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

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**JJPVAMC**

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Abstract

Epidemiological estimates suggest that approximately 11,390,400 Americans, and 90,300 Veterans in VA care experience symptoms for months after initial COVID-19 infection, a phenomenon known as Sequelae of Sars CoV-2 infection (PASC) or more colloquially known as Long-COVID. Common symptoms of Long-COVID include prolonged fatigue, impairment of memory, concentration disorder, headache, pain, insomnia, anxiety, post-traumatic stress disorder (PTSD), and depression. Longer term effects of COVID-19 have been reported in all age groups and demographics including persons with asymptomatic, mild, or severe initial COVID-19 infection. A recent VA-based Nature publication representing the largest cohort of Long-COVID patients studied to date (n= 73,435 non-hospitalized patients with COVID-19, 13,654 hospitalized patients with COVID-19 and 5 million other VA patients without COVID-19) reported on 6-month outcomes post-infection. Long-COVID patients had an increased risk of death, use of health resources, and a substantial burden of health loss spanning multiple organ systems. Post COVID-19 VA patients also showed increased mental health problems including sleep disorders, anxiety disorders, trauma and stress-related disorders as well as used more opioid and non-opioid pain medications, antidepressants, and sedatives to treat these conditions. These findings are critical to estimating the impact of Long-COVID on Veterans, who may have unique vulnerabilities due to increased incidence of trauma, physical, and psychiatric risk factors.

Long-COVID Coping and Recovery (LC-CR) is a promising new manualized psychotherapeutic intervention focusing on illness management, functional improvement and moving towards recovery from Long-COVID. This study will pilot test the acceptability and feasibility of LC-CR. The treatment aim is to improve psychological adjustment to Long-COVID symptoms, promote resilience, and facilitate coping, based on skills training, acceptance-based and identity-based principles The results of the proposed study will provide data to 1) identify adaptations needed to optimize LC-CR for Veterans with Long-COVID: 2) identify possible benefits of LC-CR; 3) inform development of a large scale RCT of LC-CR for Veterans with Long-COVID.

List of Abbreviations

Provide a list of all abbreviations used in the protocol and their associated meanings.

| | |
|---|---|
| AE | Adverse Event |
| CHIME | Connectedness; Hope and optimism about the future; Identity; Meaning in life; and Empowerment. |
| CPRS | Computerized Patient Record System |
| LC-CR | Long-COVID Coping and Recovery |
| MERS-CoV | Middle East Respiratory Syndrome Coronavirus |
| OCC | Office of Connected Care |
| PASC | Post-Acute Sequelae of Sars CoV-2 infection |
| SAMHSA | Substance Abuse and Mental Health Services Administration |
| SARS-CoV | Severe Acute Respiratory Syndrome Coronavirus |
| VA CONNECT | VA Caring for Our Nation's Needs Electronically during the COVID-19 Transition |
| VHA | Veterans Health Administration |
| VVC | VA Video Connect |

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**Protocol Title:** Developing an Integrative, Recovery Based, Post-Acute COVID-19 Syndrome (PACS) Psychotherapeutic Intervention, "PACS Coping and Recovery"

## 1.0 Study Personnel

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**Participating Sites:** All research procedures will take place at the James J. Peters VA Medical Center, except for the Ecological Momentary Assessment (EMA) procedures which will be executed out of the Minneapolis VA Medical Center. However, all participants will be recruited and consented via the James. J. Peters VA Medical Center.

## 2.0 Introduction

Epidemiological estimates suggest that approximately 11,390,400 Americans, and 90,300 Veterans in VA care experience symptoms for months after initial COVID-19 infection, a phenomenon known as Post-Acute Sequelae of Sars CoV-2 infection (PASC) or more colloquially known as Long-COVID. Common symptoms of Long-COVID include prolonged fatigue, impairment of memory, concentration disorder, headache, pain, insomnia, anxiety, post-traumatic stress disorder (PTSD), and depression (Taquet et al., 2021). Longer term effects of COVID-19 have been reported in all age groups and demographics including persons with asymptomatic, mild, or severe initial COVID-19 infection. Despite Long-COVID symptoms resulting in significant functional impairment, there are few empirically supported treatment approaches specifically designed to address this population. Many in the field contend that given the complexity and variability of Long-COVID manifestations, successful treatment cannot be considered from a single organ point of view, but rather require a patient-tailored multidisciplinary approach that steps beyond amelioration of psychological symptoms (Ambrosino et al., 2021; Lerner et al., 2021). Long-COVID treatment requires specialists across medical, neurological, rehabilitation, and mental health fields in conjunction with recovery-based approaches such as Whole Health, and Chaplain Services.

Our proposed intervention, Long-COVID Coping and Recovery (LC-CR), aims to improve psychological adjustment to Long-COVID symptoms, promote resiliency, and facilitate coping, all of which can impact functional status and quality of life. LC-CR is designed to help to build a relevant and personally meaningful action plan to address the symptoms Veterans may be experiencing due to Long-COVID and to assist Veterans with Long-COVID in managing their illness, increasing function, and moving towards recovery. LC-CR focuses on psychological adjustment and coping, and augments medical, rehabilitation, and neurological treatment for this population. Our approach is based on the CHIME model of personal recovery which includes five overarching processes: 1) Connectedness; 2) Hope and optimism about the future; 3) Identity; 4) Meaning in life; and 5) Empowerment. We will target the CHIME processes using established psychotherapeutic techniques such as skills training, acceptance-based and identity-based principles. Our integrative approach will incorporate rehabilitative strategies from specialists treating Long-COVID patients (e.g., pulmonologists; nutritionists; chaplains; rehabilitation therapists, etc.) with the focus of restoring functional capacities, fostering resiliency, and bolstering life satisfaction.

Our ability to access the Icahn School of Medicine at Mount Sinai's COVID Registry longitudinal data, and leadership in our local James J. Peters VA's Long-COVID Clinical Recovery Center, coupled with our expertise in recovery-based psychotherapy (see preliminary studies), we are uniquely poised to pilot an innovative treatment for Veterans with Long-COVID.

Based on adaptations from existing recovery-based and COVID-19 distress group interventions that our team has developed/piloted, we have developed a treatment framework that consists of twenty 75-minute weekly sessions. ". The therapy will be divided into two modules consisting of 8 sessions each (16 sessions total): Module 1 (the first 8 sessions) will target more immediate symptoms and Long-COVID related issues as part of the recovery process. Module 2 (the second 8 sessions) will focus on more long-term recovery and creating a meaningful and purposeful future. We specifically are designing a group intervention to build support and mitigate the loneliness associated with chronic conditions such as Long-COVID. The core sessions will focus on the impact of Long-COVID on mental and physical health, teach coping skills to foster resiliency and hope, identify barriers to employment/education due to Long-COVID, and review relapse prevention.

# 3.0 Objectives

**Overall Goal:** To pilot a Long-COVID psychotherapeutic intervention, "Long-COVID and Recovery" (LC-CR) while collecting pilot data to assess its acceptability and feasibility.
**Aim 1:** Identify adaptations needed to optimize LC-CR for Veterans with Long-COVID through veteran and stakeholder consultation.
**Aim 2:** Identify possible benefits of LC-CR.
**Aim 3:** Inform development of a large scale RCT of LC-CR for Veterans with Long-COVID.

**3A) Significance**
**Long-COVID in the VA:**

A recent VA-based Nature publication representing the largest cohort of Long-COVID patients studied to date (n= 73,435 non-hospitalized patients with COVID-19, 13,654 hospitalized patients with COVID-19 and 5 million other VA patients without COVID-19) reported on 6-month outcomes post-infection (Al-Aly et al., 2021). Long-COVID patients had an increased risk of death, use of health resources, and a substantial burden of health loss spanning multiple organ systems. Post COVID-19 VA patients also showed increased mental health problems including sleep disorders, anxiety disorders, trauma and stress-related disorders as well as used more opioid and non-opioid pain medications, antidepressants, and sedatives to treat these conditions (Al-Aly et al., 2021). The authors also found that the severity of initial COVID-19 infection predicted later Long-COVID symptom severity. A recently published report on one-year longitudinal follow-up data on hospitalized COVID-19 patients, noted statistically significant increases in anxiety or depression from the six-month to twelve-month time points (Huang et al., 2021). **These findings are critical to estimating the impact of Long-COVID on Veterans, who may have unique vulnerabilities due to increased incidence of trauma, physical, and psychiatric risk factors** (Marini et al., 2020; Na et al., 2021; Hill et al., 2021)**.**

**Previous coronavirus epidemics demonstrated long term psychiatric sequelae**:
The two global epidemics from coronavirus outbreaks include Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV) and Middle East Respiratory Syndrome Coronavirus (MERS-CoV); both left survivors with fatigue, persistent shortness of breath, reduced quality of life and significant mental health problems (O'Sullivan, 2021). A Lancet meta-analysis of MERS and SARS psychiatric sequelae noted post-infection point prevalence of post-traumatic stress disorder (32.2%), depression (14.9%), and anxiety disorders (14.8%) and a mean return to work of almost three years (Rogers et al., 2020). Also concerning was the lengthy duration of psychiatric symptoms; up to 4 years for SARS-CoV (Lam, 2009) Moreover, one third of SARS survivors experienced a psychiatric disorder 30 months post infection (Mak et al., 2009). **These statistics highlight the prevalence and chronicity of mental health sequalae of CoV infections.**

**Long-COVID and Functional Impairment:**
There is a growing literature recognizing the negative impact of Long-COVID on functioning in individuals with severe presentations of COVID-19 requiring hospitalization (Olezene et al., 2021; Daunter et al., 2021), and also more mild cases (Jacobson et al., 2019; Havervall et al., 2021). Colleagues at Stanford University examined longitudinal functional outcomes in 118 COVID+ patients, including 22 who were hospitalized (18%; Jacobson et al., 2019). Four months post infection, in those with employment, 11.5% missed work and just under 40% reported health-related impairments at work. For the full cohort, approximately 50% reported health-related impairment in daily activities. Long-term impairment at home or at work did not differ by initial hospitalization status highlighting the chronicity of dysfunction extending to less severe presentations. Similarly, a report of healthcare providers with COVID-19 noted that a considerable portion of low-risk individuals with mild COVID-19 infection reported a diversity of long-term symptoms, and that these symptoms disrupted work, social, and home life (Havervall et al., 2021). While research examining the direct impact of COVID-19 on functional impairment is limited at this point, past work among other medical illnesses suggests that that the link between disease severity and functional impairment is moderated by co-occurring mental health symptomatology (i.e. anxiety and depression; Kim et al., 2000). Similarly, anxiety sensitivity has been found to moderate the impact

of COVID-19 perceived stress on functional Impairment (Julious, 2005) **This data highlights the importance of addressing mental health symptoms directly to positively impact functional status.**

**Mental health treatment for Long-COVID patients:**
Despite Long-COVID symptoms resulting in significant functional impairment, as of yet, there are few empirically supported treatment approaches specifically designed to address this population. Many in the field contend that given the complexity and variability of Long-COVID manifestations, successful treatment cannot be considered from a single organ point of view, but rather require a patient-tailored multidisciplinary approach (Ambrosino et al., 2021; Lerner et al., 2021).

**Recovery-oriented care is a valuable approach to helping Veterans:**
The traditional medical model of mental illness focuses on treating mental illness as a disease and on finding a 'cure' leading to the absence of clinical symptoms. However, in recent years, mental health recovery has been understood to extend beyond remission of symptoms. During the 1980s, through a deepening understanding of the lived experience of those suffering from mental illness, recovery was understood to involve living a fulfilling, rewarding life, even with the ongoing presence of mental illness (Taquet et al., 2021). Recovery was seen to involve positive changes in how people think about and experience themselves which may occur regardless of whether they experience symptom reduction or improved function (Taquet et al., 2021). There have been several attempts to provide concrete frameworks for 'recovery'. The Substance Abuse and Mental Health Services Administration (SAMHSA) has developed a working definition of 'recovery' from mental illness; "a process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential" (p. 3; Leamy et al., 2011). SAMHSA, in 2012, identified ten guiding principles to recovery (Hope, Person-Driven, Many Pathways, Holistic, Peer/Ally Supported, Relationships/Social Network Supported, Culturally Based, Addresses Trauma, Involves Strengths/Responsibilities, and Respect; Leamy et al., 2011). Finally, an influential review of 89 studies focusing on personal recovery in mental health found five overarching recovery processes with high levels of relevance to clinical research and practice: 1) Connectedness; 2) Hope and optimism about the future; 3) Identity; 4) Meaning in life; and 5) Empowerment (summarized with the acronym '**CHIME'**; Goodman et al., 2020). A study with 7 focus groups (N=57) found individuals receiving recovery-oriented mental health care report increases in CHIME areas (Sokol et al., 2021). **The CHIME recovery framework fits with the overall VA mental health mission and has increasingly been implemented in the VAMC system as well as nationally and internationally** (Marini et al., 2020).

**3B) Innovation**

**Applying recovery model to Long-COVID:**
The VHA is a leader in the movement towards recovery-oriented mental health care, which focuses on creating collaboration between users and providers guided by the user's vision of the life they want to lead. There is a need to apply recovery approaches from chronic illnesses as this approach best matches the trajectory of Long-COVID patient's needs. Within this paradigm, interventions will focus on positive identity, growth through Long-COVID related challenges, building optimism, connection, personal control and meaning in order to improve functioning and quality of life. In addition, our treatment includes integration of a skills development approach for facilitating increased coping and building resilience.

**Long-Term Impact:**
Given the number of individuals who have been or will be infected with COVID-19, the public health impact will continue to be profound. The VHA will undoubtedly be greatly affected by the lasting impact of infection. As of August 19, 2021, the VHA has diagnosed over 300,000 Veterans with COVID-19 infection, 273,732 convalescent cases and 13,254 deaths (data from the VA COVID-19 National Summary website). If only a small fraction of SARS-CoV-2 infections lead to longer term effects, the burden of disease will be significant. Despite large numbers of individuals experiencing post-COVID symptoms and psychiatric sequelae (upwards of 30%; (Logue

et al., 2021), impacting quality of life and functional status, few empirically validated treatment approaches exist, and none in the Veteran population.

## 4.0 Resources and Personnel

The proposed research will benefit from our well-developed infrastructure for developing and implementing recovery-oriented, group therapeutic interventions, some of which are described below. The research team includes Marianne Goodman M.D. as the primary investigator and a research health science specialist in the MIRECC with clinical and research experience regarding group therapy development and implementation. In addition, Marianne Goodman has extensive clinical and research experience with Long-COVID Veterans, including the development and implementation of VA CONNECT (VA Caring for Our Nation's Needs Electronically during the COVID-19 Transition), a manualized telehealth intervention with designated content for each session that enables Veterans to share concerns, exchange information, help one another, learn immediately helpful coping strategies, practice breathing and mindfulness exercises each session, while building personalized action plans for combatting the physical and mental impacts of COVID-19.

Yosef Sokol PhD is a co-investigator and is a MIRECC faculty member with experience in developing recovery-oriented group therapies based on acceptance and identity principles. Dr. Sokol is a CDA 2 recipient for his novel recovery-based intervention Continuous-Identity Cognitive Therapy (CI-CT).

Emily Edwards PhD is a co-investigator and is a MIRECC faculty member with experience conducting individual and group psychotherapy in the inpatient and outpatient centers at the VA for individuals at risk for suicide.

Brittany Stevenson PhD is a co-investigator and is responsible for leading the EMA portion of the protocol. She is a staff Clinical Psychologist at the Minneapolis VA and Assistant Professor of Psychiatry and Behavioral Sciences at the University of Minnesota, and she has expertise in ecological momentary assessment.

Amelia Kiliveros is a research staff member who will serve as a liaison with the Long-COVID clinic at the JJPVAMC. She is a Licensed Mental Health Counselor who has been working as a Clinical Research Manager at JJPVAMC since 2017. She has experience managing clinical trials for COVID 19 treatment and serving as a liaison between patients and their providers to assist with medication compliance and knowledge of their disease and treatment.

Ariana Dichiara, PsyD is a research staff member (therapy facilitator/clinician) and is a JJPVAMC employee with experience conducting group psychotherapy. She specializes in evidence-based therapies that address trauma, comorbid mental and physical health conditions, and substance use. She is experienced in facilitating telehealth therapy groups.

## 5.0 Study Procedures

## 5.1 Study Design

**Group Intervention**. Veterans will participate in a LC-CR group (75 minutes 1x/week for a total of 16 sessions) via the HIPAA-compliant telehealth platform VA Video Connect (VVC) in accordance with the Office of Connected Care (OCC)'s best telehealth practices. VA WebEx will be available as an approved back-up telehealth platform in the event of VVC technical difficulties.

The intervention will be delivered in two modules consisting of 8 sessions each (16 sessions total):
**Module 1:** The first 8 sessions of the treatment will focus on skill based coping strategies to target more immediate symptoms and Long-COVID related issues as part of the recovery process.
**Module 2:** The second 8 sessions will focus on more long-term recovery and creating a meaningful and purposeful future.

Sessions will be co-facilitated by Dr. Ariana Dichiara and another co-therapist. Dr, Goodman will be the co-therapist for Module 1 of therapy (first 8 sessions) and Dr. Sokol will be the co-therapist for Module 2 of therapy (second 8 sessions).

**Timeline**: (See **GANTT chart)** For the first 3 months we will complete the needs assessment interviews. In months 4-7, we will revise the psychotherapy workbook and therapist manual *and will consult with stakeholders monthly for input on revisions throughout our piloting phases.* In months 18-24, we will develop and submit a RR&D Merit grant application for an RCT to test the treatment.

| **Project dates: 10/1/22- 9/30/24** | Year 1 | | | | Year 2 | | | |
|---|---|---|---|---|---|---|---|---|
| | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| Activity | October - December (2022) | January-March (2023) | April-June (2023) | July-September (2023) | October-December (2023) | January-March (2024) | April-June (2024) | July-September (2024) |
| IRB | | | | | | | | |
| Train RA and other startup activities | | | | | | | | |
| Complete PACS needs assessment | | | | | | | | |
| Analyze needs assessment results | | | | | | | | |
| Finish developing psychotherapy materials and therapist manual | | | | | | | | |
| Consult with stakeholders on proposed intervention and revise materials | | | | | | | | |
| Run first set of pilot group | | | | | | | | |
| Revise treatment based on trial particiapants and stakeholder feedback | | | | | | | | |
| Run second set of pilot groups | | | | | | | | |
| Present findings | | | | | | | | |
| manuscript preparation | | | | | | | | |
| Merit preparation/sSubmission | | | | | | | | |

## 5.2 Recruitment Methods

Long-COVID Patients will be recruited through recruitment from James J. Peters VAMC Long-COVID clinical program and clinician referrals. The Bronx had significantly higher rates of COVID-19 infection than other boroughs in New York City. Thus, recruitment of *up to 36 Veterans* is feasible within the 18-month timeframe.

**Limitations and Future Directions.** One potential issue may be the recruitment of Veterans with Long-COVID. However, a strength of the proposed study is it's involving telehealth, making it more appealing to participants and less prone to no-shows. We will also recruit from our in-house Long-COVID center and multiple existing national Long-COVID programs. While the JJPVAMC is diverse in race and ethnicity, our

study may still have a diversity limitation as it will be conducted in an urban northeast VAMC and may not fully generalize to other areas of the USA. Future studies should extend the findings across other VAMCs. During year 2 we will submit a Merit Award to complete the planned follow up study testing the final manualized version of LC-CR (developed in this SPiRE project) in a multi-site clinical efficacy RCT.

Veteran participants will be offered financial compensation for their participation 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 (Mod 2). | $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).

Participants who consent to enroll in the EMA portion of the research study will be compensated for their participation. The JJPVAMC will be responsible for compensating patients.Participants will be compensated per survey initiated (i.e., at least one question is answered). Participants can receive up to $135 across all three week-long bursts of daily surveys.

At this time, we anticipate providing a maximum of $135 per person for participating. Each burst listed below lasts for 7 days. The payment schedule is as follows:

- Burst 1, baseline: $4 per daily assessment initiated
    - Maximum: $28 for this burst
- Burst 2, mid-treatment: $5 per daily assessment initiated
    - Maximum: $35 for this burst
- Burst 3, end of treatment: $6 per daily assessment initiated
    - Maximum: $42 for this burst
- In addition, we will offer an extra $10 incentive for initiating 5 or more daily assessments per burst.
- Thus, total possible is $135 per person, including all $10 bonuses.

Note: initiation means filling in at least 1 question on the survey (out of approximately 20).

## 5.3 Informed Consent Procedures

Veterans will be recruited from the Post-COVID Clinic and other medical providers at the JJPVAMC.

Prior to participation in the protocols, patients are called by research personnel at which time the nature of our program, the procedures involved, and alternatives to the study are discussed. The patient must understand and be able to articulate the risks and benefits of the research protocols and understand the alternatives. Patients who agree to participate are reimbursed for their time and inconvenience at rates that do not represent inducement. After the protocol is described to the subject and the subject's questions are answered, the subject will be asked to summarize the procedures that he/she will undergo and to describe 2 risks involved in the study. If there is any doubt about the subject's capacity to give consent, an independent psychiatrist will assess the subject to determine whether they understand the study and can give informed consent.

Consent will be obtained upon talking with the Veteran if s/he agrees to participate in the study (over the phone at this time if it is unsafe to consent in person). The individuals communicating information to the participant during the consent process will provide that information in language understandable to the participant.

The information being communicated to the participant during the consent process will not include exculpatory language through which the participant is made to waive or appear to waive any of the participant's legal rights. When the investigator verbally obtains consent, the participant will not be made to feel as if he or she has waived any of his or her rights as a human subject. The main purposes of the consenting process are for the investigator to inform the participant in detail about what will take place during the study, to allow the participant to ask any questions that he or she may have, and to explain to the participant that he or she is a volunteer for the study and may choose to decide against taking part at any point in time.

We ensure that the information being communicated to the participant during the consent process will not include exculpatory language through which the investigator, the sponsor, the institution, or its agents are released from liability by providing patients with contact information for the PIs and co-investigators should they feel that they have suffered an injury. Furthermore, patients are informed in the consent document that if they are eligible veterans, they are entitled to medical care and treatment if they experience any adverse effects resulting from the study. Participants are also provided with the contact information for the JJP VA IRB should they have questions regarding the research or their rights.

The informed consent form includes information related to the procedures, risks, and benefits of the optional EMA study. Those participants who consent to the optional EMA study will be given an Information Sheet with additional information about the EMA study, its risks and benefits, and assessment and compensation plan.

## 5.4 Inclusion/Exclusion Criteria

Inclusion criteria include: (1) U.S. Veteran (2) Age 18-80 (3) Screened positive for Long-COVID (e.g., COVID-19 positive, diagnosed with a PCR test and/or an antibodies blood test, and symptoms lasting 1 month or longer after infection (4) Participation in VA Services the JJPVA (5) Sufficient clinical stability and readiness to participate in a group therapy as deemed by their VA Service provider,

Exclusion criteria include: (1) Active alcohol or opiate dependence requiring medically supervised withdrawal. ( (2) Active psychosis. (3) MINI Mental Status < 23 or inability to function in a group setting. (4) Those unable to operate telehealth platforms or other devices. (5) Unable to speak English. (6) Lack of capacity to consent. (7) Unable or unwilling to provide at least one contact for emergency purposes.

## 5.5 Study Evaluations

**Clinical Assessments and Schedule**. Patients will have been screened/diagnosed as a part of their local VAMC's Long-COVID Clinical Center. Interested eligible participants will enroll and undergo assessments at pre (consent & baseline), immediately post module 1 of therapy (after first 8 sessions) andimmediately post module 2 of therapy (after second 8 sessions) via either in person, over the phone, or via HIPAA-compliant web platform VA Video Connect (VVC) (with Audacity audio recording software) with VA WebEx as a viable backup depending on the participant's preference/availability.

**The following scales will be piloted for our future RR&D Merit submission.**

1. The ***MINI Mental State Examination (MMSE)*** will be used to test for adequate cognitive function to participate in this study. This 11-question measure tests five areas of cognitive function: orientation, registration, attention and calculation, recall, and language. The maximum score is 30. A score of 23 or lower is indicative of cognitive impairment (Folstein et al.,1975).
2. ***The World Health Organization Disability Assessment Schedule, 2nd Version*** *(**WHODAS 2.0**)* will be used to measure functional status as relates to health (Üstün et al., 2010). The WHODAS 2.0 has been validated in the general population and amongst those with non-acute health conditions, and has a Cronbach's alpha of .96 (Saltychev et al., 2021)
3. We will measure resilience using the ***Measure of Current Status Part A*** *(**MOCS***), the first section of two-part Likert scale; participants' current self-perceived status and potential nonspecific effects of the intervention and alphas ranging from 0.71 to 0.89 (Antoni et al., 2006; Antoni et al., 2006a).
5. ***The Quality of Life Scale (QOLS)*** measures domains that diverse patient groups with chronic illness define as quality of life. The QOLS is a valid instrument for measuring quality of life across patient groups and cultures and is conceptually distinct from health status or other causal indicators of quality of life (Burckhardt & Anderson, 2003)Identity concerns will be assessed with the ***Future Self-Continuity Questionnaire,*** *(**FSCQ***), which measures an individual's sense of personal identity from the present to the future (Sokol & Serper, 2019). This Likert scale questionnaire (responses between 0-6) is a 10-item self-report instrument that addresses three areas of future self-continuity: vividness, similarity, and positivity. The FSCQ has demonstrated high levels of reliability (α=.85) and validity.
6. Suicidal ideation and behavior will be measured with the ***Suicide Behaviors Questionnaire- Revised (SBQ-R).*** In view of its moderate to strong reliability, its construct and fact validity, its ease of administration and scoring, and its brevity, the SBQ is recommended as a brief screening instrument for suicidality for researchers and clinicians (Cotton et al., 1995).
7. ***Questionnaire about the Process of Recovery (QPR)*** is a 22-item scale designed to assess progress through the process of recovery. The QPR is a self-report questionnaire and items are designed to measure recovery. The survey asks participants to rate their agreement with statements on a 5-point Likert scale (0=strongly disagree, 5=strongly agree). This measure has demonstrated high reliability and validity (Neil et al., 2009).

The following assessments are conducted as part of admission to the Long-COVID Clinic at the JJPVAMC. Therefore, to eliminate repetitive measures from those recruited from the Long-COVID clinic, these assessments will be pulled from enrolled participants' CPRS charts. These assessments will only be pulled if they had been completed **less than or equal to 3 months** prior to enrollment in the study:

8. ***COVID-19 Yorkshire Rehabilitation Scale (C19-YRS)*** consists of 22 items with each item rated on an 11-point numerical rating scale from 0 (none of this symptom) to 10 (extremely severe level or impact). The C19-YRS is divided into four subscales (range of total score for each subscale): symptom severity score (0–100), functional disability score (0–50), additional symptoms (0–60), and overall health (0–10). The C19-YRS can be freely obtained under license from the University of Leeds(O' Connor et al., 2022).

9. ***Patient Health Questionnaire- 9 (PHQ-9)*** is the 9-item depression module from the full PHQ. Major depression is diagnosed if 5 or more of the 9 depressive symptom criteria have been present at least "more than half the days" in the past 2 weeks and 1 of the symptoms is depressed mood or anhedonia. As a severity measure, the PHQ-9 score can range from 0-27, since each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day). An item was also added to the end of the diagnostic portion of the PHQ-9 asked patients who endorsed symptoms: "How difficult have these problems made it for you to do your word, take care of things at home, or get along with other people?" (Kroenke et al., 2001).

10. ***GAD-7 Anxiety*** is a valid and efficient tool for screening for GAD and assessing its severity in clinical practice and research (Spitzer et al., 2006).

If a participant does not have these measures previously completed in their medical chart and/or they are more than 3-months old, they will be conducted by the study staff following consenting procedures.

| Test /Procedure: | Outcome | When: | # of times: |
|---|---|---|---|
| ***MINI Mental State Examination (MMSE)*** | **Cognitive Function** | **Consent & baseline** | **1** |
| ***The World Health Organization Disability Assessment Schedule, 2nd Version (WHODAS 2.0)*** | **Functional Status as relates to health (primary outcome)** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***Suicide Behaviors Questionnaire- Revised (SBQ-R).*** | **Suicidal Risk/Behavior** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***Measure of Current Status (MOCS)*** | **Resilience** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***The Quality of Life Scale (QOLS)*** | **Quality of Life** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***Future Self-Continuity Questionnaire, (FSCQ)*** | **Identity Concerns** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***GAD-7 Anxiety*** | **Anxiety** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***Patient Health Questionnaire- 9 (PHQ-9)*** | **Depression** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***COVID-19 Yorkshire Rehabilitation Scale (C19-YRS)*** | **Long COVID Symptom severity** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |
| ***Questionnaire about the Process of Recovery (QPR)*** | **Progress through Recovery Process** | **Consent & baseline, post-Mod 1, Post Mod 2,** | **3** |

**Feasibility and acceptability metrics.** Feasibility will be tracked through 1) implementation ease - tracking the hours clinicians spend in preparation, delivery, and supervision with a target of 100 hours/ cycle (5 hours per group). 2) recruitment - tracking referrals and 3) attendance/retention - tracking the sessions Veterans attend. Our criteria for retention will be "adequate" if *60%* attend at least 5 of the first 8 sessions (Module 1), 5 of the second 8 sessions (Module 2), and 10 of the total 16 sessions (Module 1 + Module 2). A similar strategy will be used for recruitment rates, with feasibility deemed "adequate" if at least *60%* of Veterans approached for participation in the study agree. At the end of each session, we will ask veterans the following questions: "What did you like about this session?" What did you not like about this session?" "Do you have any suggestions for improvement?" to gauge acceptability, feasibility, and appropriateness of each session.

Veterans will complete the AIM, IAM and FIM ( Weiner et al., 2017) prior to and after completion of the program. These are four-item measures of implementation outcomes (acceptability and feasibility of intervention and intervention appropriateness) that are often considered "leading indicators" of implementation success (Proctor et al., 2011). We will also track homework adherence by percent complete. Lastly, upon completion of all LCCR sessions we will ask the veterans' additional questions to obtain *participants' feedback on the group.* Responses will be de-identified and analyzed for future development and implementation purposes.

| Test /Procedure: | Outcome | When: | # of times: |
|---|---|---|---|
| **Acceptability of Intervention Measure (AIM) Weiner et al., 2017)** | **How acceptable or satisfactory is the LC-CR group is to Veterans** | **Pre-treatment, Post-treatment (Mod 1), Post treatment (Mod 2)** | **3** |
| **Intervention Appropriateness Measure (IAM) Weiner et al., 2017)** | **How is the perceived fit, relevance, or compatibility of LC-CR to Veterans** | **Pre-treatment, Post-treatment (Mod 1), Post treatment (Mod 2)** | **3** |
| **Feasibility of Intervention Measure (FIM) Weiner et al., 2017)** | **How easy is it to participate in LC-CR** | **Pre-treatment, Post-treatment (Mod 1), Post treatment (Mod 2)** | **3** |
| **Qualitative Interviews** | **Acceptability, Feasibility, and Appropriateness of Intervention to help identify other needed implementation strategies for future dissemination** | **Post-treatment (Mod 2)** | **1** |

**5.5.1 EMA Protocol (to be carried out at Minneapolis VA by Dr. Stevenson's team):** Participants who opt-in to the optional EMA component of the study during the consent process will be scheduled to receive three different week-long bursts of daily surveys (one at baseline, mid-treatment, and end of treatment). Each survey will contain approximately 20 questions and will be delivered at the end of the day (at a personalized time). They are expected to take approximately 3 minutes to complete. The surveys do not contain any intervention component. Participants will receive links to these questionnaires via text message.

5.5.2 Risks and Benefits of the Optional EMA Protocol
Reasonably foreseeable physical, psychological, social, economic and privacy risks, side effects or discomforts associated with the research and their expected frequency and severity:
Loss of confidentiality:

- The primary risk is the potential for loss of confidentiality. This risk is not expected to be greater than the risk of loss of confidentiality routinely involved in accessing mental health care via a virtual platform. In order to mitigate privacy risks that are inherent to using mobile phones and websites, we will be implementing several strategies.
- First, all information collected outside of the VA network will be gathered via Qualtrics surveys that are protected using SSL certification to ensure the encryption of all information shared between the study website and potential participants. Accordingly, all responses related to the screening questions, consent process, and survey instruments will be encrypted prior to being uploaded to the study server. We will be using the VA Office of Research Development (ORD)'s instance of the Qualtrics application, which resides in the FedRAMP environment. This has been approved under the Authorized to Operate (ATO) to store "moderate level protected health information and personally identifiable information". This level of security is maintained even when participants complete study surveys on personal devices, such as their own mobile devices.
- Study records will be maintained in a secure location (at Minneapolis, this is the R: drive) and destroyed according to VA Federal Records requirements in VHA Record Control Schedule (RCS 10-1), currently at 5 fiscal years following the closure of the study.
- The following personal identifiers are necessary to deliver surveys on Qualtrics: name, email address, and phone number. All of these identifiers will be tracked in central Participant Spreadsheet that tracks participants in our study, stored on the R: drive. Once enrolled, text and/or email will be used to send reminders to complete study surveys, schedule interviews, and answer any questions that participants may have as they are completing the EMA protocol, unless the participant requests we contact them by phone call instead. Names and telephone numbers must be inputted into Qualtrics to send EMA surveys via text message.
- All personal identifiers will be permanently removed from the dataset at the conclusion of the study, ensuring that the final dataset for analysis is fully de-identified. To enable merging our dataset with the data at JJP VAMC, we will establish ID numbers with the JJP VAMC team prior to deleting any identifying information.
- In addition to the above measures, we will ensure staff are trained in protections for PII and PHI prior to accessing any study data.

Burden of protocol:

- Veterans may perceive the protocol to be burdensome and may become frustrated with the frequency or repetition of the daily assessments. Based on past research, we expect this frustration to be low in intensity, as most frustrated participants simply choose not to respond to the survey, which alleviates the frustration. Also, the intensity of the proposed protocol (one 3-minute survey per day for one week at a time; three bursts) is considerably lower than the average ecological momentary assessment study (4 surveys per day for 4 continuous weeks; Jones et al., 2019). The risk of excess burden will be further minimized by reducing the length of surveys to the minimum necessary, designing surveys to accommodate skipped questions, encouraging Veterans to end the assessment as soon as they sense fatigue, and making the daily assessment portion of the original study optional. If a Veteran expresses frustration with the protocol, we will offer to terminate their participation in the daily assessment protocol with no impact on their enrollment in the clinical trial taking place at JJP VAMC. Finally, we will adjust the protocol's length and/or intensity if Veterans report that either of these is unacceptable.

Discomfort with questions:

- The daily assessments will ask Veterans to reflect on and report their current mental health and long COVID symptoms, including levels of hopelessness, loneliness, and ability to function. This process may increase Veterans' awareness or focus on their own symptoms or impairment. Though increased awareness is often desirable in treatment and can result in improvements in mental health outcomes, it is possible that increased awareness may increase distress as well. Veterans will be provided with resources (i.e., Clinic contact info, principal investigator info, and the Veterans Crisis Line) at the end of every survey in the event that they need support. They will be encouraged to reach out to the principal

investigator to withdraw from the study if the surveys are upsetting (with no impact to the care they receive at their VA or in the main clinical trial), and JJP VAMC mental health providers (primarily the co-investigators on the JJP VAMC clinical trial, who are clinicians for the proposed participants) will be in contact with the principal investigators at both sites if a Veteran shares that the study is upsetting.

### 5.6 Data Analysis

All data will be de-identified before it is entered into a redcap database at the JJPVA over the intranet.

**5a. Statistical approach.** Descriptive statistics will be calculated, and outcome measures will be compared across the time points using repeated-measures mixed models. Data will be used to examine acceptability and feasibility, and iteratively improve the treatment. Then, we will apply for a RR&D VA Merit to determine efficacy of LC-CR in an RCT.

**5b. LC-CR Fidelity Measure**. Our research team (Drs. Sokol and Goodman) have experience establishing fidelity of psychosocial interventions. After the first pilot, an adherence scale will be created to assess 1) general LC-CR requirements, 2) session specific requirements, and 3) general group psychotherapy requirements.

### 5.7 Withdrawal of Subjects

The recruitment process will not be coercive or unduly influencing, as participants enter the research study voluntarily and understand that they have the right to withdraw at any time. Subjects will be told that non-participation in the study will not affect any current treatments they are receiving at VA or elsewhere.
There are no consequences if subjects to withdraw from this study. For subjects that withdraw, our research team will work closely with the suicide prevention team to establish contact, assess reasons for discontinuing treatment and attempt to address concerns. This research team will ask for emergency contact numbers and an emergency contact person that may assist us if you drop from treatment or an emergency occurs.

## 6.0 Reporting

**6a) Reporting in Medical Charts**

Group sessions will be documented in the patients' CPRS charts. Each session will generate a progress note so that anyone reading the chart will be able to recognize that the patient is actively participating in the therapy and when the most recent group session was.

Adverse events will be monitored through regular contact with study participants, as well as contact with providers. Participants will be carefully monitored during the interview by the research staff who will be trained in noticing when the participant is uncomfortable or needs to take a break. Participants who demonstrated distress during the interview will be closely monitored through follow-up phone calls and the PI and RA will notify the primary provider of the participant's experience during the interview.

**6b) Risk Management Plan:**

To manage potential risk during group sessions, we will follow the OCC's ***CAPS Lock process***; **C – Consent:** Obtain or confirm that verbal consent for telehealth has been documented. As part of this step, we will review the OCC approved Group Telehealth Agreement. This is a one-time requirement for service between a telehealth health care professional and a Veteran. **A – Address:** In the VVC e911 feature, obtain or confirm

the Veteran's present location and address. Pre-validate the address to validate whether e911 is available. Ensure that the location is private and safe**. P – Phone Numbers:** Obtain or confirm the Veteran's phone number. If others are present, obtain their name(s) and phone number(s). Obtain the name and phone number of the emergency contact if e911 is not available. We will also use the Emergency Call Relay Center (267-908-6605) if e911 services are not available.**S – Survey**: Confirm that you can see and hear the Veteran. Identify all others in the room. Review with the Veteran and others present how to alert you if/when an emergency occurs. **Lock:** Lock the virtual medical room once all participants have joined.

In the event of an emergency during group sessions, we will follow the OCC's Emergency Handoff Procedures:

**Step 1 – Contact Emergency Services**

Use e911 services, the Emergency Call Relay Center at 267-908-6605, or contact the local emergency services or other emergency contact number that the Veteran provided. Give the dispatcher (or emergency contact number) the Veteran's location and specific information about the emergency.

**Step 2 – Remain in contact with the Veteran**

Remain in contact with the Veteran, either by VA Video Connect or by phone, until local emergency responders arrive.

**Step 3 – Hand off and document the incident**

Provide emergency responders (or the emergency contact) with the necessary information for a handoff. Complete the appropriate documentation following local facility procedures and Office of Connected Care guidance.

In addition, if a participant is in distress during the session, the co-therapist will be available to transfer off the group call to an individual call with that participant to evaluate, assess for safety concerns, and engage de-escalation strategies.

## 7.0 Privacy and Confidentiality

The Principal Investigator (Dr. Goodman) will be responsible for study monitoring to ensure the safety of participants and the validity and integrity of the data. Data will be collected using standardized forms and will only be identified with the ID of the study participant. The codes that link the name of the participant and the study ID will be kept confidential. Study staff will have weekly contact with the PI for care review conferences and supervision, and the PI will be available in-person for additional monitoring as needed. Should a mental health crisis arise, several steps will be followed according to the safety management plan detailed in the sections 'protection from risk' below (7a) and 'risk management plan' above (6b).

**7a) Protection from Risks**

Privacy/Confidentiality: In the informed consent form, subjects are told that the information they provide, and all findings will be kept strictly confidential, with access limited to the research staff at the JJPVA, and the possible exception of state or federal regulatory personnel. Diagnostic interviewers will only enter coded identifiers on their notes and forms. The only forms that will contain the subjects' names and identifying information will be the consent forms, which will be stored in a locked file at each site. No identifying information is printed on subject data forms or in individual data files. No one but the project staff has access to the master list linking subjects' names to code numbers, and all information obtained is coded by ID. Identifiable information is kept in locked file drawers. Data from assessments will be stored on a secure VA server with no identifying

information. Results are published as group data without the use of characteristics that would identify individual subjects. We quote information only by number in conference discussions, scientific reports, or publications, in order to maintain anonymity. Additionally, the research team will be using the telehealth platform VA Video Connect to complete study procedures which provides a HIPAA- compliant secure and end-to-end encrypted connection to protect participant privacy.

LC-CR groups may be uncomfortable. This project is evaluating the acceptability, feasibility and initial efficacy of newly developed Long-COVID recovery group treatment. Subjects may find the content uncomfortable and may not want to share details of their clinical condition and symptomatology with others. Group members will not be required to disclose the contents of their Long-COVID recovery plans to others and are never required to share information or speak in sessions. Any specific concerns about the Veteran's reactions will be shared with the individual's psychiatrist and mental health case manager.

Long-COVID follow-up assessments might be stressful. Interviewers will receive training in the importance of study information confidentiality, and in how to manage any participant distress that may be associated with responding to research questions and interviews. We have developed a safety management plan for emergent mental health distress and behavior detected on any of the subsequent follow-up assessments. If there is any indication of mental health distress or suicide risk, co-Is Dr. Emily Edwards and Yosef Sokol (VA psychologists with expertise in Veteran suicide risk assessment and management) and PI Dr. Marianne Goodman (VA psychiatrist with expertise in clinical and research Veteran suicide risk assessment and management) will be available to evaluate.

EMA surveys will be delivered using ORD's iteration of Qualtrics. Contact information and surveys responses will be stored on their encrypted server. The primary risk involved is the potential for loss of confidentiality. This risk is not expected to be greater than the risk of loss of confidentiality routinely involved in accessing mental health care via a virtual platform. In order to mitigate privacy risks that are inherent to using mobile phones and websites, we will be implementing several strategies.

- First, all information collected in EMA surveys will be gathered via Qualtrics surveys that are protected using SSL certification to ensure the encryption of all information shared between the study website and potential participants. Accordingly, all responses will be encrypted prior to being uploaded to the study server. We will be using the VA Office of Research Development (ORD)'s instance of the Qualtrics application, which resides in the FedRAMP environment. This has been approved under the Authorized to Operate (ATO) to store "moderate level protected health information and personally identifiable information". This level of security is maintained even when participants complete study surveys on personal devices, such as their own mobile devices.
- Study records will be maintained in a secure location (the R: drive) and destroyed according to VA Federal Records requirements in VHA Record Control Schedule (RCS 10-1), currently at 5 fiscal years following the closure of the study.

Participants who consent to enroll in the EMA portion of the study may find may perceive the protocol to be burdensome and may become frustrated with the frequency or repetition of the daily assessments. Based on past research, we expect this frustration to be low in intensity, as most frustrated participants simply choose not to respond to the survey, which alleviates the frustration. Also, the intensity of the proposed protocol (one 3-minute survey per day for one week at a time; three bursts) is considerably lower than the average ecological momentary assessment study (4 surveys per day for 4 continuous weeks; Jones et al., 2019). The risk of excess burden will be further minimized by reducing the length of surveys to the minimum necessary, designing surveys to accommodate skipped questions, encouraging Veterans to end the assessment as soon

as they sense fatigue, and making the daily assessment portion of the original study optional. If a Veteran expresses frustration with the protocol, we will offer to terminate their participation in the daily assessment protocol with no impact on their enrollment in the clinical trial taking place at JJP VAMC. Finally, we will adjust the protocol's length and/or intensity if Veterans report that either of these is unacceptable.

Veterans enrolled in the EMA protocol may experience some discomfort with questions asked in the questionnaires. The daily assessments will ask Veterans to reflect on and report their current mental health and long COVID symptoms, including levels of hopelessness, loneliness, and ability to function. This process may increase Veterans' awareness or focus on their own symptoms or impairment. Though increased awareness is often desirable in treatment and can result in improvements in mental health outcomes, it is possible that increased awareness may increase distress as well. Veterans will be provided with resources (i.e., Clinic contact info, principal investigator info, and the Veterans Crisis Line) at the end of every survey in the event that they need support. They will be encouraged to reach out to the principal investigator to withdraw from the study if the surveys are upsetting (with no impact to the care they receive at their VA or in the main clinical trial), and JJP VAMC mental health providers (primarily the co-investigators on the JJP VAMC clinical trial, who are clinicians for the proposed participants) will be in contact with the principal investigators at both sites if a Veteran shares that the study is upsetting.

**7b) Sources of Materials**
Sources of research material for the proposed research include the patient self-report measures and questionnaires involved in the project. Clinical and demographic data are derived from patients' assessment results specifically for research purposes. All relevant data is collected separately for each patient and stored in locked areas to ensure confidentiality.

## 8.0 Communication Plan

All risks and potential complications are discussed with the subjects during consent signing, and any new information regarding risks will be provided by phone immediately. Patients are monitored closely and should any unanticipated findings arise, the IRB will be notified. Supervision and weekly consultation team meetings will provide a forum for study staff/clinicians to review results of ongoing safety monitoring. During this meeting, any concerning results will be discussed, troubleshooted, and a plan of action will be developed (e.g., decisions about referrals to outside treatment services, termination of subject participation. The PI will work in conjunction with the IRB to evaluate any emerging information and determine if and how the study should be continued.

Chart reviews will be conducted during recruitment of each cohort to ascertain which/if participants have an assigned mental health care provider and safety plan (if they have history of suicidal behavior).

Safety monitoring for adverse events (AEs) will be conducted in real time by the Principal Investigators and the research coordinators. The PI will supervise the research and respond directly to patient problems. In the case of AEs, all of them will be indicated on the source documentation for the specific adverse event report form. The PI will determine the severity of the event, will assign attribution to the event, and will monitor the event until its resolution.

Additionally, the PI Dr. Goodman (licensed psychiatrist),and co-Is Dr. Emily Edwards (licensed psychologist) and Dr. Yosef Sokol (licensed psychologist), and therapy facilitator Dr. Ariana Dichiara (licensed psychologist)

will be available to evaluate through mental health assessments if at any point a participant is displaying psychological distress and subsequent behavior. They and other research staff will be able to alert the participants' primary mental health provider through CPRS in case additional support is needed.

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