REC-MURA.07

Non-experimental Study Protocol Template for Ramathibodi EC submission

(All information can be written in **Thai** or **English**. <u>Descriptions in red</u> must be deleted before submission) <u>หมายเหตุ</u>: ห้ามตัดหัวข้อออก คงไว้ตามแบบฟอร์ม หากไม่มีข้อมูลที่เกี่ยวข้อง ให้ระบุว่า" ไม่มี" (<u>ตัดเฉพาะคำอธิบายสีแดงออก</u>) และสามารถระบุรายละเอียดเป็นภาษาไทยได้

Study Title (English): A Cross-sectional Study of the Prevalence of Depression and Suicidal Thoughts and Associated Factors Among Thai Seniors During the COVID-19 Pandemic.

Study Title (Thai): การศึกษาแบบภาคตัดขวางความชุกอาการซึมเศร้าและความคิดฆ่าตัวตายและปัจจัยเกี่ยวข้องใน ผู้สูงอายุในยุคสมัยโควิด 19

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โทรศัพท์ 0-2201-2588 มือถือ 087-982-0202

Sponsor or planned sponsor, grant, scholarship <if applicable>:

- None

Conflict of Interest:

- None

Study sites:

- Faculty of Medicine Ramathibodi Hospital, Mahidol University , 270 Rama VI Road, Rajataewe,
Bangkok 10400, Thailand

Background and Significance:

Depression is a significant mental health condition affecting the elderly population, with varying prevalence rates reported in Thailand ranging from 17.5% to 82.3% in different elderly groups and contexts (1-4). The prevalence of depression in this population is influenced by a variety of factors, including temporal variations, differences among elderly groups, discrepancies in measurement tools, and social structures. Notably, suicidal ideation is closely associated with depression, particularly in the elderly. A review of the literature confirms that depression is a significant predictor of suicide among older adults, demonstrating a direct correlation between depression and death by suicide(5).

In December 2019, the emergence of a novel virus causing a range of symptoms from mild respiratory infection to severe acute respiratory distress in Wuhan, China sparked global concern(6). This virus, known as coronavirus disease 2019 (COVID-19) or SARS-CoV-2, rapidly spread worldwide, leading to its

declaration as a pandemic on March 11, 2020. In response, governments implemented a range of isolation and protective measures, including physical distancing, face mask usage, hand hygiene practices, stay-at-home policies, and restrictions on social gatherings, to mitigate the spread of the virus(7-8).

The elderly population is recognized as the most vulnerable group to develop SARS-CoV-2 infection, with their decreased immune function increasing the severity of illness(9). The severity of illness is further increased in older adults as they have decreased immune function. Although the risk of death in the general population infected with the virus is relatively low, it increases exponentially with age, with a mortality rate as low as 0.1% in children and as high as 14.8% in older adults, representing a more than 100-fold increase across the lifespan (9).

Furthermore, the COVID-19 pandemic has been associated with decreased social life and fewer inperson social interactions, which have been linked to reduced quality of life and increased depression. Other
reported consequences of the pandemic include difficulties in accessing services, sleep disturbances, and
reduced physical activity(10). Research from the United Kingdom has highlighted the impact of COVID-19 on
the mental wellbeing of elderly individuals, with levels of depression among older adults in the UK
significantly worsening following the pandemic (11). A study conducted in Thailand revealed that the older
adult population residing in long-term care facilities has experienced considerable impact from the COVID19 pandemic, particularly in terms of financial well-being. The study found that a notable percentage of

participants, specifically 5.5%, reported symptoms of post-traumatic stress, 7.0% reported depression, and 12.0% reported anxiety. Furthermore, the research indicated that heightened psychological stress resulting from COVID-19 and the manifestation of respiratory tract infection symptoms were significantly and independently linked to the development of post-traumatic stress, depression, and anxiety among the elderly(12). According to a previous study conducted in an urban area of Thailand, the prevalence of depression was reported to be 20.5%. Furthermore, individuals classified as "non-workers" were found to be 3.54 times more likely to exhibit symptoms of depression (13). Interestingly, a study conducted in Greece reported that during the COVID-19 pandemic, older adults and those in middle age exhibited lower rates of depression—11% and 12%, respectively—compared to the 28% observed in young adults. Despite these lower depression rates, the same older and middle-aged groups demonstrated higher suicide risks, recorded at 15% and 12% respectively, when compared to young adults (14). However, during the COVID-19 pandemic, the investigation into suicidal thoughts among the elderly population, particularly in Thailand, has been notably limited.

To date, there is a notable scarcity of data on the prevalence of depression and suicidal thoughts, as well as their associated factors, among Thai seniors during the COVID-19 pandemic. Therefore, this study aims to investigate these aspects to better understand the mental health challenges faced by this demographic during such a critical period.

Objectives:

Primary Objective:

1. To determine the prevalence of depression and suicidal thoughts among Thai seniors during the COVID-19 pandemic.

Secondary Objectives (if any):

1. To identify the associated factors of depression and suicidal thoughts among Thai seniors during the COVID-19 pandemic.

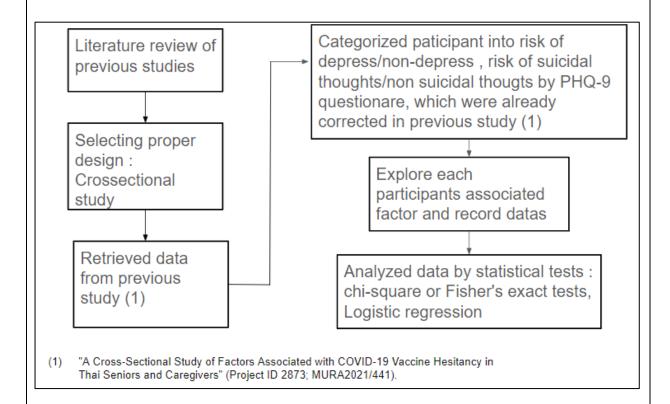
Study design/methodology:

This research will utilize a quantitative cross-sectional design, specifically employing telephone surveys to collect data. The methodology is modeled after the approach used in the project titled "A Cross-Sectional Study of Factors Associated with COVID-19 Vaccine Hesitancy in Thai Seniors and Caregivers" (Project ID 2873; MURA2021/441). The design chosen is highly suitable for addressing the primary objectives, which are to investigate the prevalence of depression and suicidal thoughts and the factors associated with these outcomes among Thai seniors during the COVID-19 pandemic.

Study Procedures and Methods: The study will begin with a literature review to understand the context and background of mental health challenges among the elderly, particularly in relation to the pandemic. Following the literature review, a cross-sectional study design will be implemented, which allows for the

analysis of data at a single point in time, providing a snapshot of the prevalence and associated factors of depression and suicidal ideation among the elderly.

Data for this study will be retrieved from a previous project, ensuring that no new data collection is necessary, which streamlines the research process and utilizes existing resources efficiently. The previously collected data includes important variables such as sociodemographic characteristics, medical history, and COVID-19 pandemic-related information, which were gathered using the PHQ-9 questionnaire to categorize participants into depress/non-depress and risk of suicidal thoughts/non-suicidal thoughts groups.



Study Population, Type and Source of Biospecimens/Data Inclusion Criteria:

- Individuals aged 60 years and older.
- Patients who have visited the geriatric clinic at Ramathibodi Hospital within the past two years.

Exclusion Criteria:

- Individuals not willing to participate in the study.

Source of Data:

- The data for this study will be sourced from a pre-existing dataset collected under the project titled "A Cross-Sectional Study of Factors Associated with COVID-19 Vaccine Hesitancy in Thai Seniors and Caregivers" (Project ID 2873; MURA2021/441), which conducted digital telephone surveys between June 20 and July 25, 2021. This dataset includes sociodemographic characteristics, medical history, and COVID-19 pandemic-related information of the participants.

Access to Materials:

- The research team has access to these materials as investigators on the previous protocol. The data were initially collected for research purposes, and necessary permissions for their secondary use in this study have been secured in accordance with ethical guidelines.

Type and Format of Data:

The data is stored digitally and includes:

- Sociodemographic and medical history: age, gender, ethnicity, marital status, education, employment status, residence, monthly income, income loss due to COVID-19, BMI, ambulation status, sensory impairments, smoking and alcohol use, underlying diseases, subjective cognitive complaints, past hospitalizations, and health perception.
- COVID-19 related information: knowledge, confidence in information sources, healthcare system confidence, government measures, perceived risk, vulnerability, and attitudes towards social distancing.
- Mental health assessments using the Thai version Patient Health Questionnaire-9 (PHQ-9) (15), which measures levels of depression and assesses suicidal risk through specific questionnaire items.

Prospective Collection:

- There is no prospective collection of biospecimens or data for this study; all data are existing and were collected for the previously mentioned project within the specified dates.

Relevance and Minimization of Data:

- The data collected is directly relevant to the aims and objectives of this research, which is to investigate the prevalence and associated factors of depression and suicidal thoughts among Thai seniors during the COVID-19 pandemic. The data collected are the minimum necessary to

accomplish the research objectives, ensuring efficient use of information while respecting participant privacy. Identifiers will be removed from the dataset before analysis to maintain confidentiality.

Appendix:

Include a copy of the data abstraction sheet or case record form used in the initial study to reflect all data elements abstracted from the dataset as an appendix to this protocol.

Study Schedule (for prospective cohort or registry study):

- None

Data Analysis Plan / Statistical Analysis Plan:

Descriptive Statistics:

- Nominal data will be summarized descriptively using numerical counts and percentages.

Continuous data will be presented as means with standard deviations (SD) if the data are normally distributed or medians with interquartile ranges (IQR) if the data are not normally distributed.

Inferential Statistics:

- Categorical variables will be compared using chi-square tests or Fisher's exact tests, as appropriate.
- Continuous variables will be assessed using independent t-tests or Mann-Whitney U-tests, based on the distribution of the data.
- For testing hypotheses regarding factors influencing depression and suicidal risks, binary logistic regression will be utilized. Variables showing statistical significance in univariate analyses will be included in a multivariate logistic regression model to control for potential confounders.
- All tests will be two-tailed, with a p-value of less than 0.05 considered statistically significant. Confidence intervals (95% CI) will be reported for all relevant estimates.

Assumption Checks:

- Prior to performing the analyses, checks for normality of data distributions will be conducted using Shapiro-Wilk tests.
- If assumptions of normality are violated, appropriate corrective measures such as data transformation or the use of nonparametric tests will be applied.

Handling of Missing Data:

- Missing data will be handled using multiple imputation techniques if the amount of missingness is substantial and deemed to be missing at random (MAR). Otherwise, a complete case analysis will be conducted.
- Sensitivity analyses will be performed to assess the impact of missing data on the study findings.

Software:

- All statistical analyses will be performed using SPSS version 26.0 for Windows (IBM Corp., Armonk, NY, USA).

Sample Size Calculation:

The sample size of 238 was determined using the formula for a Chi-squared test, which assesses whether observed categorical data fit an expected distribution:

$$n = \left(\frac{\mathbf{Z}_{1-\frac{\alpha}{2}} + \mathbf{Z}_{\beta}}{w}\right)^{2}$$

Where:

 $\mathbf{Z}_{1-\frac{\alpha}{2}}$ is the critical value from the standard normal distribution corresponding to the significance level α . For $\alpha = 0.05$, $\mathbf{Z}_{1-\frac{\alpha}{2}} \approx 1.96$.

 \mathbf{Z}_{β} is the critical value from the standard normal distribution corresponding to the desired power β . For = \mathbf{Z}_{β} \approx 0.84.

 \boldsymbol{w} is the effect size, which in this case is set to 0.3 (indicating a medium effect size).

df represents the degrees of freedom, which is k – 1 for a goodness-of-fit Chi-squared test, where k is the number of categories.

Parameters Explained:

Test Type: Goodness of fit test.

Explanation: This test determines if our observed data aligns with a hypothesized model, crucial for understanding how well a theoretical distribution fits real-world observations in medical contexts. Digits: 6.

Explanation: Refers to the precision of our calculations, ensuring results are detailed to six decimal places, which is standard for statistical accuracy in medical research.

Significance Level (α): 0.05.

Explanation: Represents the threshold for accepting or rejecting the null hypothesis. In medical research, a significance level of 0.05 is widely accepted, ensuring robustness in our conclusions.

Power: 0.8.

Explanation: Power reflects the likelihood of detecting a true effect when it exists. A power of 0.8 (or 80%) is considered adequate in medical research, minimizing the risk of false negatives and ensuring the reliability of our findings.

Effect: Medium.

Explanation: The effect size in our study is categorized as medium, with a value of 0.3. Effect size measures the magnitude of the difference or relationship being studied, indicating how substantial and meaningful the observed effect is. In the context of our research focusing on depression and suicidal thoughts among Thai seniors during the COVID-19 pandemic, a medium effect size of 0.3 signifies a moderate but significant impact.

Studies on depression among elderly populations in Thailand have shown varied prevalence rates, ranging from 17.5% to 82.3%, underscoring the complex nature of mental health issues in this demographic (1-4). The emergence of the COVID-19 pandemic exacerbated these challenges, leading to increased symptoms of depression, anxiety, and post-traumatic stress among older adults, particularly those in long-term care facilities (7-12). Despite these findings, there remains a significant gap in specific data regarding the prevalence of suicidal thoughts among Thai seniors during the pandemic. Our study aims to address this gap by investigating the prevalence and associated factors of depression and suicidal thoughts, thereby elucidating the medium-sized effect of these mental health challenges during this critical period."

Categories: 22.

Explanation: Represents the number of distinct groups or outcomes being analyzed. Understanding how different factors affect various categories is crucial for drawing accurate conclusions in medical studies.

Clinical Relevance: The decision to use a sample size of 238 is rooted in ensuring sufficient statistical power (0.801571) to detect the hypothesized effects within our study population. This sample size allows us to confidently assess the distribution of a key characteristic across 22 categories, aligning with best practices in medical research for robust and reliable data analysis.

Informed Consent Process (for interview, group discussion, observe, survey, prospective cohort, or registry study):

Description of Procedures:

The data utilized in this study were collected from a prior cross-sectional telephone survey titled "A Cross-Sectional Study of Factors Associated with COVID-19 Vaccine Hesitancy in Thai Seniors and Caregivers". During the original study, the recruitment process involved accessing patient contact information from the hospital database. Potential participants were then contacted by phone and invited to take part in the survey.

Informed Consent Process:

Due to the challenges posed by the COVID-19 pandemic, including restrictions on face-to-face interactions and handling of physical documents, verbal informed consent was obtained from all participants. This method was approved by the Human Research Ethics Committee of the Faculty of Medicine, Ramathibodi Hospital, Mahidol University. The consent process was conducted over the telephone, where trained interviewers provided a thorough explanation of the study's purpose, procedures, potential risks, and benefits. Participants were given sufficient time to ask questions and consider their involvement before giving their consent, which was recorded for documentation purposes.

Documentation and Ethical Compliance:

The verbal informed consent procedure was specifically designed to respect participant autonomy while adapting to the logistical constraints of the pandemic. This approach was deemed appropriate and ethical by the overseeing ethics committee, and all participant consents were audibly recorded to ensure compliance and accountability.

Attachments:

As this study is a review and analysis of previously collected data, the original patient advertisement document and informed consent form used during the initial data collection will be attached as separate documents. These documents provide additional transparency about the recruitment and consent processes employed.

Privacy and confidentiality:

Responsibility for Data Management:

The principal investigator will be primarily responsible for the overall data management. This includes overseeing data collection, storage, access, and disposal. The principal investigator will ensure that all data management practices comply with the Thai Personal Data Protection Act.

Data Collection and Generation:

As this study involves analyzing previously collected data, no new data will be collected. The existing digital data were obtained from a prior study titled "A Cross-Sectional Study of Factors Associated with COVID-19 Vaccine Hesitancy in Thai Seniors and Caregivers."

Types, Formats, and Volumes of Data:

The data include sociodemographic characteristics, medical history, and COVID-19 pandemic-related information. These data are stored digitally in formats such as spreadsheets and text files, which are suitable for analysis in statistical software.

Organization, Documentation, and Description of Data:

Data will be organized and documented meticulously. Metadata describing each dataset, including the scope, structure, and specifics of data collection, will be maintained to ensure quality control and reproducibility. Standard operating procedures (SOPs) will be followed to document all data handling processes.

Data Storage and Backup:

Data will be stored on encrypted digital media such as secure USB flash drives. These drives will be kept in a locked security box within the division of geriatric department of medicine, accessible only to the research team.

Regular backups will be made to an encrypted external hard drive, which will also be stored in a secure location to prevent data loss.

Data Security and Protection:

All digital data will be encrypted using state-of-the-art encryption software to ensure data security and protection of sensitive information.

Access to sensitive data will be restricted through the use of strong passwords and physical security measures.

Compliance with Personal Data Legislation:

Compliance with the Thai Personal Data Protection Act will be ensured by adhering to legal standards for data protection, implementing regular audits, and conducting training sessions for all team members on data security and privacy protection.

Access Control:

Access to the data will be restricted to the research team members only. A log will be maintained to track access to the data.

The principal investigator will control access to the data, and keys to the security box will be distributed only to authorized personnel.

Data Sharing and Access:

Plans for data sharing will be evaluated based on the outcomes of the study and in accordance with ethical guidelines and legal requirements. Any sharing of data will be done under strict controls and with appropriate data use agreements.

Data Preservation and Retention:

Data will be preserved for a period of 10 years after the completion of the study to allow for analysis and to fulfill any regulatory requirements.

After this period, data will be securely destroyed in compliance with institutional guidelines and legal requirements.

Ethical Considerations:

Risks to Participants and How to Minimize the Risks:

- Since this study involves retrieving data from existing records, there is no direct risk of emotional distress arising from discussions on depression and suicidal thoughts for participants. However, to ensure ethical conduct:
- Trained interviewers with experience in handling sensitive topics will oversee the retrieval process.
- Confidentiality of personal information will be strictly maintained through measures such as data encryption, secure storage, and restricted access to authorized personnel only.

Direct Benefits to Participants:

- This study does not offer direct medical benefits to participants, as the data collection does not involve clinical interventions or diagnostics that could influence treatment decisions. However, participants will contribute to important research that seeks to improve the understanding of mental health issues among the elderly during the COVID-19 pandemic, which may indirectly benefit society by informing future interventions and policies.

Scientific or Social Value:

- The study will provide valuable insights into the prevalence and factors associated with depression and suicidal thoughts among Thai seniors during the COVID-19 pandemic. This knowledge can help healthcare providers and policymakers develop targeted strategies to address mental health issues in this vulnerable population, thereby improving public health outcomes.

Justification for Enrolling Potentially Vulnerable Subjects:

- The inclusion of elderly individuals, who are often considered a vulnerable population, is justified by the study's focus on understanding mental health challenges specific to this group during the pandemic. Special measures, such as verbal consent and sensitivity training for interviewers, have been implemented to protect their dignity and wellbeing during the research process.

Travel Compensation and Compensation for Participating in the Study:

- As the study utilizes previously collected data from telephone surveys and does not involve new participant engagement, there is no provision for travel compensation. Similarly, no additional incentives or compensation are provided, as the data use involves retrospective analysis without direct interaction with participants.

Study Timeline:

Data Retrieval and Preparation: First week of the study period. This phase involves accessing and preparing the existing dataset for analysis. Necessary data cleaning and organization will be conducted during this time to ensure the data is ready for detailed analysis.

Data Analysis: From the second week to the end of the sixth week. During this period, the statistical analyses described in the protocol will be performed. This includes descriptive statistics, inferential tests, and any necessary assumption checks and data transformations.

Results Compilation and Report Drafting: Seventh week of the study period. The findings from the data analysis will be compiled into a comprehensive report detailing the outcomes and interpretations.

Review and Revision: Eighth week. The draft report will be reviewed for accuracy, coherence, and completeness. Revisions will be made based on feedback to prepare the final report.

Final Submission: By the end of the second month. The finalized report will be prepared for submission to the relevant stakeholders or publication as per the study's dissemination plan.

Budget (if applicable):

- None

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	Date	
Signature.		Major Advisor (if any)
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	Date	