COVID-19 Vaccination Status and The Characteristics and Clinical Outcomes of Long COVID-19 Patients in Dr. Cipto Mangunkusumo General Hospital

Principal Investigator:
Eric Daniel Tenda
Dr. Cipto Mangunkusumo General Hospital
Jakarta, Pangeran Diponegoro St No. 71, 10430
Phone +62 813-8033-3818
Email eric.tenda@ui.ac.id

STUDY PERSONNEL AND ROLES

dr. Eric Daniel Tenda, DIC, Ph.D, SpPD	Principal investigator
dr. Mira Yulianti, SpPD-KP	Co-Principal Investigator
Dr. dr. Evy Yunihastuti, SpPD-KAI	Chief Investigator
Prasandhya Astagiri Yusuf, S.Si, M.T, Ph.D	Co-Chief Investigator
Dr. dr. Kuntjoro Harimurti, SpPD-KGer, M.Epid	Medical Statisticians
dr. Reyhan Eddy Yunus, Sp. Rad, M.Sc	Data Protection Rep.
dr. Ni Nyoman Indira, SpPD	Study Coordinator
Dr. dr. Cleopas Martin Rumende, SpPD-KP, FCCP	Research Team
Dr. dr. Lugiyanti Sukrisman, SpPD-KHOM	
Dr. dr. Sally Aman Nasution, SpPD-KKV	
dr. Ceva Wicaksono Pitoyo, SpPD-KP, KIC	
dr. Pringgodigdo, SpPD-KGH	
dr. Rudi Putranto, SpPD-KPsi	
dr. Findy Prasetyawati, SpPD-KHOM	
dr. Lusiani, SpPD-KKV	
dr. Wita Septiyanti, Sp.Rad	
dr. Moses Mazmur Asaf	
Department of Neurology	
Department of Psychiatry	
Department of Functional Improvement and Rehabilitation	
Department of Dermatovenereology	

PROTOCOL SYNOPSIS

Title	COVID-19 Vaccination Status and The Characteristics and Clinical Outcomes of Long COVID-19 Patients in Dr. Cipto Mangunkusumo General Hospital
Sponsor	University of Indonesia
Study Rationale	Long COVID is the persistence or emergence of symptoms for more than four weeks beyond the acute phase of Severe Acute Respiratory Syndrome – Coronavirus-2 (SARS-CoV-2) infection. Various multi-organ complications after COVID-19 infection include respiratory, cardiovascular, gastrointestinal, hepatobiliary, metabolic, and neuropsychiatric disorders. The symptoms and characteristics of Long COVID vary in each country. Vaccination against SARS-CoV-2 has been documented to increase the clinical resolution of Long COVID. However, in Indonesia, current full-dose vaccination coverage has merely reached 15.6% of the national vaccination target. This condition can be predictably associated with a longer duration and higher severity of symptoms in Long COVID patients. This study's point of view is to describe the incidence and the characteristic of long COVID in patients and the impact of COVID-19 vaccination on the clinical outcome of long COVID. In addition, this study is expected to reinforce the recommendation for the COVID-19 vaccine implementation in Indonesia. The result of this study can be applied in clinical practice to ascertain the benefits of SARS-CoV-2 vaccination to improve clinical outcomes and quality of life; and reduce symptoms, duration, and frequency of long COVID.
Study Objectives	**Primary** • To provide an overview of the symptoms and characteristics of Long COVID patients at Dr. Cipto Mangunkusumo General Hospital. • To determine whether vaccination against SARS-CoV-2 could improve clinical outcomes and quality of life of Long COVID patients at Dr. Cipto Mangunkusumo General Hospital. **Secondary** • To determine whether vaccination against SARS-CoV-2 could increase functional exercise capacity of Long COVID patients. • To determine whether vaccination against SARS-CoV-2 could reduce symptoms, duration, and frequency of Long COVID.
Study Design	Prospective cohort study

Subject Population **Key criteria for Inclusion and Exclusion:**	**Inclusion Criteria** 1. Adult patients, aged ≥ 18 years old with a history of laboratory-confirmed SARS-CoV-2 infection via a positive molecular (RT-PCR) or antigen (lateral flow assay) test, receiving outpatient/inpatient care from Dr. Cipto Mangunkusumo General Hospital, any time prior to enrollment in this study. 2. Patients with/without comorbidities. 3. Willing to fill-out online Long COVID symptoms follow-up questionnaire. 4. Willing and able to comply with the trial protocol, 6 Minutes Walking Test (re-visits and physical testing). **Exclusion Criteria** 1. Patients with no registered medical record number (MRN) at Dr. Cipto Mangunkusumo General Hospital. 2. Refusal to participate in the study or to sign the informed consent form. 3. Contraindicated to perform the 6 Minutes Walking Test. 4. Patients with no access to a smartphone or computer (desktop, laptop, or tablet) to fill out the online screening questionnaire. 5. Patients who died during or before enrollment in the study.
Number of Subjects	A total of 250 subjects are divided into 4 groups according to SARS-CoV-2 vaccination status: • Never been vaccinated. • Received 1st dose of vaccination. • Received 2nd dose of vaccination. • Received 3rd dose of vaccination.
Study Location	Dr. Cipto Mangunkusumo General Hospital, Central Jakarta, Jakarta, Indonesia
Study Duration	Each subject's participation will last for 6 months. The estimated duration for the main protocol is approximately 1 year.
Study Phases	
Screening	Screening for eligibility and obtaining consent.
Study Examination	Online questionnaire filling, 6-Minute Walking Test (6MWT)
Follow-up	Follow-up examination 3 and 6 months after baseline.
Safety Evaluations	Adverse events will be monitored and collected by the study team from the point of signed consent until the adverse event(s) are resolved and subjects are stabilized. Adverse events will be managed according to the 6MWT guidelines of the American Thoracic Society (ATS).

Statistical and Analytic Plan	Statistical analyses will be performed using SPSS version 20. Descriptive statistics will describe the incidence of long COVID in participants and its characteristics, the clinical outcome, and the quality of life. The bivariate analysis will be performed using *chi-square* or *fisher*, to find the correlation between COVID-19 vaccination status and the characteristics and clinical outcomes of long COVID patients. The value of the limit of significance is 0.05.
Data and Safety Monitoring Plan	If there were any serious adverse events (SAE), the case will be reported to the ethics committee as soon as possible, less than 24 hours from the first time they were discovered, and actions were carried out as quickly as possible until the series of events ends. SAE was written in detail on the SAE form, including the following; when it was first discovered, the manifestation of the incident, the conditions before the incident, the handling of the event, and the outcome.

STUDY PROTOCOL

1. Introduction

Long COVID is defined by the persistence or emergence of symptoms for more than 4 weeks beyond the acute phase of Severe Acute Respiratory Syndrome-Corona Virus-2 (SARS-CoV-2) infection. As the number of cases increases and various strains of SARS-CoV-2 emerge, so does the number of long COVID cases. Various multi-organ complications after COVID-19 infection include respiratory, cardiovascular, gastrointestinal, hepatobiliary, metabolic, and neuropsychiatric disorders. The symptoms and characteristics of Long COVID vary in each country.

Vaccination against SARS-CoV-2 has been documented to increase the clinical resolution of Long COVID. In Indonesia, current full-dose vaccination coverage had merely reached 15.6% of the national vaccination target. This condition can be predictably associated with a longer duration and higher severity of symptoms in Long COVID patients.

2. Study Objectives

2.1. Primary

- To provide an overview of the symptoms and characteristics of Long COVID patients at Dr. Cipto Mangunkusumo General Hospital.
- To determine whether vaccination against SARS-CoV-2 could improve clinical outcomes and quality of life of Long COVID patients at Dr. Cipto Mangunkusumo General Hospital.

2.2. Secondary

- To determine whether vaccination against SARS-CoV-2 could increase functional exercise capacity of Long COVID patients at Dr. Cipto Mangunkusumo General Hospital.
- To determine whether vaccination against SARS-CoV-2 could reduce symptoms, duration, and frequency of Long COVID at Dr. Cipto Mangunkusumo General Hospital.

3. Study Location

Patient consent and data collection and analysis will occur at the hospital facility in Dr. Cipto Mangunkusumo General Hospital.

4. Study Duration and Timeline

No.	Activity	Description	Timeline
1.	Preparation and approval of the proposal	Create and revise proposals and activity plans according to the discussions of the research team and collaborators	September 2021
2.	Ethics approval	Submit an ethical review to the health research ethics committee of FKUI-RSCM	October 2021
3.	Data collection phase I	Collecting data from the patient's medical record	November 2021 – December 2021
4.	Data collection phase II	Collecting data from the online questionnaire, 6MWT, and follow-up	March 2022 – November 2022
5.	Data analysis	Data tidying, completing, and analysis	December 2022 – February 2023
6.	Report writing	Writing the final report on the results of the research	March 2023
7.	Publication	Publication of research results	April 2023

5. Methods

5.1. Study Design

This is a prospective cohort, cross-sectional study involving two hundred and fifty (250) subjects of post-acute COVID-19 patients, receiving outpatient/inpatient care from Dr. Cipto Mangunkusumo General Hospital during the acute phase of the infection, any time prior to enrollment in this study.

5.2. Study Population and Selection Criteria

All participants will be required to sign a written informed consent, be willing and able to comply with all study requirements, and should meet the following criteria:

1. Adult patients, aged ≥ 18 years old with a history of laboratory-confirmed SARS-CoV-2 infection via a positive molecular (RT-PCR) or antigen (lateral flow assay) test, receiving outpatient/inpatient care from Dr. Cipto Mangunkusumo General Hospital, any time prior to enrollment in this study
2. Patients with/without comorbidities
3. Willing to fill-out online Long COVID symptoms follow-up questionnaire
4. Willing and able to comply with trial protocol (re-visits and physical testing)

Subjects will be **excluded** from the study based on the following criteria:

1. Patients with no registered medical record number (MRN) at Dr. Cipto Mangunkusumo General Hospital
2. Refusal to participate in the study or to sign the informed consent form
3. Any contraindications for 6 Minute Walking Test according to the guidelines of the American Thoracic Society (ATS)
4. Patients with no access to a smartphone or computer (desktop, laptop, or tablet) to fill out the online screening questionnaire
5. Patients who died during or before enrollment in the study

5.3. Recruitment Methods

All patients, aged ≥ 18 years old with a history of laboratory-confirmed SARS-CoV-2 infection via a positive molecular (RT-PCR) or antigen (lateral flow assay) test, receiving outpatient/inpatient care from Dr. Cipto Mangunkusumo General Hospital (any time prior to enrolment in this study) are offered to be a participant in this study. One of the research team, dr. Andry Setiadharma will be examining the supervision of the primary investigator, dr. Eric Daniel Tenda, DIC, Ph.D., SpPD, and study coordinator, dr. Ni Nyoman Indira, SpPD.

5.4. Data Collection

Data on age, sex, height, weight, body mass index, income, education, comorbidities, smoking, alcohol consumption, documented SARS-CoV-2 vaccination

status (including the amount, type, and when the vaccine was received), detailed history of laboratory-confirmed SARS-CoV-2 infection, Long COVID symptoms, severity, and duration are collected through online screening questionnaire.

Data on quality of life (QoL) are collected through St George's Respiratory Questionnaire (SGRQ) and Short Form (SF)-36 Health Survey self-assessment questionnaire at baseline, 3 and 6 months after enrollment. SGRQ addresses QoL in the domains of symptoms, activity, and impacts within the last 4 weeks; and the SF-36 Health Survey questionnaire addresses QoL in the domains of vitality, physical functioning, bodily pain, general health perceptions, physical and emotional and social role functioning.

Data on functional exercise capacity is measured using the Six-Minute Walking Test (6MWT) at baseline, 3 and 6 months after enrollment. The 6MWT is performed according to the guidelines of the American Thoracic Society (ATS). During the 6MWT, such data are collected: Blood pressure, oxygen saturation (SpO2), heart rate, dyspnea, and overall fatigue score using the Modified Borg scale before and after the test, and also one-time measurement (total distance walked in 6 minutes, symptoms at the end of exercise).

5.5. Expected Outcomes

It is the investigator’s expectation that vaccination against SARS-CoV-2 could improve clinical outcomes and quality of life; and reduce symptoms, duration, and frequency of Long COVID.

5.6. Adverse Reactions

There is no expectation of any adverse outcomes or reactions, should there be any adverse outcome or reactions, necessary management and will be taken in accordance with the standard medical protocol at the Dr. Cipto Mangunkusumo General Hospital. All participants will be given access to the contact information of the research team performing this study. Any adverse reactions will be reported immediately to the primary investigator or study coordinator.

6. Potential Benefits and Risks

The 6MWT is a safe test with rare complications. It is a practical, simple test that requires, in ideal circumstances, a 100-foot hallway, no exercise equipment, and no advanced training for technicians. Walking is a daily activity for all but severely

impaired patients and so can be used by most patients in a practice. Patient involvement is based on voluntary participation, is self-directed, and is easily terminated in the event of a complication.

Safety considerations when administering the 6MWT include both technical and clinical aspects. Technical aspects for safety include proper training and knowledge for the person administering the test, adequate facility provision, and emergency provisions. Clinical aspects of safety considerations for the 6MWT include knowledge of absolute and relative contraindications and conditions requiring immediate cessation of the 6MWT. Study documentation of adverse effects reveals oxygen desaturation as the most common adverse effect, with desaturation to less than or equal to 80% in approximately 5% of testing, and patient symptoms prematurely terminating the test in 1% of testing. The absolute contraindications are unstable angina and/or myocardial infarction in the past 30 days. The relative contraindications are resting heart rate above 120 bpm, systolic blood pressure over 180 mmHg, and diastolic blood pressure above 100 mmHg. The reasons for cessation according to the ATS guideline are sudden chest pain, intolerable dyspnoea, leg cramps, staggering, diaphoresis, and pale or ashen appearance.

We take extra effort during the study period to maximize patient safety. Fulfilling this goal, the study staff employs stringent procedures to reduce the risk of adverse events during the study period.

7. Consent Process

Approval for medical treatment is obtained by first briefly explaining the background, objectives, and benefits of the research. The informed consent must be fully explained by the investigator or member of the study staff including the study aims, methods, benefits, and risks, and signed by the subject before enrollment into the study. Potential subjects will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment. The subjects will be informed that they will be authorized access by investigational staff to confidential medical records. The subjects will be given sufficient time to read the consent and ask any questions. Research participants who are willing to take part in this study then sign an informed consent. Patients who are willing to participate in the study will receive compensation.

8. Compensation

The participants will accept the transportation fee of Rp100.000,00.

9. Reasons for Withdrawal or Termination

A subject may be discontinued from the study at any time if the subject or the investigator feels that it is not in the subject's best interest to continue. The following is a list of possible reasons the subjects will be **dropped out** from the study:

1. Participants withdraw their informed consent and refuse to participate in the study.
2. Any contraindications for 6 Minute Walking Test according to the guidelines of the American Thoracic Society (ATS).
3. Participants who died before the sixth-month follow-up.

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Reasonable attempts will be made by the investigator to provide a reason for subject withdrawals. The reason for the subject's withdrawal from the study will be specified in the subject's source documents and the Case Report Form (CRF). If a subject is withdrawn from treatment due to an adverse event, the subject will be followed and treated by the investigator until the adverse event has resolved or stabilized.

10. Handling of Participant Withdrawals or Termination

Although subjects may withdraw from the study at any time and for any reason, (or may be withdrawn at the investigator's discretion), subject withdrawal should be avoided as much as reasonably possible. In any case, appropriate follow-up for withdrawals or termination. Subjects who are discontinued are not to be replaced. For subjects considered discontinued, the CRF must be completed up to the last visit performed.

11. Privacy and Confidentiality

Paper records for this study will be maintained in locked cabinets in Internal Medicine Departments. Electronic records for this study will be maintained on password-protected computers on which security is protected by firewalls. Files containing patient data will be stored in a locked office and/or on a password-protected

computer with access granted only to those individuals listed on the research team. Presentation of research results in scientific meetings/conferences and publications in scientific journals will not include participants' identities.

STATISTICAL ANALYSIS PLAN

1. Randomization

Subjects who meet all inclusion and exclusion criteria will be allocated into four groups; Never been vaccinated, received 1st dose, received 2nd dose, and received 3rd dose of vaccination. Subject allocation will be carried out through block randomization and known only by the pharmacist, and confidentiality is maintained so that subjects, doctors/nurses, researchers, and data analysers do not know the allocation of each subject.

2. Sample Size Calculation

The sample size of this study is obtained from the two-way hypothesis testing formula for the two mean values in two independent groups with a confidence index (α) of 95% and power of 80%. Results are considered statistically significant if p < 0.05. The details of the estimated size of the research subject are as follows:

Descriptive study: Cross-sectional sampling

$$n = \frac{{Z_\alpha}^2 \ P(1-P)}{d^2} = \frac{1.96^2 \ 0.4(1-0.4)}{0.1^2}$$

n = **92,1 subjects → 93 subjects**

Legends:

N : Number of subjects

Z_α : Z value in 95% confidence index = 1.96

P : Long COVID prevalence according to literature = 0.40

d : Standard deviation = 0.10

Analytic study: Prospective Cohort, consecutive sampling method

$$n = \left(\frac{Z\alpha\sqrt{2PQ} + Z\beta\sqrt{P1Q1 + P2Q2}}{P1 - P2}\right)^2 = \left(\frac{1.96\sqrt{2\ x\ 0.553\ x\ 0.447} + 0.80\sqrt{0.653\ x\ 0.347 + 0.453\ x\ 0.547}}{0.20}\right)^2$$

n = **93 subjects → N = 186 subjects**

Legends:

n : Number of subjects

Z_α : Z value in 95% confidence index = 1.96

Z_β : Z value of test power = 0.80

$P_1 - P_2$: Minimal difference in proportion considered significant = 0.20 (P_1 = 0.653)

Q : 1 - P

Assuming a 20% loss to follow-up event, the final sample size is:

n = 186 + (186 * 20%)

n = 186 + 37

n = **223 subjects**

3. Analysis methods

3.1. Data entry

Before entering data (data entry), the existing data is edited first to facilitate the stages of data entry. The data entry process goes through the coding process in the SPSS Statistics 20.0 program.

3.2. Data analysis

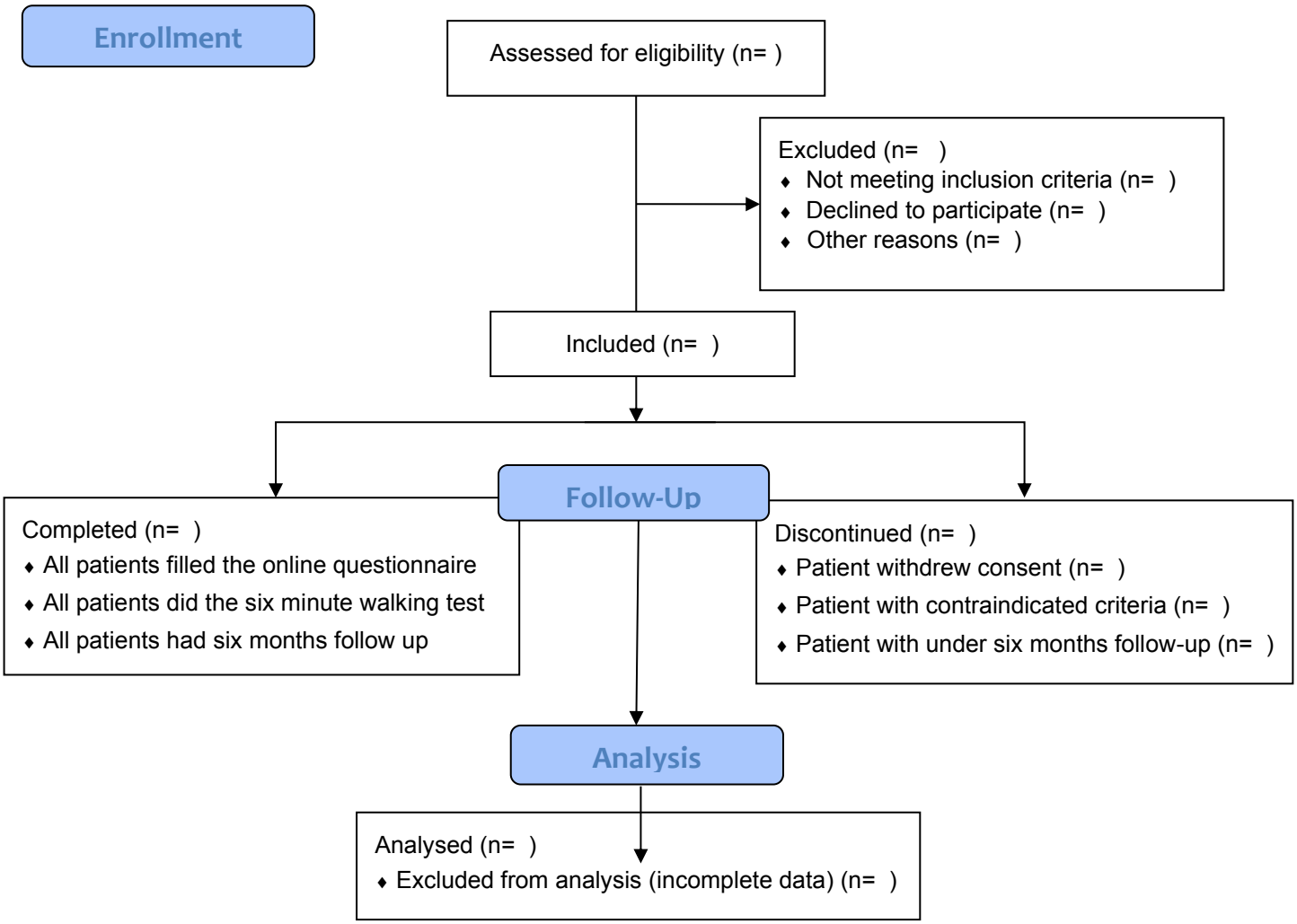
3.2.1. Univariate analysis

The analysis is intended to obtain descriptive data regarding the incidence of long COVID events and the characteristic profile of long COVID patients.

3.2.2. Bivariate analysis

This analysis is used to see the relationship between the effect of the COVID-19 vaccine on clinical long COVID and the quality of life of long COVID patients. The level of significance used is 0.05. Variables are statistically significant if p-value <0.05. The independent variables in this study are nominal scale, so the test used in this analysis is the chi-square test or fisher's test (in the group of independent variables with a dichotomous scale of 2x2 if the chi-square does not meet the requirements.

4. Flow diagram



INFORMED CONSENT FORM

EXPLANATION SHEET FOR PROSPECTIVE SUBJECTS

I am **dr. Ni Nyoman Indirawati K, Sp.PD**, member of the research team chaired by **dr. Eric Daniel Tenda, DIC, Ph.D., Sp.PD, FINASIM** from **the Department of Internal Medicine**. We will conduct a study entitled **Characteristics and Effects of COVID-19 Vaccination on Clinical and Quality of Life of Long COVID Patients at Dr. Cipto Mangunkusumo General Hospital**.

We invite you to take part in this study, which seeks to get an overview of the characteristics of long COVID patients at Dr. Cipto Mangunkusumo National Central Public Hospital as well as to assess the effectiveness of the COVID-19 vaccine against long COVID symptoms and the quality of life of long COVID patients. Taking part in this study is entirely voluntary. We urge you to discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to decide.

If you choose to participate, you must sign this form to show that you want to participate. If you refuse to participate or withdraw from this research, that decision will not affect your affiliation with me. Furthermore, it will not affect the services that apply at this hospital.

If you do not understand each statement in this form, you can ask us about it.

1. Research objectives

To get an overview of the characteristics of long COVID patients at Dr. Cipto Mangunkusumo National Central Public Hospital from May 2021 to December 2021, as well as to assess the effectiveness of the COVID-19 vaccine against long covid symptoms and the quality of life of long COVID patients.

2. Participation in research

Overall, the study will run for six months. If you are willing to participate in this research, you will follow the schedule and ensure that you can follow the plan. This research will involve filling out an online questionnaire and conducting a 6-minute walk test (6MWT) in the 3rd and 6th months.

3. Participants' criteria

1. Age 18 years old and above.
2. Patients who are confirmed positive for SARS-CoV-2 through molecular examination (RT-PCR SARS-CoV-2, Naso-oropharyngeal swab) or antigen (lateral flow assay) at least two months before recruitment; or have received a

diagnosis of a previous or confirmed clinical COVID-19 patient (has received treatment in a hospital with a diagnosis of COVID-19; any time before recruitment as a research subject).

3. Patients with or without comorbidities: diabetes mellitus, hypertension, tuberculosis, asthma, chronic obstructive pulmonary disease, chronic kidney disease, heart disease, chronic liver disease, malignancy, nervous system disease, psychiatric disorders, elderly patients, and patients with physical impairment or disability.

4. Research procedure

4a. Intervention procedure

1. The research team will explain the purpose and procedure of this research.
2. Fill out the online questionnaires or via your mobile phone.
3. The research team will collect your clinical, laboratory, and radiological data through medical records.
4. In the 3rd and 6th months, you will do a walking test for 6 minutes. You will walk as far as possible for 6 minutes on a specific track/area under the supervision of the research team.

4b. Currently available alternative procedures or treatments

None.

5. Risks, side effects, and management

There were no clinical risks or side effects in this study because there was no intervention or treatment.

There is a risk of leakage of your medical record data. However, the research team will minimize that risk through direct data handling and processing and a password to protect patient data.

6. Benefits

The benefits you can get are that you get information about your general condition after COVID-19 infection and a fitness check through a 6-minute walking test for free.

7. Compensation

You will receive a transportation fee of **Rp. 100,000.**

8. Financing

The researcher will entirely bear the funding for this research.

9. Confidentiality

The research team will handle and process data directly by the data, and a password will protect the participants' data. Presentation of research results in scientific meetings/conferences and publications in scientific journals will not include your name.

10. Obligations of research subjects

As research subjects, you must follow the rules or research instructions as written above. If something is not clear, you can ask the research team further.

11. Right to refuse and withdraw

You do not have to participate in this research if you don't want to. However, you must understand that even if you agree to participate, you have the right to withdraw from this research. If you refuse to participate or withdraw from this research, that decision will not affect your relationship with the researcher. I will allow you to consider the decision at the end of this explanation.

12. Post-trial access

There were no interventions or treatments in this study.

13. Additional Information

You can ask all things that are unclear in connection with this research. Suppose at any time you need further explanation. In that case, you can contact **dr. Ni Nyoman Indirawati K, SpPD** at the Department of Internal Medicine, Division of Respirology and Critical Illness Dr. Cipto Mangunkusumo National Central Public Hospital Jakarta with phone number +6281390705913.

RESEARCH PARTICIPATION APPROVAL SHEET

I have received all the explanations and **dr. Ni Nyoman Indirawati K, Sp.PD** has answered all my questions. I understand that if I need an explanation, I can ask **dr. Ni Nyoman Indirawati K, Sp.PD**.

Certificate of Approval	
I have read all the descriptions of this research. Furthermore, I had the opportunity to ask questions and the research team answered all my questions. Therefore, I am willing to participate in this research study voluntarily.	I confirm that participants are allowed to ask questions about this study and that all questions have been answered correctly. Furthermore, I confirm that consent has been given voluntarily.
_____ Name of participant/guardian	_____ Name of researcher
_____ Signature	_____ Signature
Date _____ day/month/year	Date _____ day/month/year

Researcher Information:

Principal Researcher:

dr. Eric Daniel Tenda, DIC, Ph.D, Sp.PD, FINASIM

Department of Internal Medicine, Division of Respirology and Critical Illness Dr. Cipto Mangunkusumo National Central Hospital, Jakarta.

+62 81380333818 / eric.tenda@ui.ac.id

Researcher:

dr. Ni Nyoman Indirawati K, Sp.PD.

Department of Internal Medicine, Division of Respirology and Critical Illness Dr. Cipto Mangunkusumo National Central Hospital, Jakarta.

+62 81390705913 / ninyoman.indira@gmail.com

KEPK FKUI-RSCM:

Jalan Salemba 6, Central Jakarta, 10430

021 3157008 / ec_fkui@yahoo.com

If the subject is illiterate:

An illiterate participant must sign it (if possible, this person should be selected by the research subject/participant, not their parents, and must not have any relationship with the research team). Illiterate research subjects/participants must also include their fingerprints.

I have witnessed the accurate reading of the consent form to the research subject/participant and have been allowed to ask questions. I confirm that the subject/participant has given their free consent.

Participant's name _____ AND Participant's fingerprint

Signature _____

Date _____
Date/Month/Year

For young children, older subjects, or subjects who, because of their capacity, cannot give consent (vulnerable subjects), the participant's parents, children, husband/wife, or legal guardian must request permission.

In general, there are several sentences on the information sheet and participation agreement sheet that must be adjusted to the conditions, for example:

"The research team invites son/daughter/father/mother/husband/wife of [***guardian***] to participate in this research. This study requires approximately [***number of***] research subjects, with the participation period of each subject being approximately [***period of study***]."

APPROVAL SHEET

The patient, _____, will participate in the research: **Characteristics and Effects of COVID-19 Vaccination on Clinical and Quality of Life of Long COVID Patients at Dr. Cipto Mangunkusumo National Central Public Hospital.** I have read and understood the information in the information sheet and have been allowed to discuss and ask questions about it. I agree to allow my child/father/mother to get involved in this research. I understand that I may refuse to participate in the research. I know I can withdraw from this study any time I wish. I understand that if I do not participate in this study, my child/father/mother will still receive proper medical care according to the patient's illness/condition.

I, as a PARENT/GUARDIAN of _____, AGREE to participate in this research.

Date: _____

Signature of Parent/Guardian: _____

Name of Parent/Guardian: _____

Witness Signature: _____

Witness Name: _____