ORIGINAL RESEARCH Prevalence and Factors Associated with Depression Among Older Adults During the COVID-19 Pandemic: A Cross-Sectional Study in Urban Areas in Thailand

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Purpose: This study examined the prevalence of and factors associated with depression symptoms among Thai older adults during the COVID-19 pandemic.

Patients and Methods: A cross-sectional survey was conducted among older adults in urban areas in Bangkok, Thailand, between July and October 2021. The 15-item Thai Geriatric Depression Scale (TGDS-15) was used to determine the prevalence of depression symptoms, and multiple logistic regression was conducted to identify the associated factors.

Results: A total 156 older adults survey responses were received. The largest group of participants (80.8%) was aged below 70, women (50.6%), married (67.9%), retired (41%), having sufficient income (67.9%), living with their families (89.1%). More than half (71.8%) had an underlying disease, with hypertension being the most common (39.1%). In addition, 17.3% of the participants had received compulsory COVID-19 vaccination. Only 0.6% had a history of COVID-19 infection. The prevalence of depression among Thai older adults was 20.5%. Univariate analysis demonstrated occupation and income sufficiency was associated with depression symptoms. The results of the multivariate analysis found that the "non-worker" group was 3.54 times more likely to experience depression symptoms than the reference group (OR = 3.54, 95% CI = 1.25-10.02, p = 0.018) when controlling for the confounding factors.

Conclusion: This study highlights the importance of addressing depression symptoms among Thai older adults, in which occupation and income sufficiency were the main variable factors for depression. Our study further suggested that the importance of interventions such as increasing job availability and establishing financial aid policies may ameliorate depression symptoms among older adults, especially in high-risk groups during the pandemic situation such as the COVID-19.

Keywords: depression, older adult, COVID-19, urban areas

Introduction

Thailand has been experiencing an ageing society since 2005. In 2019, the older population aged 60 years and above accounted for 18% of the total population and was predicted to reach 20% in 2025.^{1,2} Older adults are more susceptible to infection than their younger counterparts owing to the physiological changes associated with ageing, such as immune system deterioration. Therefore, older adults have been categorised as a high-risk group, more prone than the general population to become infected with the novel and widespread coronavirus disease 2019 (COVID-19).³ In Thailand, the COVID-19 pandemic presented occurred in three waves over a period of 17 months, with the number of cases increasing by over 100,000 as a result of a number of risk factors, including close contact with a confirmed patient, community risk, cluster communities, and active and community surveillance.^{4,5} COVID-19 pandemic not only effect on physical health but also has a negative impact on quality of life and well-being.⁶ COVID-19 patients are likely to be more vulnerable to stressful situation.

COVID-19 has affected a significant portion of the population globally including students, older adults and physically active individuals who have faced increased stress and anxiety during the pandemic.⁷ Moreover, the pandemic has also resulted in increased depression symptoms worldwide.^{8,9} These psychological effects can be detrimental to health, quality of life, and well-being.^{9,10} During the pandemic, psychological effects commonly occur with anxiety, anger, stress, confusion, and social isolation during the pandemic leading to stress and depression.^{11–13} The prevalence of depression symptoms was increase comparing between before and during lockdown was 14.3% to 33.2%, respectively, with the increase of anxiety symptoms, insufficient sleep, unsatisfactory sleep, and unsatisfactory quality of life.¹⁴ The worsen of depressive symptoms, anxiety symptoms, sleep quantity were also reported during lockdowns.¹⁴

Currently, depression has become a disease burden with a prevalence of 4.4% accounting for the sixth-ranked disease causing the most disability in Thailand.¹⁵ Depression in older adults is associated with an increased risk of morbidity, increased risk of suicide, impaired cognitive and social function, and self-neglect which of all leads to increased mortality risk.¹⁶

While early detection of depression among older adults is limited since the symptoms are likely to be unrecognized, underestimated, and interfered with normal aging. The diagnostic criteria for major depression for the general population according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition, include sadness and anhedonia, although older adults are less likely to present with affective symptoms. In addition, depression symptoms among older people are more likely to display changes in cognitive, somatic symptoms, impaired daily function, and loss of interest.^{16,17} Thus, the screening instruments such as the 15-question Thai Geriatric Depression Scale (TGDS-15) had been developed and validated. TGDS-15 has been widely used to early detect the depression symptoms typically presented in older adults such as feeling of loneliness, helplessness, hopelessness, emptiness, worthlessness, impaired memories, and loss of their energy. TGDS-15 has been translated into Thai and validated among the Thai older population.¹⁸

Since COVID-19 pandemic could impact on psychological illness, especially depression symptoms among older people. Our study aimed to determine the prevalence of depression symptoms and their associated risk factors during the COVID-19 pandemic among older adults who visited a family medicine clinic. Such an attempt could guide the healthcare system to endorse mental health promotion, preventive mental health programs, appropriate screening programs, and referral systems to promote quality of life and well-being in older adults. Furthermore, psychological support should be provided to help relieve older adults of adverse psychological events effects and overcome this challenging situation.¹⁹

Materials and Methods

Study Design

A cross-sectional design was adopted to collect data from older adults aged 60 and older who attended a family medicine clinic at the Faculty of Medicine Vajira Hospital, Bangkok, Thailand, from July to October 2021. The study was approved by the ethics committee of the Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand. (COA 121/2564). All experiments were performed in accordance with relevant guidelines and regulations, in the Declarations section.

Participants

Older people aged 60 years old and older living in urban setting of Thailand, with the ability to read Thai was included. The exclusion criteria were declining participation and diagnosis of cognitive impairment(s), such as severe depression, excluded by screening the individual's medical history. The sample size was calculated using an infinite population proportion formula to achieve a suitable power level.²⁰

Data Collection

Data was collected by face-to-face, which the participants were given an information sheet and provided written informed consent. The voluntary participants were provided the instructions to fill in the questionnaire. All participants

have been performed in accordance with the Declaration of Helsinki and have been approved by an appropriate ethics committee.

Questionnaire

The questionnaire was self-reported (see <u>Supplementary Files 1</u> for details). For older adults with reading and writing limitations, trained research staff read out all the items to the participants in a clear monotone while maintaining a neutral facial expression. They then filled in their responses for them.

Measures were divided into two sections. First, the demographic section included 11 items: gender, age, educational level, occupation, marital status, income sufficiency, debt, underlying diseases, residence, history of substance use such as alcohol and tobacco, and history of COVID-19 infection. Second, the Thai Geriatric Depression Scale (TGDS-15) was used to ascertain depression symptoms.^{21,22} The TGDS-15 is a self-administered assessment that focuses on psychiatric symptoms such as mood (eg, emptiness, boredom, and life satisfaction) and cognitive changes rather than somatic symptoms (eg, weight loss and sleep disturbances).

The TGDS-15 has demonstrated good internal consistency (Cronbach's alpha of 0.85) among the older Thai population.^{21,22} It comprises 15 yes/no questions, with yes and no scored as 1 and 0, respectively, and a maximum score of 15 points. A total score \geq 5 was classified as the cutoff to detect significant depression symptoms, demonstrating a sensitivity of 86% and specificity of 91%.¹⁸

Statistical Analysis

Demographic data were analyzed and reported using descriptive statistics. The prevalence of depression was demonstrated by frequency and incidence rate with a 95% confidence interval (CI). Univariate analysis was performed using a simple logistic regression analysis to identify the factors associated with depression symptoms; these factors were presented with crude odds ratios (ORs). We then identified potential confounding factors that were significant (p-value <0.100) using a multivariate analysis; these factors were further analyzed using a multiple logistic regression analysis and presented with adjusted odds ratios (AORs) and 95% CIs. Data were analyzed using SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA), at a statistical significance of p > 0.05.

Results

Participants' Characteristics

A total of 156 questionnaire responses were obtained, and socio-demographic and clinical characteristics are presented in Table 1. The largest group of participants (80.8%) was aged below 70 old (range 60–69 years old), women (50.6%), married (67.9%), education higher than bachelor (55.1%). Approximately half were retired (41%), having sufficient income (67.9%). Most participants lived with their families (89.1%).

In terms of clinical characteristics, more than half (71.8%) had an underlying disease, with hypertension being the most common (39.1%). Almost one-fourth (24.4%) had a history of alcohol use, whereas only 8.3% had a history of smoking over 10 years period. In addition, regarding vaccine history, 17.3% of the participants had received compulsory COVID-19 vaccination. Only 0.6% had a history of COVID-19 infection.

Prevalence of Depression Among Older Adults

The prevalence of depression symptom is presented in Table 2, which is 20.5%, using the TGDS-15 as the criteria for depression symptoms. Current occupations and income insufficiency were significantly associated with depression symptoms. Gender, age group, marital status, level of education, monthly income, housing, underlying diseases, history of substance use, and history of COVID-19 infection among the participants and their communities were not associated with depression symptoms.

Characteristics	n	%
Age (years)		
< 70 (range 60–69 years old)	126	80.8
≥ 70	30	19.2
Gender		
Male	77	49.4
Female	79	50.6
Marital status		
Single	23	14.7
Married	106	67.9
Divorced/separated/widowed	27	17.3
Highest level of education		
No education/Primary school	20	12.8
High school/Vocational certificate	50	32.1
Bachelor's degree or higher	86	55.1
Current occupation		
Retired	64	41.0
Worker	63	40.4
Non-worker	29	18.6
Monthly income in baht (USD)		
≤ 15,000 (420 USD)	70	44.9
> 15,001 (421 USD)	86	55.1
Sufficient income		
Sufficient	106	67.9
Insufficient	50	32.1
Housing		
Living with family	139	89.1
Living alone	17	10.9
Underlying disease	112	71.8
Hypertension	61	39.1
Dyslipidemia	49	31.4
Diabetes mellitus	21	13.5
Osteoarthritis	14	9.0
Heart disease	12	7.7
Kidney disease	2	1.3
Others	16	10.3
Alcohol and smoking (over 10 years period)	-	
Alcohol	38	24.4
Smoking	13	8.3
History of COVID-2019 infection		
Participant		
History of COVID-19 infection	1	0.6
History of being quarantined	5	3.2
Received compulsory COVID-19 vaccination	27	17.3
Community of participant		.,
History of COVID-19 infection	71	45.5
History of being quarantined	43	27.6

 Table I Participants' Demographic Characteristics (n = 156)

Association Between Factor Variables and Depression Among Older Adults

Table 3 shows the association of the factor variable depression score among older adults during the COVID-19 pandemic based on logistic regression models. The univariate analysis showed that the factors significantly related to depression symptoms were current occupation and income sufficiency. First, the "non-worker" group was 4.39 times more likely to

Variables		p-value			
	Yes (n = 32)		No (n = 124)		-
	n	(%)	n	(%)	
Gender					
Male	15	(19.5)	62	(80.5)	0.753 ^c
Female	17	(21.5)	62	(78.5)	
Age (years)				(,	
< 70 (range 60–69 years old)	26	(20.6)	100	(79.4)	0.938 ^c
≥ 70	6	(20.0)	24	(80.0)	
Marital status		()		()	
Single	2	(8.7)	21	(91.3)	0.315 ^c
Married	24	(22.6)	82	(77.4)	0.010
Divorced/separated/widowed	6	(22.2)	21	(77.8)	
Highest level of education	Ū	(22.2)	21	(77.0)	
No education/Primary school	7	(35.0)	13	(65.0)	0.166 ^c
-	, ,		39		0.100
High school/Vocational certificate Bachelor's degree or higher	11	(22.0)	72	(78.0)	
	14	(16.3)	12	(83.7)	
Current occupation	10		F.4	(04.4)	0.002* ^c
Retired	10	(15.6)	54	(84.4)	0.002**
Worker	9	(14.3)	54	(85.7)	
Non-worker	13	(44.8)	16	(55.2)	
Monthly income (baht)					
≤ 15,000	19	(27.1)	51	(72.9)	0.064 ^c
> 15,001	13	(15.1)	73	(84.9)	
Sufficient income					
Sufficient	17	(16.0)	89	(84.0)	0.044* ^c
Insufficient	15	(30.0)	35	(70.0)	
Housing					
Living with family	30	(21.6)	109	(78.4)	0.527 ^f
Living alone	2	(11.8)	15	(88.2)	
Underlying disease					
No	6	(13.6)	38	(86.4)	0.182 ^c
Yes	26	(23.2)	86	(76.8)	
Alcohol and Smoking (over 10 years period)					
Alcohol					
No	21	(17.8)	97	(82.2)	0.139 ^c
Yes	11	(28.9)	27	(71.1)	
Smoking		, , , , , , , , , , , , , , , , , , ,			
No	29	(20.3)	114	(79.7)	0.731 ^f
Yes	3	(23.1)	10	(76.9)	
History of COVID-2019 infection		()		()	
Participant					
History of COVID-19 infection					
No	31	(20.0)	124	(80.0)	0.205 ^f
Yes	1	(100.0)	0	(80.0)	0.205
		(100.0)		(0.0)	
History of being quarantined	22	(21.2)		(70.0)	0 FO 4
No	32	(21.2)	119	(78.8)	0.584 ^f
Yes	0	(0.0)	5	(100.0)	
Received compulsory COVID-19 vaccination		(22.5)			
No	29	(22.5)	100	(77.5)	0.183 ^c
Yes	3	(11.1)	24	(88.9)	

Table 2 Prevalence of Depression Symptoms (TGDS ≥ 5) by Demographic Characteristics

(Continued)

Table 2 (Continued).

Variables		Depression Symptoms			
	Yes (Yes (n = 32)		No (n = 124)	
	n	(%)	n	(%)	
Community of participant					
History of COVID-19 infection					
No	19	(22.4)	66	(77.6)	0.533 ^c
Yes	13	(18.3)	58	(81.7)	
History of being quarantined					
No	21	(18.6)	92	(81.4)	0.333 ^c
Yes	11	(25.6)	32	(74.4)	

Notes: P-value corresponds to c Chi-square test or f Fisher's exact test. *Significant at p-value < 0.05.

 Table 3 Multiple Logistic Regression Analysis for Factors Associated with Depression Symptoms Among Older

 Adults

Factors	ι	Univariate Analysis			Multivariate Analysis		
	OR ^a	95% CI	p-value	\mathbf{OR}_{adj}^{b}	95% CI	p-value	
Gender							
Male	1.00	Reference					
Female	1.13	(0.52-2.47)	0.753				
Age (years)							
< 70 (range 60–69 years old)	1.00	Reference					
≥ 70	0.96	(0.36-2.60)	0.938				
Marital status							
Single	1.00	Reference					
Married	3.07	(0.67–14.05)	0.148				
Divorced/separated/widowed	3.00	(0.54–16.6)	0.208				
Highest level of education		. ,					
No education/Primary school	2.77	(0.94-8.18)	0.065				
High school/Vocational certificate	1.45	(0.60-3.50)	0.408				
Bachelor's degree or higher	1.00	Reference					
Current occupation							
Retired	1.00	Reference		1.00	Reference		
Worker	0.90	(0.34–2.39)	0.832	0.76	(0.28-2.10)	0.596	
Non-worker	4.39	(1.62–11.87)	0.004	3.54	(1.25–10.02)	0.018	
Monthly income (baht)		· · · ·			· · · ·		
≤ 15,000	2.09	(0.95-4.61)	0.067				
> 15,001	1.00	Reference					
Sufficient income							
Sufficient	1.00	Reference		1.00	Reference		
Insufficient	2.24	(1.01–4.98)	0.047	1.89	(0.79-4.51)	0.152	
Housing		· · · ·			· · · ·		
Living with family	1.00	Reference					
Living alone	0.48	(0.11–2.24)	0.353				
Underlying disease		, ,					
No	1.00	Reference					
Yes	1.92	(0.73–5.03)	0.188				

(Continued)

Factors	Univariate Analysis			Multivariate Analysis		
	OR ^a	95% CI	p-value	OR _{adj} ^b	95% CI	p-value
Alcohol and smoking (over 10 years period)						
Alcohol						
No	1.00	Reference				
Yes	1.88	(0.81-4.38)	0.143			
Smoking						
No	1.00	Reference				
Yes	1.18	(0.31-4.56)	0.811			
History of COVID-2019 infection						
Participant						
History of COVID-19 infection						
No	1.00	Reference				
Yes	-	-	NA			
History of being quarantined						
No	1.00	Reference				
Yes	-	-	NA			
Received compulsory COVID-19 vaccination						
No	1.00	Reference				
Yes	0.43	(0.12–1.53)	0.194			
Community of participant						
History of COVID-19 infection						
No	1.00	Reference				
Yes	0.78	(0.35–1.71)	0.534			
History of being quarantined						
No	1.00	Reference				
Yes	1.51	(0.66–3.46)	0.335			

Table 3 (Continued).

Notes: Variable was included in multivariate model due to have p-value < 0.100 in univariate analysis. ^aCrude Odds Ratio estimated by Binary Logistic regression. ^bAdjusted Odds Ratio estimated by Multiple Logistic regression.

Abbreviations: OR, crude odds ratio; OR_{adj}, adjusted odds ratio; CI, confident interval; NA, data not applicable.

experience depression symptoms than reference group (OR = 4.39, 95% CI = 1.62-11.87, p-value = 0.004). Second, the "insufficient income" group was 2.24 times more likely to experience depression symptoms than reference group (OR = 2.24, 95% CI = 1.01-4.98, p-value = 0.047). Then, the following factors with a significance level of 0.100 (p-value < 0.100) were included in the multivariate analysis: level of education, current occupation, monthly income, and income sufficiency.

The results of the multivariate analysis demonstrated that the "non-worker" group was 3.54 times more likely to experience depression symptoms than the reference group (OR = 3.54, 95% CI = 1.25-10.02, p = 0.018) when controlling for the confounding factors. The monthly income factor was not significantly associated with depression symptoms in the multivariate analysis. Therefore, gender, age, marital status, education, monthly income, housing, underlying diseases, history of substance use, and history of COVID-19 infection among the participants and their communities were not associated with depression symptoms.

Discussion

In the current situation, the COVID-19 pandemic has been one of the risks for depression to both individuals and communities. This is the first study (n = 156) on depression among older adult based on TGDS-15 in urban areas in Bangkok, Thailand, conducted during the COVID-19 pandemic. To the best of our knowledge, we found that older adult has a higher prevalence (20.5%) of depression than the pre-pandemic situation accounted for the prevalence rate of 9.6% reported in an outpatient study of a similar population in Songklanagarind, a provincial area of Thailand.²³ In addition,

factor variables were presented that occupation and income sufficiency were statistically significantly associated with depression (p < 0.05). Our results were similar to previous findings regarding the prevalence of depression in community-dwelling older adults during the COVID-19 pandemic: 22.9% among an urban population in Singapore and 19.8% in Ireland.^{9,24} Our study might indicate that the COVID-19 pandemic has enhanced depression among older adults in urban areas. In addition, the pandemic could result in negative health outcome such as insufficient sleep, unsatisfaction sleep, unsatisfactory quality of life; in addition, the used of at least one psychotropic drug increased compared to prelockdown.^{6,14,25}

Association Between Factor Variables and Depression Among Older Adults

Our study found occupational presented that not having a job was associated with depression. As job is a crucial way to earn a living, unemployed participants might have been struggling financially and having a job could alleviate older adults' problem and increase their self-esteem. Our study demonstrated the consistent finding with previous result from Malaysia,²⁶ which found that depression was associated with unemployment and low-income older participants, as well as from Russia, which demonstrated that participants who were employed at the time of the study had low ORs for depression.²⁷ Moreover, this might imply that not having a job might reflect the diminish of physical activity, since lack of physical activity has a negative effect on mental health outcome especially during the pandemic.²⁸ Hence, our results present that the occupational status of non-workers may have effects on mental health, which should influence policy planners to increase job availability, such as volunteer work, for older adults, as this may decrease their depression symptoms.

In addition, insufficient income was associated with depression symptoms while the amount of income itself was not. Our result is comparable with findings from the US,^{29,30} showing that participants with lower social and economic resources had a higher Odds Ratios for depression,³⁰ and the aforementioned study in Malaysia.²⁶ Since the financial challenges are associated with poorer mental health outcome, older adult with insufficient income could led to negative impact toward their quality of life and well-being.³¹ Moreover, the pandemic crisis also affected the worldwide economic activity particularly during the lockdown which leads to economic challenges among older people. Our result might reinforce the policy planners to promote financial aid and security net to provide the daily needs for older adults facing financial challenges, especially during pandemics such as COVID-19, to alleviate their depression symptoms. Regarding housing factors, our study demonstrated that depression had no statistically significant relationship with either living alone or with family. This result is consistent with that of another study in a rural area in Thailand,³² which examined factors associated with depression among community-dwelling older adults with chronic diseases. This consistency in results might be underpinned by communication and how older adults keep in touch with others. As there are various ways to interact with others, such as via phone and social media platforms that allow them to communicate with others, hence living on their own was not associated with depression. Furthermore, the factor underlined in the housing factor could be loneliness, which is associated with depression.³³ Further studies could investigate loneliness during a pandemic and its effect on depression.

Regarding the factors related to underlying disease, our results showed that diabetes mellitus, hypertension, dyslipidemia, heart disease, kidney disease, and osteoporosis, as well as the presence of two or more underlying diseases, were not statistically associated with depression. This could be because the participants, who attended a family medicine clinic, had stable conditions. Furthermore, the treatment of non-communicable diseases was well managed in cooperation with tertiary prevention programs. This result is comparable with that of a study among community-dwelling older adults demonstrating no association between chronic diseases such as diabetes and depression.³²

Smoking and alcohol intake over 10 years period were not associated with depression. This finding is similar to the finding of Japanese study using the Geriatric Depression Scale demonstrating smoking status and current alcohol drinking were not associated with depression symptoms.³⁴ Still, these two similar findings cannot clarify the causal link of smoking status and alcohol consumption with depression. Finally, in terms of socio-demographics including gender, age, marital status, education, income level, and history of COVID-19 infection among the participants and their communities were not associated with depression symptoms. The results regarding gender, age, marital status, education, and income level are consistent with those from another study.²² Although a history of COVID-19 infection among the

participants and their communities was not associated with depression symptoms, the factors that we included had not been examined in the previous literature.

Our study has a few limitations. The survey was conducted at a family medicine clinic during the pandemic; therefore, these findings may not be generalizable to the general population of older adults or those at other clinics. The survey did not include patients using telemedical facilities or those who were unable to attend the clinic during the pandemic.

This study highlights the importance of addressing depression symptoms among older adults, with occupation and income sufficiency being statistically significantly associated with depression. Our study would suggest further that both identification and interventions are needed for older adults to prevent and reduce the risk of depression symptoms. Further studies should use qualitative methods such as in-depth or group interviews to investigate the underlying factors associated with depression in older adults and identify further interventions to decrease their depression symptoms. However, owing to the COVID-19 pandemic, data collection methods may need to be adjusted per the circumstances, such as by using online and telephone interviews. Our participants comprised only older adults who attended a specific family medicine clinic. Further studies could include participants from multiple centers and compare urban and rural areas to evaluate the factors associated with depression. Thus, the government should provide support in these areas to prevent a humanitarian crisis.

Implications for Research, Practice, and Policy

A geriatric depression screening tool should be applied to every older adult attending a primary care clinic, and those in high-risk groups, such as non-workers and those with insufficient incomes, should be monitored for early detection and prompt treatment. In addition, health promotion programs for older adults should be advocated during the COVID-19 pandemic to promote mental health and well-being and prevent depression. Moreover, policies planner could promote job availability and establish financial aid for older adults in high-risk group to diminish depression symptoms during events such as the COVID-19 pandemics.

Conclusion

During the COVID-19 pandemic, factors such as occupation and income sufficiency were the majority on depression symptoms prevalence in urban areas, Thailand. Depression can lead to deteriorations in health, quality of life, and wellbeing. The pandemic may alert healthcare personnel to the need for early recognition of psychological problems in older adults when stressful events occur. Policy planner could provide intervention such as increasing job availability and establishing financial aid policies that might ameliorate depression symptoms in high-risk groups during the events such as the COVID-19 pandemic.

Abbreviations

COVID-19, coronavirus disease; TGDS-15, The 15-item Thai Geriatric Depression Scale; WHO, World Health Organization; OR, odds ratio; CI, confidence interval.

Data Sharing Statement

The data sets generated and analyzed during the current study are not publicly available due to identifiable information but are available from the corresponding author on reasonable request answering the survey.

Ethical Approval

This study was approved by the ethics committees of Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand (Approval no. COA 121/2564). The Institutional Review Board of the Faculty of Medicine Vajira Hospital is in full compliance with the international guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS Guideline and International Conference on Harmonization in Good Clinical Practice (ICH-GCP).

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Author Contributions

All authors read and approved the final manuscript. ATmade a significant contribution to the work reported, conception, study design, execution, acquisition of data, analysis, interpretation, and drafting.BM made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, execution, acquisition of data, analysis and interpretation, or critically reviewing the article; gave final approval of the version to be published. All authors have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Supplementary Material

Additional File 1. The full English language version of the questionnaire.

Disclosure

The authors declare no potential conflicts of interest with respect to this research and authorship.

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