BACKGROUND AND SPECIFIC AIMS

Coronavirus disease COVID-19 is a highly infectious condition caused by the severe acute respiratory virus coronavirus 2 (SARS-CoV-2). Since the report of the first cases, in Wuhan, China in December 2019, the spread of this virus throughout the world has resulted in a pandemic characterized by high morbidity and mortality and saturation of health care services in nearly all countries[1]. Worldwide, it is estimated that more than 400 million cases have occurred, with more than 6,000,000 deaths[2]. In Puerto Rico, the first case of the disease was identified on March 16, 2020, and since then, a total of 1,139,253 cases have been reported. At least 1 in 579 residents have died from coronavirus, a total of 5,848 deaths by March 2023.

To address the need to generate new information on the impact of COVID-19 and its sequelae among underserved racial and ethnic minority populations, we implemented of the Puerto Rico COVID-19 Assessment Study (PR-COAS), sponsored by the Puerto Rico CEAL program, to evaluate the sociodemographic and clinical characteristics, risk factors, outcomes, healthcare utilization, and quality of life of patients after acute infection of COVID-19 and the long-term sequelae among patients receiving services in federally qualified health centers (FHQCs) and community hospitals in Puerto Rico. In addition, we collected information on health care utilization and barriers related to access to care, including testing and vaccination. The Puerto Rico COVID-19 Assessment Study (PR-COAS) successfully established partnership with five FQHCs and the Hospital UPR in Carolina to better characterize the epidemiological and clinical profile of patients with suspected and confirmed COVID-19 infection and to estimate the prevalence of Long COVID in this population. In our first study, we were able to review 2,625 medical records and collect data on the sociodemographic and clinical characteristics of confirmed and suspected COVID-19

patients. We identified a high prevalence of comorbidities among confirmed COVID-19 cases with almost 50% reporting at least one chronic condition, including hypertension (20%), mental health conditions (19%), and diabetes (11%).

Our second study was designed to establish a cohort of Hispanic patients living in Puerto Rico with laboratory-confirmed COVID-19 infection to evaluate the clinical, epidemiological, and risk factors associated with the development of post-COVID-19 sequelae and its impact on the quality of life. Sociodemographic characteristics, comorbidities, vaccination status, persistent or new symptoms after acute infection, healthcare utilization, and quality of life were collected in the initial or follow -up interviews done at 3, 6,9 and 12 months (in progress). In our preliminary results we found that of 261 patients recruited, 256 had a SARS-CoV-2 infection at least four weeks before the interview. Of these, the mean age was 48.1±15.9 years, 201 (78.8%) were women, and **191 (74.6%) had signs and symptoms compatible with Long-COVID**. Participants with and without Long COVID had a similar mean age, were mainly women, had similar education, and had received their third dose or booster of COVID-19 vaccine. However, participants with Long COVID had a significantly higher prevalence of tiredness, muscle pain, headaches, joint pain, and anxiety than those without Long-COVID. After adjusting for age, sex, and disease severity, **having a chronic condition was significantly associated with higher odds of Long COVID** (OR=3.38; 95% CI=1.62 – 7.04) including asthma (OR=4.78; 95% CI, 1.92 – 11.9), obesity (OR=3.42; 95% CI, 1.64 – 7.13), hypertension (OR=3.04; 95% CI, 1.33 – 6.98), and diabetes (OR=2.76; 95% CI 1.12- 6.77). In addition, we identified a significant impact in the quality of life where those patients living with Long COVID were more likely to report difficulties with daily activities (24% vs. 9%, p = 0.01), pain or discomfort (52% vs. 17%, p <0.001), and anxiety or depression symptoms (37% vs. 11%, p< 0.001).

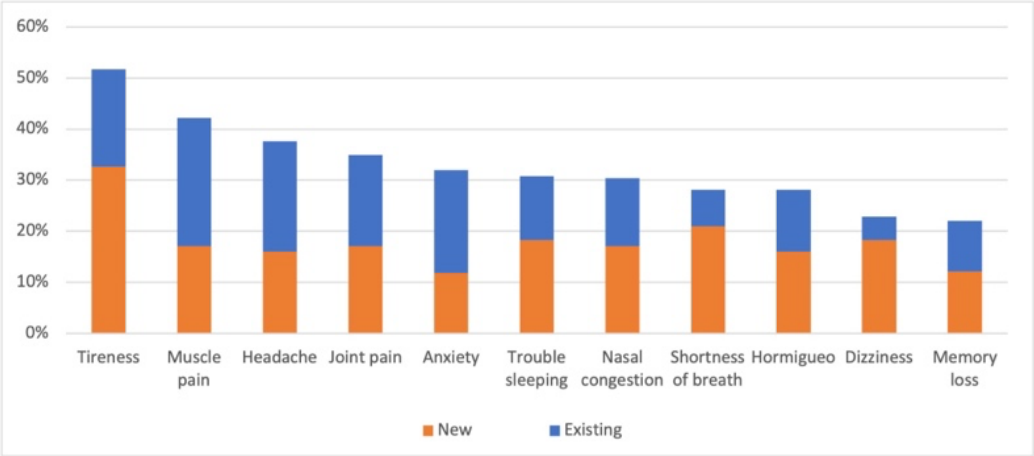

Figure 1: Prevalence of Long-COVID Symptoms, Puerto Rico COAS

We found a high prevalence of Long-COVID associated with an increased risk among those patients living with comorbidities in Puerto Rico. In addition, our preliminary data suggest that patients with Long COVID and chronic conditions experience a significant impact in their quality of life. Since there is no cure for Long COVID at this moment, patients living with Long COVID could experience symptoms for a long period of time. This might result in challenges for managing their diseases that are similar to those experienced by patients with other chronic illnesses. What are the main challenges and how these patients might benefit from chronic disease self-management interventions to address the impact of Long COVID in their quality of life is still unknown. Therefore, our specific aims are:

Specific Aim 1:

To evaluate the impact of an evidenced-based intervention for chronic disease self-management in the health-related quality of life (HRQoL) of patients living with Long-COVID in Puerto Rico. To do this we will evaluate the implementation of "**Tomando control de su salud**" (TCS) among patients with Long COVID and chronic diseases participating in the PR-COAS cohort study, and the changes (if any) in data related to HRQoL measures, included data from the baseline and follow up interviews, before and after this implementation. "Tomando control de su salud" is an evidenced based intervention in Spanish and a culturally appropriate version similar to the Chronic Disease Self-Management program of the Centers for Disease Control and Prevention (CDC) aimed to improve disease management skills, including decision-making, problem solving, and action planning among patients with at least one chronic condition.

Specific Aim 2:

To evaluate the impact of TCS to support chronic disease self-management in patients with Long COVID living in low-income Hispanic communities in Puerto Rico on self-efficacy, disease monitoring, use of health care services, medication use and risk behaviors. To do this we will evaluate the implementation of "**Tomando control de su salud**" (TCS) among patients with Long COVID and chronic diseases participating in the PR-COAS cohort study, and the changes (if any) in data related to measures of chronic diseases management, included data from the baseline interview and follow up interviews before and after this implementation. We will use Kirkpatrick's evaluation model[59-60] as a framework and guide in analyzing the impact of the TCS program on the participants' self-management of chronic diseases. This model has been widely used for evaluating participants' outcomes in training programs, including research studies aimed to evaluate training programs regarding self-management of chronic health conditions.[61-63] Like

other chronic diseases self-management related studies that have applied this evaluation model[62, 64], we will use in our study the first three levels of this model as follows:

1. Reaction - At this level, we will evaluate the degree of satisfaction and perception of the participants regarding the TCS program; we will seek to know their opinion and experience about TCS. To do this, we will use data from the TCS program's final survey, titled Formulario Final (Post-Prueba & Evaluación). It includes close-ended questions regarding the TCS sessions' attendance, general satisfaction with the discussed topics and leaders' evaluation, and an open-ended question about the experience participating in the TCS program (the study participants can express their feelings, ideas, opinions, comments or reactions after having participated in the program).
2. Learning - This evaluation level refers to "the degree to which participants acquire the knowledge, skills, attitudes, confidence and commitment expected based on their participation in the learning event".[59] At this second level, we will assess what participants learned from TCS, measuring their progress (if any) and learning attributed to the program in terms of knowledge, skills, attitudes and confidence in managing their chronic health conditions. To do this, we will have a control group and two intervention groups, and we will compare data from the baseline (pre-training) and follow up interviews (post-training), and TCS's initial (Formulario Inicial: Pre-Prueba) and final surveys, before and after the program implementation.
3. Behavior - At this level, we will examine the extent to which TCS program participants are applying what they have learned during the program TCS, as applicable, in terms of self-management of their chronic health conditions. To do this, we will use follow up interviews (3-6 months after program implementation), based on instruments and adapted questions from standardized questionnaires developed and currently used by the Centers for Disease Control and the National Institutes of Health, among others, to evaluate the

impact of TCS program to support chronic disease self-management in patients with Long COVID living on self-efficacy, disease monitoring, use of health care services, medication use, risk behaviors, and health-related quality of life (HRQoL). In addition, we will evaluate the self-management of chronic diseases in patients with Long COVID through the Self-Care of Chronic Illness Inventory V4c, Spanish version[58]. We are going to compare data from the baseline and follow up interviews, and TCS's initial and final surveys, before and after the program implementation, having a control group and two intervention groups.

On the other hand, we will use the Health Belief Model (HBM) as theoretical framework to evaluate the impact of TCS (changes, if any) on the seeking and utilization of healthcare services by adult patients with Long COVID-19 and chronic health conditions, based principally on Agymang-Duah and Rosenberg study (2023). [65] HBM establishes that people adopt appropriate and preventive health behaviors in accordance with core individual factors that can help predict and explain health-related behavioral changes.[58] These essential components of the model are the following:

1. Perceived susceptibility: Beliefs or perceptions of an individual in relation to the possibility that he or she has of becoming ill with a health condition.
2. Perceived severity: Beliefs or perceptions about the severity of a health problem or condition and its possible effects.
3. Perceived benefits: Perceptions about the possible benefits of certain health behaviors.
4. Perceived barriers: Limitations or obstacles perceived by the individual to carry out a certain health action.
5. Cues for action: Factors that motivate the individual to appropriate health action.
6. Self-efficacy: It is the confidence that a person can feel to successfully perform a certain health behavior. [58]

HBM has been used to evaluate the impact of the COVID-19 pandemic on the health service utilization of adult patients with chronic diseases, among other related-aspects.[28, 57]

METHODS

Study design: We propose to conduct a pilot non-randomized-controlled trial to evaluate the impact of "Tomando control de su salud", an evidenced-based intervention for chronic disease self-management, in the quality of life of patients living with Long-COVID in Puerto Rico.

Participant selection: We will invite patients from our cohort study during the 12-month follow-up call. All participants identified with conditions associated with Long COVID or chronic diseases will be invited to participate. These are the inclusion and exclusion criteria:

Inclusion criteria:

1) Adult patients 21 years or older
2) Participant of PR-COAS cohort that completed the last interview (12-month-follow-up) and authorized to be contacted for further studies.
3) Having at least one chronic condition (excluding cancer) diagnosed by a physician or healthcare provider.
4) Ability to attend weekly sessions (applicable to intervention group).

Exclusion criteria

1) Any clinical or cognitive impairment that limits the participant's ability to decide to participate in the study or complete the interviews.
2) Presence of a life threatening or extreme medical condition.

3) Planning to move out of the municipality within the next year.

Sample size determination: The primary goal of this study is to pilot the potential implementation of this intervention for Long COVID patients. We are therefore not powering for a definitive assessment of the difference between any two groups. However, we expect the preliminary data from this study to provide adequate pilot data from which we will be able to determine the required sample size for a larger scale study. The sample selected will provide an estimate of the effect size and thereby allow preliminary evaluation of the clinical utility associated with the intervention.

Sampling strategy: Participants with Long-COVID and chronic diseases that agree to participate in the intervention will be allocated into one of the study intervention groups that will participate in the "Tomando Control de su Salud" workshops. Those not interested in participating in the intervention will receive general information about chronic disease management available at the CDC website in Spanish, by email, regular postal mail or in person, in addition to their regular health care and will be asked to answer the post questionnaires approximately 3 months after the last interview of the PR-COAS cohort. With an estimated participation rate of about 25 – 30% we expect to identify between 20-25 participants with Long-COVID with at least one-chronic condition. We estimate that about half will be interested in receiving the intervention; therefore, we expect to have about 20-25 participants in the intervention arm divided into two or three workshops of 8 – 12 participants based on the number of patients recruited and about 30-40 participants in the general care group. Figure 2 summarizes the expected recruitment and procedures.

Proposed intervention: "Tomando control de su salud" (Spanish Chronic Disease Self-Management) [1, 2] is a culturally appropriate program developed in Spanish to support Hispanics

patients to build confidence in their ability to manage their health. This intervention was developed by Lorig et al. at Stanford University and has been widely used by the Puerto Rico Department of Health since it is recommended by the CDC as an evidenced-based intervention for chronic disease management.

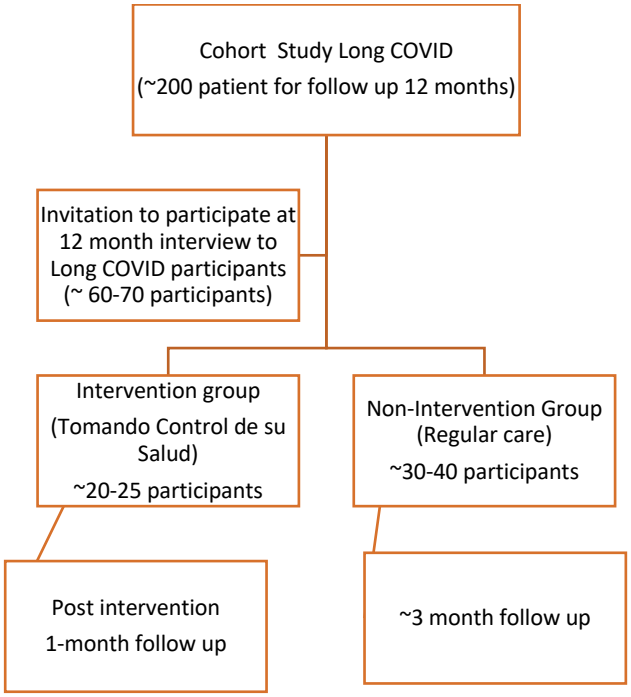

Figure 2: Summary of study recruitment and procedures, PR COAS_TCS

The intervention consists of small group workshops with 8 to 15 participants lead by two certified trainers, offered virtually or face-to-face (at the EHSRC Office of Clinical and Community Health Research located at the Hospital UPR in Carolina) for 2 1/2 hours once per week for six-week period open to Spanish-speakers with any physical or mental chronic condition or multiple chronic conditions. As part of the intervention, a pre and post TCS assessment will be collected.

Topics included in the training are:

1) Healthy eating
2) Appropriate exercise for maintaining and improving strength, flexibility, and endurance
3) Managing depression
4) Appropriate use of medications
5) Communicating effectively with family, friends, and health professionals
6) Relaxation techniques
7) Appropriate use of the health care system
8) How to evaluate new treatments
9) Better breathing
10) Action-planning, problem-solving, and decision-making skills.

Our research group has experience with this intervention including the successful implementation of the program among patients with diabetes and hypertension living in a low-income community in Puerto Rico. The intervention will be implemented in collaboration with Puerto Rico Department of Health and the participating FQHC centers.

Outcome measures, study variables and instruments: We will use instruments and adapted questions from standardized questionnaires developed and currently used by the Centers for Disease Control, the National Institutes of Health, the World Health Organization, or clinical centers to develop the interviews to collect data related the study variables. We will use questionnaires that are available for public use, and the questions will be used as stated or modified if needed. The use of these standardized questionnaires will allow us to standardize the data collection process and eventually compare the experiences in Puerto Rico with those in other locations. The Table 1 summarizes the data to be collected and instruments.

The last interview of the cohort study (PR-COAS) in which the participants will be identified, which collect information on general aspects of self-care of chronic diseases, healthcare utilization, vaccination status, lifestyles modifications, and health-related quality of life among others, will be used as baseline for the purposes of this study. In addition, a follow up interview will be coordinated one month after completing TCS for the intervention group and approximately 3 months after the last interview of the cohort study for the control group. The following indicators will be collected: Health care services utilization (primary care, emergency room and hospitalizations), compliance with prescribed medications, risk behaviors (such as smoking, physical activity, alcohol use), nutritional awareness, self-efficacy for disease management based on the level of confidence) and quality of life. The standard data collected by the PRDOH for this intervention (*Formulario 1: Formulario Inicial, Preprueba, and Formulario 2: Formulario Final, Post-Prueba & Evaluación, Rev. Enero 2022*) will also be used for analysis. The Form 1 is a self-administered questionnaire of 28 closed-ended questions that collects TCS participants' sociodemographic and contact information (name, municipality of residence, marital status, education, age, sex, medical plan, email), general information on diagnosed health chronic conditions, COVID-19 vaccination, level of confidence in managing chronic conditions, general health, use of health services, and lifestyles (e.g. consumption of vegetables, fruits and alcoholic beverages, physical activity and whether or not you smoke). The Form 2 is a 40-question self-administered questionnaire that mainly collects general information about the lifestyles of TCS workshop participants (consumption of vegetables, fruits and alcoholic beverages, physical activity and whether or not they smoke), general health status, level of confidence in managing health chronic conditions, utilization of health services, attendance, evaluation and experience in TCS workshop.

The impact of health-related quality of life will be assessed using the following scales:

- EQ-5D-5L (Spanish version), which includes five dimensions: mobility, self-care, daily activities, pain or discomfort, and anxiety or depression. [26-27]
- Fatigue (NIH PROMIS© Neuro-QoL Item Bank v1.0, Short Form, Spanish version)
- Post-COVID-19 Functional Status Scale (PCFS, Spanish version) - It is an ordinal tool that focuses on relevant aspects of daily life during follow-up after the COVID-19 infection[36]. PCFS includes the entire range of functional outcomes by focusing on limitations (if any) in usual duties/activities either at home or at work/study, as well as changes in lifestyle.
- Anxiety (GAD-7, Spanish version) - It is a validated one-dimensional 7-item questionnaire for generalized anxiety disorder assessment, as listed in the DSM-IV. [52, 54-56]

In general terms, chronic diseases self-management and auto-efficacy will be assessed through the following scales:

- Self-Care of Chronic Illness Inventory (SC-CII v4.c, Spanish version) – It is an internationally generic measure used to assess self-care in chronic diseases, and it is based on the Theory of Self-Care of Chronic Illness. [23, 40-42, 47] SC-CII comprises four scales: self-care maintenance (Section A), self-care monitoring (Section B), self-care management (Section C), and self-care confidence (Section D) [31]. For our study, we will just use the first three sections of this instrument.
- NIH PROMIS© 4-item Short Forms v1.0, 4a - Self-Efficacy for Managing Chronic Conditions, which is a multidimensional categorical model to estimate individual's self-efficacy for managing their heath chronic diseases through the following five behavioral domains:
    - Self-Efficacy for Managing Daily Activities
    - Self-Efficacy for Managing Emotions

- Self-Efficacy for Managing Medications and Treatments
- Self-Efficacy for Managing Social Interactions
- Self-Efficacy for Managing Symptoms [46]

Table 1: Data to be collected at baseline and follow up interviews

Indicator	Variables	Source of questions
General health and lifestyles	Health perception and disability Lifestyles and risk behaviors: consumption of vegetables, fruits, tobacco use, alcohol consumption, and physical activity	RADx-UP[16], PROMIS-10 Global Health, v1.2 [21], All of Us Surveys[30, 31] and WHO Global COVID19 Clinical Platform[18], Cuestionario del BRFSS 2020[57]
Vaccination	Vaccination status and perceptions	CEAL Common Survey 2[20] , RADx-UP[16], All of Us COPE Survey COVID-19[31] and Folcarelli *et al*., 2021[37]
	Compliance with booster recommendations	CEAL Common Survey 2[20], Folcarelli *et al*., 2021[37], and new questions
	Access and perceived barriers	CEAL Common Survey 2[20], Folcarelli *et al*., 2021[37], Yoshida *et al*., 2022[36] and new questions
Management of health chronic conditions	Health chronic conditions, use of medications, medical consultations, self-care, disease monitoring, self-management	BRFSS 2020[57], PhenXToolkit[54-56], Self-Care of Chronic Illness Inventory (SC-CII v4.c, Spanish version)[36, 46-48]
Self-Efficacy for Managing Chronic Conditions	Daily activities, medications and treatment, symptoms, social interactions, emotions	PROMIS Item Bank v1.0 - Self-Efficacy for Managing Chronic Conditions - Short Forms 4a[52]
Healthcare utilization for chronic diseases	Health care access, postponed medical procedures, studies and appointments, missed scheduled appointments with any health care provider, missed taking any medications, healthcare challenges	PhenXToolkit[54-56], CDC National Health Interview Survey (NHIS) Utilization Questionnaire, 2020[56], BRFSS 2020[57], Ryder *et al*. 2022[49], Singh *et al*., 2021[51], Uzun, *et al*., 2023[58]; Abraham *et al*., 2023[28], new question
Quality of life assessment (follow up)	Health-related QoL (HRQoL) scales: • EQ-5D-5L • PROMIS v1.0 Fatigue SF for adults • The Post-COVID-19 Functional Status (PCFS) • Anxiety (GAD-7)	PROMIS Health Measures[19, 29, 52], EQ-5D-5L[24-25], PCFS[26-28], GAD-7[52-56]

Data management: Trained interviewers will collect data through structured interviews. To ensure the quality of the data collection process, all interviewers will receive an intensive training session regarding the consent process, interviews, and data collection process. This training will include using the questionnaires and standardized electronic forms for the data collection, along with a protocol that clearly outlines how the information will be collected. Although a unique study identification number will be assigned to each patient, we will maintain patient identifiers to be able to contact them in the follow-up interviews. These identifiers will include name, physical address, postal address, phone, email, and Facebook contact. After finishing the data collection process and following up with the patients and database cleaning, all personal identifiers will be removed, and the final database for analysis will be anonymized.

Participant-specific data will be entered via a web-based interface using Research Electronic Data Capture (REDCap) (Harris et al., 2009).23 REDCap is a secure, web-based application that allows the construction and implementation of online instruments. We will program the system with validation rules at the time of entry, and comprehensive edits after data has been submitted to the main database. Edits will check for validity, consistency, and normal range values. As part of our standard operating practices, we will implement a data cleaning protocol, which checks for consistency and examinations of frequency tabulations.

This project will strictly apply all procedures established by the UPR-School of Medicine for data security and management. The collected information and any other relevant document will be kept strictly confidential. To ensure confidentiality, all study data and documents will be kept secured with locked files in the clinic area of the Office of Clinical and Community Health Research of the EHSRC located on the Ground floor of the UPR Hospital in Carolina, PR. Electronic data will be password-protected and not be shared through emails or clouds. To protect the study data from improper use and disclosure, we will assign a study number to each questionnaire and de-

identify the databases. Study data and related documents will be kept for five years and then destroyed.

Data analysis: Since this is a pilot study the primary focus of the statistical analysis of this study is estimation (effect sizes and associated uncertainty). We will conduct pre- and post-intervention analysis among participants of the intervention group and between group comparisons with intervention and non- intervention groups. Descriptive analyses will be done using frequency distribution and contingency tables for categorical data. Continuous variables will be reported using mean, median, standard deviation, inter-quartile range and range. Chi-square or Fisher's exact test will be done to assess differences in sociodemographic or health indicators between the groups and to compare the independent domains of the quality-of-life scale among patients in the intervention or non-intervention group. To evaluate changes in quality of life before and after the intervention, estimates and 95% confidence intervals will be generated based on the change scores, i.e., using paired data with each subject acting as their own control. Estimates and confidence intervals will be provided for both the individual group changes as well as the difference in change between each pair of groups. We will perform Wilcoxon/Mann-Whitney U-tests (non-parametric) comparing the change scores in each group with each other. These Wilcoxon tests will be performed in addition to a Kruskall-Wallis test (non-parametric ANOVA) in order to test for an overall group effect. The Wilcoxon paired sample test will be used for ordinal data and the Mc Nemar test for significant changes will be used to evaluate dichotomous data. All analyses will be conducted using Stata version 11(Stata Corporation, College Station, Texas, USA).

HUMAN SUBJECT PROTECTION

Consent process: After the patient expresses interest in participating in the study, study staff will contact the potential participant via phone or face to face to discuss the study informative sheet following the appropriate consent process as described in the method section. The consent process will be done only by the investigators, study staff, or trained interviewers. The study coordinator will oversee the training of the interviewers about the process of consent by the discussion of the informative sheet and the study procedures prior to any contact with potential participants. A script will be developed to explain the process of consent over the phone. The information in the script will include the purpose of the study, duration of subject participation, description of the procedures, risks, benefits, and confidentiality. In addition, it will include information about the voluntary nature of participation and whom to contact for questions. During the process, the subjects will have the opportunity to ask questions, and if the potential participant requests any other information about the study, it will be provided. Although a written consent form will not be collected, the person who will conduct the discussion of the informative sheet should document all the activities, including the date and time of the call, duration, and if there were questions regarding the process. The person in charge of the consent process should also document and certify in a form that the information provided by them is correct and that the subject consented.

Participants will receive an incentive for transportation and/or parking expenses and for the time dedicated for their participation. The intervention group will receive $25 for each session of the TCS workshop. This incentive will be given to them at the end of each session at the Endowed Health Services Research Center (EHSRC). Upon completion of the final interview, one month after the end of the workshop, the participant will receive a $25 incentive that can be sent to them by certified mail or can be hand-delivered at the EHSRC office in a specific time scheduled. In the

case of the non-intervention group, participants will receive a $25 incentive upon completion of the final interview, approximately 3 months after completing the baseline interview, that is, the final PR-COAS interview.

Benefits: This study does not directly benefit the person for their participation. Participating in this study has not cost. Although participants would not derive any direct benefit, the potential benefit to society is an increased understanding of the factors associated with post-COVID19 sequelae in our population, critical information for making patients guidelines, and public health recommendations and decisions. In addition, the participants will receive information about the general management of management of chronic disease that could be of benefit for them.

Risks: This study poses minimal risk to the study participants. There could be some risk to the privacy and confidentiality of the participants as part of their participation in group discussions. Also, there could be some discomfort on answering some of the questions in the interview. We do not expect the participant to be harmed or have any additional risk as a result of their participation in the study. The intervention and the interviews will be done by trained personnel that will let the participant know they can stop their participation at any moment or refuse to answer a question. This will not affect the participants' rights, or the clinical services received at the healthcare center.

Privacy and confidentiality: All study-related data will be maintained confidential with restricted access only available to the PI, project coordinator, and designated study staff. All study procedures, including the phone interviews, will be done in a private location at the Office of Clinical and Community Health Research. Confidentiality of participant's information will be assured. Participants' contact information will be collected and is needed to coordinate the follow-up interviews. This information will be collected in the screening registry and will include the name,

telephone numbers, residential and postal address, email, Facebook account, and preferred contact method. This form will be collected in an electronic database and kept separated from the study questionnaire. The contact information collected from interested participants will not be shared or disclosed with other people or organizations.

This protocol will be modeled after our previous studies, which used a REDCap tracking database to minimize any breach in subject's confidentiality. We will keep a separate file that includes only the patient's study identification number. All documents in the form of hard copies will be kept in safely locked cabinets located in the PI's office at the Office of Clinical and Community Health Research located at the Hospital UPR in Carolina, whereas all electronic data will be kept on a secured server at UPR School of Medicine with multiple levels of password protection (encrypted files in password-protected computers) to which only the investigators will have access. The entire research staff has completed the human subjects' protection and the management and security of health information certification process as required by the IRB of the UPR. It will receive extensive study-specific training in data collection and transfer. A request for a waiver of authorization for the release of health information will be completed. At the end of the data collection process and following up of the patients and database cleaning, all personal identifiers will be removed, and the final database for analysis will be anonymized. After five years, all data in the form of hard copies will be shredded.

TABLE 2: PROPOSED TIMELINE

		9 - Months								
Proposed Activities		1	2	3	4	5	6	7	8	9
Intervention for Long-COVID – chronic disease self-management	Training or recruitment of trainers for “Tomando Control de su Salud” intervention	X	X							
	Submission and approval of IRB		X	X						
	Participant selection and group allocation				X	X	X			
	Intervention workshops (8 – 12 participants)							X	X	
	3-month follow-up interview								X	X
	Data analysis and dissemination							X	X	X

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