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Effectiveness of video-based psychotherapy in reducing distress in patients with COVID-19 treated in a hospital isolation ward in Jakarta

STUDY PROTOCOL & STATISTICAL ANALYSIS PLAN

20 MARCH 2021

STUDY PROTOCOL

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1. Introduction

1.1 Background

The coronavirus disease 2019 (COVID-19) pandemic has brought severe consequences worldwide. Until now, there has been 693,282 cases and 33.106 mortality associated with this disease, with Italy having the highest number of cases and death globally. World Health Organization (WHO)'s disease risk assessment has shown that this disease has a very high risk on a worldwide scale [1].

Indonesia is one of the countries which has been affected by this pandemic. There has been 1,285 cases and 114 death recorded so far [1]. Through the Department of Health, the Indonesian government has responded to the pandemic by conducting several measures to prevent and to mitigate the disease. The measures include surveillance, early detection, contact tracing, quarantine, plague mitigation, clinical management, prevention and infection control, management of laboratory specimens, risk communication, as well as community empowerment [2].

The examination, treatment, and monitoring of individuals with COVID-19 often requires them to be in a hospital isolation ward [2]. There are a lot of factors which could negatively affect the mental health of such patients during their isolation, to the point that they develop significantly debilitating conditions. Studies on the effect of treatment in isolation wards on hospitalized patients demonstrate detrimental effects on the patients' psychological condition and associated behavioural disturbance as a result of isolation, including affective states of depression, anxiety, anger, hostility, fear and loneliness [3].

Several psychotherapy interventions have been known to be effective during a pandemic situation. The interventions include those based on techniques of relaxation, managing thoughts and feelings, and mindfulness. These methods could help reducing negative and catastrophic thoughts about the future, reducing distress level and hyperarousal, and other beneficial effect [4]. However, due to the high transmission rate of SARS-CoV-2 virus, face-to-face therapy sessions are rendered difficult to hold under the circumstances.

Kiara Ultimate is the place where COVID-19 patients are treated and monitored in CMH (Cipto Mangunkusumo Hospital). A psychotherapy intervention is a potentially promising intervention that could be provided to reduce the distress of the many patients being treated or monitored in this ward. In practice, providing psychotherapy via video is an alternative method when face-to-face therapy sessions are not possible in order to practice adequate infection control, especially with patients treated in an isolation ward. This study will be conducted with hopes that it could show how video-based psychotherapy could reduce the distress of COVID-19 patients treated in an isolation ward.

1.2 Research Problem

Being treated in an isolation ward for treatment or monitoring purposes could bring detrimental effects to the psychological condition of COVID-19 patients. The psychotherapy techniques based on relaxation, managing thoughts and feelings, and mindfulness are methods of intervention that could be applied to reduce distress on those patients. Therefore, an investigation on the role of video-based psychotherapy in reducing the distress of COVID-19 patients treated in an isolation ward would be needed before the interventions could be practiced in real-life clinical settings.

1.3 Hypothesis

H0: There is no significant change in SUDS score of COVID-19 patients in isolation ward before and after watching the video-based psychotherapy.

H1: There is a significant change in SUDS score of COVID-19 patients in isolation ward before and after watching the video-based psychotherapy.

1.4 Objectives of Research

1.4.1 General Objective

- To determine the effectivity of video-based psychotherapy on reducing the distress of COVID-19 patients in Kiara Ultimate CMH isolation ward.

1.4.2 Specific Objectives

- To acquire the mean or median of the score of psychological distress of COVID-19 patients in Kiara Ultimate CMH isolation ward before receiving video-based psychotherapy.
- To acquire the mean or median of the score of psychological distress of COVID-19 patients in Kiara Ultimate CMH isolation ward after receiving video-based psychotherapy.
- To acquire the mean or median of the changes in the score of psychological distress of COVID-19 patients in Kiara Ultimate CMH isolation ward after receiving video-based psychotherapy, compared to before receiving the intervention.

1.5 Significance of Research

Determining the role of video-based psychotherapy in reducing the distress of COVID-19 patients in Kiara Ultimate CMH isolation ward could bring about these benefits:

- In the field of clinical setting and community services:
 - COVID-19 patients who are treated in the hospital isolation ward could receive psychotherapy services in the form of techniques based on relaxation, managing thoughts and feelings, and mindfulness, which could help reduce their psychological distress as they go through their treatment.
 - Acquiring a general idea on what kind of psychotherapy technique would be the most effective to be provided to COVID-19 patients treated in an isolation ward.
- In the field of science:

- A study on psychotherapy for COVID-19 patients treated in an isolation ward could contribute further knowledge for the field of psychiatry, especially on the field of psychotherapy.
- In the field of research:
 - The outcome of this research could be used as a reference for further studies on the methods of psychotherapy that could be delivered to patients being treated in an isolation ward in the future.

3. Methodology

3.1 Study Design

This study utilized the quasi-experimental design with a pre-test-post-test and without a control group.

3.2 Time and Location of the Study

This study will be conducted in Kiara Ultimate CMH isolation ward, from June 2020 until August 2020.

3.3 Population and Sample

The target population of this study is all COVID-19 patients in hospital isolation wards. The accessible population of this study is all COVID-19 patients in the Kiara Ultimate CMH isolation ward. Samples would be COVID-19 patients in the Kiara Ultimate CMH isolation ward who fit the inclusion criteria. Due to the limited number of patients in the isolation ward that would make performing a true randomization difficult, participants would be selected through convenience sampling.

3.4 Sample Size

The sample size required in this study is determined through the formula for testing the hypothesis on the mean of two paired populations as following:

$$n = \left[\frac{(Z_\alpha + Z_\beta) \times S_d}{d} \right]^2$$

Description:

n = minimal sample size required

α = type I error

β = type II error

S_d = standard deviation of mean difference

d = mean difference of SUDS score that is determined as clinically significant

α is determined as 0,05, power as 0,9 ($Power = 1 - \beta$), standard deviation of mean difference as 4, and mean difference of SUDS score of 2 is determined as clinically significant. By these values, the minimum sample size required was determined as:

$$n = \left[\frac{(1,96 + 1,28) \times 4}{2} \right]^2$$

n = 42 subject

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion Criteria

The inclusion criteria for participating in this study are:

- Patients with COVID-19 in Kiara Ultimate CMH isolation ward who are at least 18 years old
- Patients with COVID-19 in Kiara Ultimate CMH isolation ward who are able to give an informed consent
- Patients with COVID-19 in Kiara Ultimate CMH isolation ward who agreed to watch the psychotherapy videos about relaxation, managing thoughts and feelings, and mindfulness using electronic devices provided by the research team or their own devices independently

3.5.2 Exclusion Criteria

The exclusion criteria for participating in this study are:

- Patients in unstable conditions such as patients on a ventilator, experiencing breathing difficulties, or in need of oxygen support, with fluctuating levels of consciousness
- Patients with physical and intellectual disabilities that may hinder ability to understand instructions of the video-based psychotherapy intervention

3.6 Research Approval

The approval that would be required to carry out this study would be:

- Approval from Department of Psychiatry Faculty of Medicine Universitas Indonesia-Cipto Mangunkusumo Hospital
- Approval from Faculty of Medicine Universitas Indonesia Research Ethics Committee

3.7 Research Procedure

A. Preparation

Preparation starts from applying for permission to carry out the study to the appropriate parties, namely the Faculty of Medicine Universitas Indonesia Research Ethics Committee, the head of Department of Psychiatry Faculty of Medicine Universitas Indonesia-Cipto Mangunkusumo Hospital, and the head of Emergency Room of Cipto Mangunkusumo Hospital.

B. Participants Recruitment and Follow-Up

- The research team provides a banner or poster with the information on the research about video-based psychotherapy to be placed in Kiara Ultimate CMH isolation ward, as well as a web link to the online research forms and the psychotherapy videos.

- Every day during the recruitment period, the health care workers in Kiara Ultimate CMH isolation ward would check if there were any patients in the isolation criteria who meet the inclusion criteria for the study
- If such patients are currently in the isolation ward, the health care workers would collect their contact information and inform it to the research team
- Patients who meet the criteria would be contacted by the research team. During contact, the research team would ask for their informed consent to participate in the study via voice call or video call
- The health care workers would provide patients who agree to participate with links for video access, online research forms, and a written informed consent form for them to sign. Patients who don't wish to participate would still be offered to watch the videos. Participants could choose to watch the videos using an electronic device provided by the research team, or using their own devices
- Participants would be given bathing equipments such as a towel and soaps as incentives for going through the research protocol
- The data which would be collected through the research form includes demographic data, length of stay in the isolation ward, as well as the distress score before and after watching the videos measured using the Subjective Units of Distress Scale (SUDS)

3.8 Data Processing and Statistical Analysis Plan

Data will be stored in a specific online data registry. Confidentiality of the data will be guaranteed by the research team. Statistical analyses will be performed using SPSS software version 20. The changes in SUDS score will be analysed through the analysis for comparison of two population means of paired samples.

The main analysis in this study is the investigation of the changes in SUDS score before and after watching the video-based psychotherapy. Analysis was also done on the participants' demographic data to generate information on the characteristic distribution of the participants. The participant's demographic characteristics data that were analysed included age, sex, level of education, occupation, and marital status. Tests of normality for the numeric data was done through the Shapiro-Wilk normality test, with the p-value of $>0,05$ as the indicator for rejecting the null hypothesis. Normality tests were performed on the numeric variables in the study namely age, SUDS score before and after watching the video-based, and participants' length of stay in the isolation ward.

Investigation of the change in SUDS score was done through a bivariate analysis, to see whether there was a significant difference between the mean SUDS scores before and after watching the three video-based psychotherapy interventions in the two paired groups. As the numeric variables turned out to have non-normal distributions, the non-parametric statistical hypothesis test Wilcoxon-signed rank test was performed on the data. A significant association was decided as p-values $<0,05$. Statistical analyses were performed using SPSS software version 20.

3.9 Instrument

The instrument that will be used for data collection in this study is Subjective Units of Distress Scale (SUDS). The SUDS is used to measure the distress level of an individual in a numeric scale. The SUDS is a self-rating instrument.

3.10 Definition of Terms

- Psychotherapy: A form of therapy which utilizes psychological methods, conducted by a professional or a trained expert who forms a professional relationship with a patient with the aim of reducing, modifying, or eliminating the symptoms and suffering caused by their mental disorders or illness.
- Video-based psychotherapy: The use of video as a medium to deliver psychotherapy to patients.
- Relaxation: A number of techniques which involves alternately tensing and relaxing specific muscle groups to reach a state of deep muscle relaxation, with the goal of reducing anxiety and mental tension.
- Managing thoughts and feelings: A cognitive therapy technique which is designed to help patients feel more comfortable about themselves and acquire the capability to adapt to their circumstances through changing their perspective about themselves, their environment, and their circumstances.
- Mindfulness: A process of focusing one's attention solely to the experiences that are occurring in the present without associating it with other thoughts or feelings in a judging way, with the aim of helping increase their capability to accept their current circumstances.
- COVID-19 patients: Patients who have been diagnosed with COVID-19, with or without other conditions.
- Subjective Units of Distress (SUDS): a self-rating instrument for measuring distress in individuals. Individuals give a score that is supposed to represent their subjective experience of distress on a scale of 0 - 10 (numeric), with a score of 0 representing "no distress" and a score of 10 representing "very severe or extreme distress".

3.11 Ethical Approval of the Research

Application for the permission to carry out this research has been submitted to the Faculty of Medicine Universitas Indonesia Research Ethics Committee. Data of all subjects in this study will be kept confidential. The informed consent form that will be given to the participants will contain a detailed explanation about the protocol of the research. Patients will be informed that they are free to refuse participating in the study and there would not be any negative consequences inflicted on them.

All participants were informed of the study protocol through the informed consent form that they had to sign. All subject data in this study were kept confidential by the research team. All procedures involving human subjects were approved by the Faculty of Medicine Universitas Indonesia Research Ethics Committee. Application for permission to carry out this research was submitted to the Faculty of Medicine Universitas Indonesia Research Ethics Committee.

3.12 Research Team

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