THE EFFECTS OF PARTICIPATING IN A RESEARCH TEAM DURING THE COVID-19 PANDEMIC ON THE EDUCATIONAL ROUTINE AND MENTAL HEALTH OF MEDICAL STUDENTS: A STUDY PROTOCOL FOR A WEB BASED SURVEY

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Abstract

Background: The COVID-19 pandemic has provided social isolation with a potential negative impact on the educational routine, including the suspension of face-to-face appointments, and mental health of medical students. The Mario Pinotti II study (MPII) is a 24-week observational study with scheduled telephone calls every 2 weeks to verify the occurrence of the COVID-19 in rheumatic patients on hydroxychloroquine chronically (from 29th, March, 2020 to 30th, September, 2020). The effects of voluntary participation in a research project, which foresees interaction by telephone contact with patients, professors, rheumatologists, and colleagues on the daily life and mental health of medical students requires evaluation.

Objective: Objectives: Considering that medical students are professionals in training with a high level of responsibility to handle emotional and physical aspects related to several diseases, this study has the aim of evaluating the impact of the COVID-19 pandemic and participation in the MPII study, on the educational routine and mental health of medical students. Methods: Methods: A web-based survey was carried out to perform a cross-sectional comparative assessment between medical

students participating in the MPII study and other their colleagues who are not involved in this research project, matched to sex, age and medical school. The web questionnaire was developed by a panel composed of graduate medical students, rheumatologists, medical school professors, and a psychology professor and it included details on demographic and life habits data, as well as evaluation of participants' impression about the MPII study and the impact of the COVID-19 pandemic on their educational routine and medical training. In addition, the depressive, anxiety, and stress domains were evaluated using the DASS-21 (Depression, Anxiety and Stress Scale), Brazilian version, and, lately, the scores were grouped as low, moderate and high risk for mental distress. This project was approved by the Federal University of São Paulo Ethics Committee (CAAE: 30246120.3.1001.5505). Results: Results: Data collection was applied for all 2 medical student groups from July 20th to August 31st, 2020. Data extraction is ongoing. Analysis is scheduled to start after extraction is completed. Conclusions: Conclusions: This study will bring light into the effects of participating in a research project on depressive, anxiety, and stress domains by using the DASS-21 (Depression, Anxiety and Stress Scale) in large sampling of medical students and the evaluation of the impact of the COVID-19 pandemic on students educational routine and medical training. Clinical Trial: This is not a clinical trial.

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ABSTRACT

Background: The COVID-19 pandemic has provided social isolation with a potential negative impact on the educational routine, including the suspension of face-to-face appointments, and mental health of medical students. The Mario Pinotti II study (MPII) is a 24-week observational study with scheduled telephone calls every 2 weeks to verify the occurrence of the COVID-19 in rheumatic patients on hydroxychloroquine chronically (from 29th, March, 2020 to 30th, September, 2020). The effects of voluntary participation in a research project, which foresees interaction by telephone contact with patients, professors, rheumatologists, and colleagues on the daily life and mental health of medical students requires evaluation.

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Committee (CAAE: 34034620.0.0000.5505).

Results: Data collection was applied for both medical student groups from July 20th to August 31st, 2020. Data extraction was completed in September, 2020. Analysis is ongoing. The authors expect the results to be published in the first semester of 2021.

Conclusions: This study will bring light into the effects of participating in a research project on depressive, anxiety, and stress domains by using the DASS-21 (Depression, Anxiety and Stress Scale) in large sampling of Brazilian undergraduate medical students and the evaluation of the impact of the COVID-19 pandemic on students educational routine and medical training.

Keywords: SARS-CoV-2; COVID-19; medical education; observational cross-sectional case-control study; voluntary; mental health; rheumatic diseases.

INTRODUCTION

In December 2019, a respiratory disease (COVID-19) caused by the novel coronavirus (SARS-CoV-2) was identified in Wuhan City, Hubei Province, China. Few weeks later, the World Health Organization (WHO) declared it as an international public health emergency and pandemic [1].

Considering the high viral community transmission, several approaches have been recommended to mitigate the global viral dissemination, especially social distancing, quarantine, intermittent hand hygiene, and universal masking. However, these government recommendations vary according to each country and have caused home isolation, fear, uncertainties, anxiety, depression, higher alcohol intake, and domestic violence, as well as education impairment and a severe economic burden [2-4].

Regarding medical education, the majority of classes and face-to-face practices were suspended for a long period while the medical schools were preparing for remote education. On the other hand, some students were invited to work on the front line, facing COVID-19 patients, and/or brought their graduation forward [5,6]. These measures, associated with virtual and not in-person training have hampered the medical training in dealing with patients and other relevant aspects, including hospital and outpatient clinics,

and regulatory processes [7]. Thus, some authors have highlighted a gradual increment in anxiety levels among medical students during the COVID-19 pandemic, suggesting that this could be impairing several aspects related to social relationships, technical performance, and mental health [7,8].

It is worth emphasizing that medical training is often exhausting due to specific technical requirements, as well as large stressful factors [9], including full-time dedication, personal life effort and sacrifice, close contact with severe diseases and death, and physical and emotional distress [10]. During the COVID-19 pandemic, more extensive and intense workloads, difficulty in reconciling personal life with studies, competitiveness, sleep deprivation, fear of making mistakes and getting sick, tiredness, and decision making under pressure may cause more anxiety and depression in medical students [9-13].

European studies have demonstrated that around 30% of medical students present some level of depression or anxiety. In Brazil, studies suggested that 20 to 50% of medical students have presented some mood changes [12]. In addition, depression and suicidal ideation rates are higher in medical students than in the general population and these students generally seeks less help from psychological or psychiatric support [5-12]. Some psychiatric illnesses or personality disturbances have been reported in this scenario, such as eating disorders, denial of reality, alcoholism, abuse of illicit drugs, lack of commitment, obsessive-compulsive disorder, anxiety, depression, and increased suicide rate [7]. Thus, medical students are vulnerable and more susceptible to an inadequate or non-adaptive response to emotional distress [7,13].

Since January 2020, the WHO has been warning the COVID-19 is generating stress in the general population [1], especially regarding uncertainties about the course and prognosis of the disease, fear, lack of resources for its diagnosis and treatment, shortage of food, medications, and adequate supplies of personal protective equipment for healthcare professionals, missing the freedom of coming and going, and conflicting information delivered by governmental authorities or the social media [14-16]. Some population psychological disorders have already been demonstrated during previous pandemics, including the Acute Severe Respiratory Syndrome (SARS) and the Middle Eastern Respiratory Syndrome (MERS), mainly related to anxiety and depression [8].

In China, during the COVID-19 pandemic, a study evaluating 217 medical students reported the occurrence of depression and anxiety in 35% and 22%, respectively [8]. Researchers at medical schools in Wisconsin believe that students are great allies of

doctors [7].

The Mario Pinotti II (MPII) study is a non-interventional observational, multi-center, parallel-group cohort study including adult volunteers (≥18 years old), with a previous known diagnosis of rheumatic diseases (RD), who were on hydroxychloroquine (HCQ) for at least 30 days prior to baseline. It is a 24-week prospective study including more than 10,000 individuals from 20 centers in Brazil. A total of six sequential telephone calls were scheduled during the community viral transmission, performed by 395 volunteering medical students [17].

Considering the close social interaction with the patients and controls through periodic telephone contact, as well as with principal investigators, study coordinators, and professors, our main hypothesis was that medical student members of the MPII study would present less emotional distress than colleagues who were not participating in this project. [12-15].

Our objectives were to evaluate the impact of participation in the MPII Study on the mental health, evaluated using de Depression, Anxiety and Stress Scale (DASS21) [19,20], professional improvement, and commitment perceptions of medical students during the COVID-19 pandemic, as well as to verify potential impairment on educational routine in the medical schools and to report COVID-19 diagnosis in this population.

METHODS

1. STUDY DESIGN

A comparative cross-sectional observational case-control study using a voluntary web-based survey. This survey was conducted according to CHERRIES statement [21].

2. STUDY POPULATION

Medical students involved in the MPII study (voluntary group) and their colleagues not participating in this research project (control group) [17].

3. SAMPLE SIZE

Convenience sampling was used according to voluntary involvement as investigators in the MPII Study. From the 20 MPII centers, 14 (70%) participated in the present study. All students consecutively answering the web questionnaire through collection data period

were included.

4. INCLUSION CRITERIA

Volunteer Group: Medical students participating as a volunteer in the MPII Study, aged 18 years or over.

Control group: Medical students not participating in the MPII. For each case in the volunteer group, at least two students were enrolled as controls, in order to assure a sufficient number of individuals for stratified analysis, mostly because the expectations for mental suffering prevalence among medical students was high [18].

An Electronic Informed Consent form was provided for both groups and it acceptance was necessary before they were granted access to the survey questionnaire.

5. EXCLUSION CRITERIA

Refusal or withdrawal of informed consent.

6. SURVEY QUESTIONNAIRE

This study was approved by the Federal University of São Paulo Ethics Committee (CAAE: 34034620.0.0000.5505) on July, 13th, 2020.

The survey questionnaire form can be assessed in full in the Appendix. It includes 69 questions. The time length for its completion was 20 minutes. The questionnaire was developed and provided to participants in Portuguese (their mother language) and was only translated in order to be published. Translation was verified by an experienced translator in Brazil.

A panel of undergraduate medical students, rheumatologists, and medical school professors involved in the MPII study, with a Psychology Professor experienced in web-based surveys evaluating the mental health of medical students and health care professionals were responsible for developing the web-survey questionnaire. The students composing the panel that developed the survey (n=3) tested the questionnaire and then it was distributed to the other participants of this survey.

The volunteer group received an invitation video with explanations about the survey and the link to access the web questionnaire.

Subsequently, the volunteers were requested to send an invitation link to their colleagues who were not participating in the MPII Study to integrate the control group.

No identification data were requested.

An informed consent form is integrated with and precedes the web questionnaire. Participants are required to check their consent to participate in the survey (Electronic Informed Consent) before assessing the questionnaire of the study or providing any information.

Individuals can provide an e-mail address if they want to receive their mental health evaluation results. Participants or researchers who identify the necessity for a psychological or psychiatric evaluation will provide, through e-mail contact, guidance on accessing these services locally. All participants were informed that the e-mail address is voluntary and precedes the survey questionnaire.

Demographic and epidemiologic data and details about comorbidities, life habits (smoking, alcohol intake, illicit drugs, physical activity), and concomitant medications were recorded.

In addition, specific aspects related to medical school, such as public or private, costs, teaching activities, and feelings about medical training during the pandemic were addressed. For individuals in the volunteer group, their impressions about the procedures in the MPII Study and their impact on the participant's daily routine were also evaluated.

The Brazilian version of the DASS-21, was used to evaluate mental health [19,20]. The DASS-21 is a set of three self-report scales with seven items each, designed to measure emotional status. The depression domain assesses dysphoria, hopelessness, devaluation of life, self-deprecation, lack of interest/commitment, anhedonia, and inertia. The anxiety domain evaluates autonomic symptoms, skeletal muscle effects, coping, and experiences. The stress domain is sensitive to levels of chronic nonspecific arousal, assessing difficulty in relaxing, nervous arousal, and being easily upset/ agitated, irritable/ over-reactive, and impatient. Scores for depression, anxiety, and stress are calculated by summing the scores for the relevant items. The DASS-21 is based on a dimensional rather than a categorical conception of psychological disorders, and it was developed regarding the differences between the depression, anxiety, and stress experienced by subjects. Therefore, the scale does not have any direct implications for diagnosis.

DASS-21 scores were set as low, moderate and high risk for mental distress, according to gender and standard deviation from this population mean (low: lower than Mean + 1 SD; moderate: from Mean + 1 to Mean + 2 SD; high: greater than Mean+2SD).

Recommended cut-off scores for conventional severity labels of depression, anxiety

and stress (normal, mild moderate, severe and extremely severe) were multiplied by 2 and used as shown in the table [20]:

Table 1: Cut-off scores for depression, anxiety and stress according to DASS21

Severity Label	Doubled DASS21 domain score [20]		
	Depression	Anxiety	Stress
Normal	0-9	0-7	0-14
Mild	10-13	8-9	15-18
Moderate	14-20	10-14	19-25
Severe	21-27	15-19	26-33
Extremely severe	28+	20+	34+

7. DATA COLLECTION

Data collection was performed through a web questionnaire generated on the Google Forms platform, disclosed to the research subjects by email and/ or WhatsApp message. The data collection period was from July 20th to August 31st, 2020.

8. STATISTICAL ANALYSIS

Descriptive analysis will be performed using absolute and relative frequencies for categorical variables and quantitative measures (mean, quartiles, minimum, maximum, and standard deviation) for numerical variables. Normality of numerical variables will be evaluated using the Kolmogorov-Smirnov test. Numerical variables with normal distribution will be described as Mean ± Standard deviation (SD) and non-normal numerical variables, as Median (Interquartile range) (IQR) or (Minimum-Maximum) (Min-Max).

The Chi-square association test will be used to assess the association between categorical variables with adjusted standardized residual calculation, or Fischer's exact test for small samples. The linear associations between two numerical variables will be evaluated using Pearson's or Spearman’s correlations.

The comparison between the means of numerical variables with normal distribution in the volunteer *versus* control groups will be verified through the Student's t test. In case of violation of the assumption of normality, the Mann-Whitney non-parametric test will be used.

Adjusted multiple linear regression models will be used to assess the simultaneous effects of sex, age, comorbidities, concomitant medications, and other confounding variables, according to the group and predefined outcomes (anxiety, depression, and stress scores evaluated on the DASS21 scale). For dichotomous dependent variables, a logistic

regression model will be used.

SPSS Version 20 will be used in all analyses. A p value below 0.05 will be considered significant.

RESULTS

Data collection was applied for both medical student groups from July 20th to August 31st, 2020. Data extraction was completed on September, 2020. Data analysis is ongoing. The authors expect the results to be published in the first semester of 2021.

FINAL CONSIDERATIONS

This study has an unprecedented design worldwide, including a huge sample of volunteer medical students from 14 Brazilian tertiary rheumatology centers who are monitoring the outcomes of 9,589 patients with rheumatic diseases on hydroxychloroquine regarding its vulnerability to SARS-CoV-2 infection.

The main implications of this study are to evaluate the impact of participating in a research project during the COVID-19 outbreak on mental distress and learning behavior in medical students. Besides, these variables are being measured by using a structured web-questionnaire regarding the volunteer participation in this task-force and other abilities to deal with patients and professors in a real-life scenario.

In addition, this manuscript has several innovative aspects, such as:

1. The evaluation of depressive, anxiety, and stress domains by using the DASS-21 (Depression, Anxiety and Stress Scale) in large sampling of medical students and a control group;
2. The medical students' impressions on handling with uncertainty and doubts of rheumatic diseases patients, including afraid of illness, fear of dying and shortage of medication during the outbreak;
3. To measure the impact of the COVID-19 pandemic on their educational routine and medical training;
4. The web questionnaire

was developed by a panel composed of graduate medical students, rheumatologists, medical school professors, and a psychology professor.

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"The survey instrument can be found in Multimedia Appendix [PDF file (Adobe Acrobat), 68 kB]"

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Supplementary Files

Multimedia Appendixes

Survey instrument.
URL: http://asset.jmir.pub/assets/c076fc97d41362efb074003224796dfe.pdf