

A Study Protocol on Methodological Approach in Mental Health Status of COVID-19 Patients in the Main Hospitals in Malaysia (MentalStatCOVID)

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Study protocol

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Abstract

Background: Mental health has always been an important marker for survival especially in the case of disaster due to pandemic disease. Therefore, we aimed to determine the burden of among COVID-19 patients in Malaysia. This article describes the study protocol on the research project entitled “Mental Health Status of COVID-19 Patients in the Main Hospitals in Malaysia”.

Method: A cross-sectional study via web-based online survey involving 401 patients in the main COVID-19 hospitals in Malaysia who were selected via quota sampling. The questionnaire consists of socio-demographic profile, Patient Health Questionnaire 9 items (PHQ-9), General Anxiety Disorders 7 items (GAD-7) and Brief COPE (Coping Orientation to Problems Experienced). The identified probable cases of depression, anxiety and suicidal ideation were subsequently referred to psychiatrists.

Discussion: The study should identify probable cases of depression and anxiety including suicidal ideation which should be managed appropriately by the psychiatrist in the participating hospital. The findings will reveal the current mental health burden towards COVID-19 patients.

Background

In any disaster or emergency, mental health has been an important marker for survival. Nearly all people affected by disasters and emergencies will experience psychological trauma which will improve over time for most people [1]. But the fact that one in five (22%) who live in the area affected is estimated to have depression, anxiety, post-traumatic stress disorder, bipolar disorder or schizophrenia was proven debilitating to the population [1]. In the case of disaster due to pandemic diseases, the prevalence was even higher among vulnerable populations i.e. patients and healthcare workers (HCW) who have been infected by pandemic diseases. For instance, the prevalence of depression among MERS-CoV patients during the outbreak was 40.7% [2].

Recently, the Coronavirus Disease 2019 (COVID-19) has been reported as world-threatening pandemic disease. COVID-19 was caused by the SARS-CoV-2 virus. This pandemic which originated from Wuhan, China has extensively invading 199 countries since November 2019 with more than 4.5 million cases reported and more than 300,00 deaths have been recorded [3].

In Malaysia, the first COVID-19 case was reported on the 24th of January 2020. Since then, over 6000 positive cases have been detected [4]. All of the patients admitted to the hospital had to undergo 14 days of treatment and isolation. Due to long hospitalization, COVID-19 patients should be monitored in terms of mental health surveillance and provided with psychotherapy services.

It is a critical time for us to understand the effect of COVID-19 on the mental health of each patient contracted with COVID-19. This study aims to determine the prevalence of depression and general anxiety disorders (GAD) of stable hospitalized COVID-19 patients at the main COVID-19 hospitals in Malaysia.

Thus, this research intended to benefits stakeholders by improving risk communication and mental health surveillance in hospital settings.

Methodology

Study design

This was a cross-sectional study using web-based online survey conducted among COVID-19 patients hospitalized in selected hospitals from 15th April 2020 until 30th June 2020.

Sampling design and sample size

1. Target population

The target population was all COVID-19 patients hospitalized in two referral hospitals at Klang Valley, one COVID-19 designated hospital at Johore, and one Low-Risk Patient Quarantine & Treatment centre. The sampled population was the proportion of stable COVID-19 patients selected via quota sampling technique at the selected hospitals.

2. Sampling frame

The sampling frame for this study was a list of all the COVID-19 patients admitted to the general wards (non-intensive) who were in a stable condition.

3. Sample size determination

The sample size was calculated using the Sample Size Calculation Formula for prevalence with finite population correction study as per the primary objective (4). The sample size calculation was based on the reported prevalence of depression among MERS-CoV patients in Korea, 40.7% (5). The calculation was done with a margin of error of 0.05 and Type 1 error determined at 5% with a finite population of 500 (2).

Selection of respondents

Patients who have been diagnosed as COVID-19 positive and in a stable condition were listed in the sampling frame. Screening for eligible respondent among COVID-19 patients in each hospital was started on 15th April 2020. An eligible respondent must be of age 18 years and above, has been diagnosed with COVID-19 but in a stable condition, has been admitted in the ward for more than 24 hours, and is able to read and understand Malay or English. Quota sampling technique was utilized in this study whereby the first 400 eligible patients who responded to the screening were recruited in this study. Participation in this study was on a voluntary basis as each respondent has the right to refuse or withdraw from the study at any point of time during the survey. If the respondent refused, all details of the respondent, as well as any response given, would then be deleted.

Survey instruments/Questionnaire

Structured questionnaires were used to collect data in this study. The questionnaires are available in both Malay and English language, programmed into the Google form for data collection via a web-based online survey. The front page (1st part) of the Google form is the Patient Information Sheet and Consent Form. The 2nd part of the Google form is the socio-demographic profile of respondents and factors contributing to mental health (Section A & Section B). The 3rd part (Section C) is the Patient Health Questionnaire (PHQ-9) to assess for probable depression with a cut-off score of 10 and above, the 4th part (Section D) consists of Generalized Anxiety Disorder questionnaire (GAD-7) to assess for probable anxiety with a cut-off score of 8 and above. The 5th part (Section E) is the coping strategies via Brief COPE (Coping Orientation to Problems Experienced). Psychometric measurements for all three questionnaires (PHQ-9, GAD-7 & Brief COPE) were locally validated beforehand (6-8).

Field implementation

A total of eight Research Assistants (RAs) were hired for this survey and training was given. Two RAs were in-charge for central team in Institute for Public Health (IPH) and the remaining RAs were stationed in the psychiatric department with two RAs on-duty per hospital. The RAs in hospitals conducted a briefing to all matrons or staff in charge of COVID-19 ward and *Google Form* link for the survey was given to them which then disseminated to the eligible respondent of COVID-19 patient.

Responses in the cloud server were downloaded daily by the central team in IPH and scoring was performed for PHQ-9 with the inclusion of suicidal ideation (item no. 9) score and GAD-7. Positive cases that require further assessment for diagnosis and management were referred to the psychiatrist in-charge at the respective hospital within 24 hours.

Data management, Quality Control (QC), Privacy and Confidentiality

Data processing activities were centralized at the Institute for Public Health (IPH) including data collection, data cleaning and data analysis. Prior to the actual survey, a pilot study involving a minimum of 30 respondents tested the system (Google form) on the 15th April 2020 to ensure its reliability. The changes to the Google form were made as per the feedback received from the respondents of the pilot study.

In order to ensure privacy and confidentiality of data, the data gathered in the database was kept in a secure manner. The access control of the dataset was managed by assigning unique password to each file. Only central team researchers were able to access the personal particulars of participants and the data were conserved.

Data Analysis

All data were cleaned and analyzed by the research team. A meaningful combination of categories was done as per indicated. Data was analyzed using SPSS version 23.0. Descriptive statistical analyses were

performed to determine prevalence of depression and anxiety among stable hospitalized COVID-19 patients. Multivariate statistics via multiple logistic regression were performed to evaluate risk factors associated with prevalence of depression and anxiety.

Data Analysis

All data were cleaned and analysed by the research team. A meaningful combination of categories was done as per indicated. Data was analysed using SPSS version 23.0 for descriptive statistics and multivariate statistics via Multiple Logistic Regression. The output will be tabulated and the findings of the study will be submitted to a peer-reviewed journal.

Discussion

The outbreak of pandemic disease is catastrophic and causes negative psychological effects among patients, healthcare workers and their surroundings [9]. The main objective of this study is to determine the prevalence of depression and general anxiety disorders (GAD) of stable hospitalized COVID-19 patients at the main COVID-19 hospitals in Malaysia. This study should be the first study revealing the burden of mental health among COVID-19 patients who admitted to the hospital for treatment and isolation. There is still scarcity of evidence in terms of burden of mental health problems and its predictors during the pandemic crisis. This study was based on the established hypothesis that general stress and negative psychological effects are increased in infected patients, particularly among infected healthcare workers [10]. Infected patients who were critically ill and required Intensive Care Unit (ICU) admission were more affected and had a lower quality of life compared to those in the general ward [11]. Therefore, the study's baseline data on stable patients should estimate the higher burden of mental health among non-stable COVID-19 patients.

In a recent cross-sectional survey done in Mainland China during the epidemic of COVID-19, it was found that the prevalence of people suffered from moderate to severe depression was 16.5% and the prevalence of people suffered moderate to severe anxiety was 28.8% [12]. Anxiety, depression and feeling angry also noted high among those who required quarantine and isolation [13]. Some of them required a psychiatric evaluation and were prescribed medication during their hospital stay. This group of patients showed mental health effects even at four to six months after removal from isolation [13]. Post-traumatic stress disorder was the most prevalent long-term psychiatric condition followed by depressive disorders [9].

This study also addresses the factors contributing to mental health issues in COVID-19 patient. A rapid review by Brooks et al. 2020 with a total of 24 studies reported negative psychological effects such as post-traumatic stress symptoms, confusion, and anger. This was due to stressors included longer quarantine duration, infection fears, frustration, boredom, inadequate supplies, inadequate information, financial loss, and stigma. This review also suggests a comprehensive psychological intervention to be implemented by the stakeholders. An assessment of the burden of mental health such as depression and anxiety, their risk factors among vulnerable patients are required especially for early intervention psychiatric care during hospital quarantine [14].

Strengths and limitation of this study

This study provides a platform for mental health surveillance and the results should benefits stakeholders to utilize essential steps in preventing mental health crises among COVID-19 patients during the outbreak. The study also served as active case detection (ACD) of COVID-19 patients having mental health problems.

Some limitation such as the research is subject to socially desirable responses, or a desire to present oneself favourably in light of social norms and standards, which favour response bias. Also, the findings of this study are also limited in terms of generalization towards hospitalised COVID-19 patients admitted at Hospital Kuala Lumpur, Hospital Sungai Buloh and Hospital Permai Johore only.

Conclusion

This is the first study to address the mental health status among stable hospitalized COVID-19 patients in Malaysia. The future study are recommended to replicate and improve the current methodology of MentalStatCOVID to suit every culture and system. The findings of this study also should benefits stakeholders and public via improvement towards risk communication and mental health surveillance programme.

Declarations

Author Contributions

MSAK, NAA, UAS, NMA, NH, MSR, NS, CYY contribute to the conceptualization and writing of this manuscript. All authors reviewed the final manuscript and approved the final version for publication.

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Conflict of Interests

We declare no competing interests.

Ethics Approval & Consent for Publication

This study was registered under the National Medical Research Registry (NMRR), Ministry of Health Malaysia (Registration number NMRR-20-711-54541) and obtained ethical approval from Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia. Permission for publication was obtained from Director General of Health Malaysia.

Data Sharing Statement

No additional data are available.

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