BMJ Open Impact of the COVID-19 pandemic on mental health of nursing students in Japan: protocol for a crosssectional study

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ABSTRACT

Introduction The COVID-19 pandemic is spreading globally with a high risk of mortality. It is also significantly affecting mental health. For nursing students, the impact of COVID-19 on mental health is predicted to be significant; however, sufficient data have not been obtained. Therefore, this study will aim to assess the mental health of nursing students and evaluate the related factors.

Methods and analysis This proposed study is a crosssectional survey using a self-report questionnaire. An online questionnaire will be distributed among all nursing students of eight universities in Japan. The survey questionnaire will consist of questions related to demography, life satisfaction, fear of COVID-19, mental health and physical activities. The target sample size is 1300 nursing students. We will calculate descriptive statistics for each measurement item and perform univariate and logistic regression analyses to evaluate the potential risk factors for anxiety, depression and insomnia symptoms in nursing students. The strength of association will be assessed using the OR and its 95% Cls. Statistical significance will be set at a p<0.05.

Ethics and dissemination The protocol was approved by the Institutional Review Board (IRB) of the University of Hyogo on 22 March 2021 (ID: 2020F29). In addition, all of the participating facilities required ethical approval from their local IRBs. The findings will be disseminated through peer-reviewed publications and conference presentations. We believe that the proposed large-scale investigation of the mental health of nursing students during the COVID-19 pandemic and the relationship between mental health and fear of COVID-19 are novel and will be a strength of this study.

INTRODUCTION

An outbreak of COVID-19 began in Wuhan (Hubei Province, China) in December 2019 and has spread worldwide. As of 26 July 2021, 194 080 019 cases and 4 162 304 deaths have been reported worldwide as stated by WHO.¹ In Japan, as of 27 July 2021, 875 506 people have been infected and 15 137 people have

Strengths and limitations of this study

- With the COVID-19 pandemic, evaluation of the mental health of nursing students, who are the future leaders of healthcare, is urgently warranted.
- A multi-institutional collaborative study is planned to obtain representative data from Japan, which is likely to be sufficient for international comparisons.
- Binary logistic regression analysis will be performed to identify factors associated with depression, anxiety and insomnia in nursing students.
- A limitation of this study is the expected low participation and response rates, which are inherent limitations of online surveys.

died.² The massive outbreak of COVID-19 has increased the risk of death and has had a significant impact on the mental health.^{3–6}

Mental health is a concept that includes emotional, psychological, and social wellbeing, and is considered to affect how we think, feel and act.⁷ A systematic review of the prevalence of anxiety in the general population during the COVID-19 epidemic reported that 27% of the people had anxiety symptoms, with a particularly high prevalence in women and the elderly.⁸ Among healthcare workers with a reported prevalence of anxiety, depression, insomnia and stress in 30%-40% of the population,⁹⁻¹¹ which is considered a public health problem. For nursing students who desire to become healthcare professionals in the future, mental health-related issues are even more complicated because such issues also directly affect their studies.

To prevent the spread of COVID-19, many countries have introduced social distancing and quarantine measures; as a result, globally, 31 453 440 students have been affected in some way in the context of their education as of 27 July 2021, as reported by the UNESCO.¹² Social distancing and quarantine measures have affected students' participation in face-to-face lectures and other learning-related activities for students. For students, participation in activities related to university is an important opportunity to maintain connections with classmates and faculty. Nursing students are missing out on hands-on training at hospitals and participation in hospital-sponsored internships due to COVID-19. The loss of such opportunities is a major obstacle for students¹³ and is predicted to affect the students' mental health. For example, in a recent study that was conducted among nursing students, investigating the impact of the COVID-19 pandemic, a low social presence and low satisfaction with remote education was reported.¹⁴ Another study conducted on nursing students reported on the development of an online environment and its impact on student satisfaction.¹⁵ Nursing students' satisfaction with their education and low social presence may have had an impact on their mental health.

During past epidemics such as SARS, it was reported that healthcare workers were at increased risk of burnout, secondary injuries, decreased job satisfaction, low morale and severe stress.¹⁶ Owing to COVID-19, nursing students are anxious about becoming a healthcare worker in the future.¹⁷ Anxiety is reported to be associated with the feelings of hopelessness,¹⁸ fear of COVID-19¹⁹ and poor sleep quality.²⁰ However, the scale of the COVID-19 pandemic is much larger than that of previous epidemics, and the demand for healthcare workers is expected to increase in the future.^{21–23} With this background, the mental health of nursing students who will become future healthcare workers can be an urgent public health concern.^{17 24} Although some universities have established health centres and have university staff with medical qualifications, to date, the impact of COVID-19 on the mental health of nursing students and evidence-based support have not been reported in a large scale, multiuniversity setting, indicating the need for further research and urgent solutions.²

In a previous study on nursing students during the COVID-19 pandemic, mental health-related symptoms, such as anxiety, depression, and stress, were investigated, and the prevalence of these symptoms was reported to be 30%-50%.²⁶⁻²⁹ Although this prevalence is higher than that in the general population³⁰ and healthcare workers,⁹⁻¹¹ studies on this subject are scarce and data are insufficient. Furthermore, these previous studies were relatively medium-sized, involving 300-1000 nursing students. Therefore, it would be desirable to conduct a study on a larger population to obtain more generalisable results. In addition, a previous study investigated the relationship between life satisfaction and anxiety, depression and stress symptoms among college students during the COVID-19 pandemic, and found that lower life satisfaction was associated with a lower behavioural ability to cope with mental health-related symptoms during the pandemic.³¹ Another study pointed out that high levels of physical activity among college students during

the COVID-19 pandemic were associated with reduced anxiety and depression.³² However, the multifactorial assessment of mental health aspects, including the fear of COVID-19, has not been well investigated.

It is necessary to assess the level of mental health-related symptoms in nursing students and to analyse the potential risk factors associated with these symptoms to provide appropriate support. The understanding of the mental health of nursing students from the findings of this study may help educators create policies that will address the students' needs quickly and may also help improve the academic performance of nursing students.

Aims

The aim of this study is to evaluate the mental health of nursing students during COVID-19 outbreak. This study will describe the protocol developed to undertake this research.

The key research questions are:

- 1. What proportion of nursing students are screened as having moderate or higher anxiety, depression or insomnia when evaluated with the Generalised Anxiety Disorder-7 (GAD-7),³³ Patient Health Questionnaire-9 (PHQ-9)³⁴ and Insomnia Severity Index-7 (ISI-7)³⁵ scales, respectively?
- 2. What is the level of fear of COVID-19 among nursing students when evaluated quantitatively using the Fear of COVID-19 scale (FCV-19S)?³⁶
- 3. What are the potential risk factors for anxiety, depression, and insomnia symptoms in nursing students?
- 4. Are there any correlations between anxiety, depression and insomnia symptoms in nursing students?

METHODS AND ANALYSIS Study design

This is a cross-sectional survey targeting all nursing students in the selected institutions. The planned dates for data collection were between 16 August 2021 and 15 October 2021. In Japanese universities, late July to early August is often the period when grades for lecture courses are finalised, and unintended coercion may possibly be applied to gain cooperation during this period. Therefore, we will avoid this period when conducting the survey. For the selected institutions, we included both regions in Japan where COVID-19 is prevalent and regions where it is not (ie, is it an area where the Japanese government has declared a state of emergency or not?). The following eight universities in Japan were selected as the target institutions: University of Hyogo, Kansai University of School Welfare, Japanese Red Cross Kyushu International College of Nursing, Kawasaki University of Medical Welfare, Okayama Prefecture University, Meio University, Kitasato University Hospital and Aichi Medical University.

Study procedure

The survey will be a web-based questionnaire conducted using Microsoft Forms (Microsoft Office 365, USA). The explanatory document will be posted on the web page 6

using the university web system or portal site system of the participating institution, or printed materials will be used to disclose information about this research. Reading the explanatory document, participants will be asked to click on the URL of the survey site, if they are interested to participate in the study. After checking the agreement column, the questionnaire will open. By checking the agreement column, the consent to participate in the study is deemed to have been obtained. In addition, it will be mentioned that the identity of participants cannot be revealed because this will be an anonymous questionnaire survey and that the answers cannot be withdrawn.

Survey items

In the questionnaire survey, we plan to inquire about background information (grade in school, age, sex and body mass index); changes in smoking, alcohol consumption and economic deprivation after the COVID-19 pandemic; living with family members; SARS-CoV-2 infection status of relatives and acquaintances; life satisfaction; mental health-related items and physical activities. Economic deprivation is asked in the following five cases: 'I became difficult,' 'I became a little difficult,' 'I remained the same,' 'I became a bit comfortable,' and 'I became comfortable'. Physical activities will be evaluated using the International Physical Activity Questionnaire-Short Form (IPAQ-SF).³⁷ The Japanese version of the IPAQ-SF has been reported to have high reliability and validity,³⁸ with an intraclass correlation coefficient that ranges from 0.87 to 0.93.

Mental health-related items Life satisfaction

Life satisfaction will be evaluated using two parameters, 'current life satisfaction' and 'change in life satisfaction since the pandemic', with reference to the previous study by Tang *et al.*³⁹ Current life satisfaction will be assessed using an 11-point Likert scale, ranging from '0: extremely dissatisfied' to '10: extremely satisfied'. The change in life satisfaction after the pandemic will be asked to rate on a 5-point Likert scale of '-2: a lot worse', '-1: worse', '0: pretty much the same', '1: better', and '2: a lot better'.

Anxiety

Anxiety will be evaluated using the GAD-7 scale.³³ GAD-7 has been shown to have high sensitivity and specificity as a screening tool for GAD-7, with seven items on a 4-point scale, with a total score of 0–21. In this, 5–9, 10–14 and 15–21 points indicate mild, moderate, and severe level of symptoms, respectively. This scale had a good factorial validity and reliability. Several studies on mental health during the COVID-19 pandemic have used GAD-7.^{10 30} The validity and utility of the Japanese version of GAD-7 have been confirmed.^{40 41}

Depression

Depression will be evaluated using the PHQ-9.³⁴ PHQ-9 is based on the diagnostic criteria for major depressive disorder. This scale is widely used as a brief diagnostic

tool and measures the severity of depression in both clinical practice and research. The reliability and validity of the scale have been confirmed.⁴²⁻⁴⁴ This includes nine items on a 4-point scale, with a total score of 0–27. In this, 0–4, 5–9, 10–14 and 15–27 points indicate a normal, mild, moderate and severe level, respectively. Several studies on mental health during the COVID-19 pandemic have used PHQ-9.^{10 30} The Japanese version of PHQ-9 has been reported for its validity and high suitability as a clinical tool for screening and monitoring depression.^{45 46}

Insomnia

Insomnia will be evaluated using the ISI-7,³⁵ which consists of seven questions regarding insomnia symptoms in the past 2 weeks: difficulty related to falling asleep, staving asleep and early waking up; satisfaction with sleep pattern; interference in daily work because of sleep problems; noticeability of sleep problems by others and worries regarding sleep problems. Responses are recorded on a 5-point Likert scale ranging from 0 to 4. The total score ranges from 0 to 28 points, with higher scores indicating higher subjective severity. According to the total score, the patients are classified as 'normal (0-7 points)', 'subthreshold level (8-14 points)', 'moderate insomnia (15-21 points)' and 'severe insomnia (22-28 points)'. The Japanese version of the ISI-7 has been reported to have high reliability and validity.⁴⁷ The Cronbach's α for the ISI-7 Japanese version was 0.84.

Sense of fear

Sense of fear will be evaluated using the FCV-19S.³⁶ Fear of COVID-19 will be evaluated using 7-items on a 5-point scale: '1: strongly disagree', '2: disagree', '3: neither agree nor disagree', '4: agree', and '5: strongly agree'. The total score is calculated by adding up each item score (ranging from 7 to 35). The higher the score, the greater the fear of COVID-19. FCV-19S has been verified for reliability and validity in many countries^{48–52} since its development, and the Japanese version has been reported to have high reliability and validity.⁵³ The Cronbach's α for the FCV-19S Japanese version was 0.87.

Statistical analysis

Descriptive statistics will be calculated for mental healthrelated items and each measurement item for nursing students. Categorical variables will be summarised using frequencies and proportions. Continuous variables will be presented using means and SD, if normally distributed or medians and IQR, if not normally distributed.

To evaluate the potential risk factors for anxiety, depression, and insomnia symptoms in nursing students, binary logistic regression analysis will be performed; the associations with risk factors will be displayed as ORs and 95% CI. The binary variables for the binary logistic regression analysis will be developed with the cut-off points being moderate or higher for each scale. A univariate analysis will be performed for the two groups developed at the cut-off points, and a multivariate analysis will be performed using the explanatory variables with p<0.2. The explanatory variables for the multivariate analysis will be the background information, life satisfaction, fear of COVID-19, and physical activity. p<0.05 will be considered significant. In addition, the correlation between anxiety, depression and insomnia will be investigated. These variables will be compared using the Pearson correlation coefficient.

Sample size

The prevalence of mental health problems among healthcare workers during the COVID-19 pandemic has been reported to be approximately 30%-40%.^{9 10} In nursing students, the prevalence of mental health-related problems is reported to be 30%-50%.^{26 27} Therefore, considering the prevalence of mental health problems in nursing students to be approximately 30%, 1300 cases would be needed to calculate a 30% frequency item with a 95% CI of 5%.

We will perform a logistic regression analysis as a secondary analysis. In logistic regression analysis, the number of samples required is at least 10 times the number of explanatory variables to be included in the prediction model.⁵⁴ We will perform logistic regression analysis with approximately 15 explanatory variables. We calculated the required sample size as $10 \times 15 = 150$. Thus, the target sample size (1300 nursing students) is estimated to be sufficient for logistic analysis. The total number of students in the eight universities is about 3000, and we estimate that about 40% of the students will cooperate, so we expect to receive 1300 responses.

Statistical software

Statistical analyses will be performed using the EZR statistical software (Saitama Medical Centre, Jichi Medical University, Saitama, Japan) and R (The R Foundation for Statistical Computing, Vienna, Austria).⁵⁵

Patient and public involvement statement

Patients and the public are not involved in the design, execution, and analysis of the study.

Strengths

First, this proposed study is the first nationwide crosssectional survey on the assessment of mental health of nursing students in Japan during the COVID-19 pandemic. In addition, the participants of the survey are nursing students studying at universities in the Kanto, Kansai, Chugoku and Kyushu/Okinawa regions, and we believe that the data will be relatively representative of Japan. Furthermore, another strength is the multidimensional assessment of psychological aspects, such as fear of COVID-19. Moreover, out intent to use life satisfaction as well as the GAD-7, PHQ-9, ISI-7, FCV-19S and IPAQ-SF scales to comprehensively assess the mental health of nursing students in Japan, will be an added strength of this study.

Limitation

A limitation of this study is the expected low participation and response rates, which are inherent in online surveys. To avoid this limitation, the following efforts will be made: First, the announcement with the survey link will be posted on the university web system or portal site system for 2 months, and reminder notices will be sent at least three times starting 2 weeks after the initial announcement to students. Assuming that the participation rate would still be low, we have planned to recruit a total of 3000 nursing students from eight universities to co-operate in the survey for this study. Second, students are most likely to respond to surveys from their smartphones; therefore, to make it as easy as possible for them to answer, we have created a drop-down option to ensure complete and correct responses.

Another possible limitation is that as a self-selection bias, nursing students who do not co-operate with the survey may have more mental health problems than those who do. To avoid this bias, the confidentiality and anonymity of the responses will be guaranteed to the participants at the time of invitation to participate in the survey, and it will be informed that they will not be at a disadvantage regardless of their participation in the survey.

Moreover, because of the cross-sectional nature of the study, misclassification bias and time-related bias may occur. In this study, we intend to investigate anxiety, depression and insomnia using the GAD-7, PHQ-9 and ISI-7 scales, respectively; therefore, the participants will be asked to recall and rate their past 2 weeks. This may lead to underestimation or overestimation of screening due to misclassification. In addition, causality may be reversed if anxiety, depression, or insomnia existed before the COVID-19 pandemic.

ETHICS AND DISSEMINATION

This study was approved by the Institutional Review Board of Research Ethics committee, College of Nursing Art & Science and Research Institute of Nursing Care for People and Community, University of Hyogo, Japan (approval no.: 2020F29, approval date: 3 March 2021). If necessary, we plan to obtain ethical approval from the following institutions: Kansai University of Social Welfare, Japanese Red Cross Kyushu International College of Nursing, Okayama Prefectural University, Meio University, Kitasato University and Aichi Medical University. This study was registered before the first participant was enrolled (University Hospital Medical Information Network, Japan (UMIN000044355)). This study will be web based, and all the participants will be instructed to respond after agreeing to the aims of the research.

In order to disseminate the results of the study, we plan to submit the results to a peer-reviewed journal and to present them at local and international conferences to share the results with a wide range of population. Furthermore, the results of this study will be disseminated widely at academic conferences in Japan through exchange meetings.

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