | Time

Person Obtaining Informed Consent (Print Name) (Investigator or Delegate as indicated on Assurance Page) | Signature of Person Obtaining Informed Consent | Date

Version Date: 01/08/2024	**Page: 15 of 16**
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This page for research staff only

only use if consenting over the phone – otherwise skip

Research Staff: After going over the consent. Do you have any questions so far that have not been answered?

Participant Answer: YES☐ NO ☐I

CONSENT: I am now going to ask you if you consent to participate in this study. Only say yes if you have understood the information, I have told you, you voluntarily agree to participate, and you are 18 years of age or older. If you have any questions or there is something you do not understand, please ask before responding.

Do you consent to participate in this research study?

Participant Answer: YES☐ NO ☐

If you just agreed to consent in the study, please sign and date the consent in your possession that you have been following along with.

Informed consent signed by patient not retained due to_____.

Please see attestations below.

How was consent obtained: _____

Version Date: 01/08/2024	**Page: 16 of 16**
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Witness:
As the one witness your signature on this form indicates you agree you were present as the study team member explained the research study to the patient named on this form. You heard the study team member review all information provided in this consent form, made sure the participant understood the information, and answered the participant's questions to the best of their ability. Your signature also indicates the participant confirmed agreement to participate in the study and signed the informed consent form. As the one witness, agree to be contacted by parties including the IRB with any questions.

Study Team Member:
As the one obtaining informed consent your signature on this form indicates you agree you provided information about the aforementioned research study to the patient named on this form. You reviewed all information provided in this consent form, made sure the participant understood the information, and answered the participant's questions to the best of your ability. Your signature also indicates the participant confirmed agreement to participate in the study and signed the informed consent form. As the one obtaining informed consent, agree to be contacted by parties including the IRB with any questions.

_____

Witness 1 Print Name and Signature Date Time

_____

Person Obtaining Informed Consent Print Name and Signature Date Time