

Reliability and validity of Beliefs on Medicine Questionnaire (BMQ) in diabetes mellitus patients: Malay Translated Version

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Abstract

Objective: In this study, the Believe about Medicine Questionnaire (BMQ) questionnaire was translated into Malay and validated among Malaysian diabetes mellitus (DM) patients.

Methodology: The cross-sectional study targeted Type II DM outpatients in 13 health clinics in Johor Bahru between October 2015 and April 2016. Ethical clearance was obtained. BMQ was translated into Malay using forward-backward translations and was pre-tested as well as validated among 180 eligible patients following written informed consent. Data was analyzed for internal consistency, reliability and confirmatory factor analysis (CFA).

Results: The response rate was 91.7%. The majority of the respondents were female (51.2%) and Malay (74.1%) with secondary education (59.6%). The mean age was 51.2 ± 10.1 years with the majority on oral DM treatment (49.4%). There were two constructs generated for BMQ-Specific and a single construct for BMQ-General. The variance of the constructs ranged from 19.5% to 35.1%. Sample was adequate for constructs extraction (Kaiser Meyer Olkin (KMO) >0.7). Construct-Need has four items similar to the original BMQ-Specific but with an additional item (loading=0.545). Other items were extracted into Construct-Concern. Eight items which were distributed into 2 constructs in original BMQ-General were gathered into a single construct-Harm/Overuse. CFA resulted in a fit model.

Conclusion: Malay BMQ-General and BMQ-Specific were fit and reliable with good internal consistencies. It is applicable to be adopted to the local DM population.

Keywords: BMQ, diabetes mellitus, Malay, reliability, translation, validity

Introduction

Adherence is defined as the extent to which a patient's behaviour matches with the agreed recommendation from the prescriber^{1,2}. However, it has been estimated that approximately 50% of patients with chronic diseases do not take their medications as prescribed³. Hence, non-adherence is

a major barrier to health improvements for patients suffering from chronic diseases⁴. One of the major factors contributing to non-adherence is poor health literacy which will affect patients' belief towards medications⁵. In order to improve patients' adherence, it is important to learn more about patients' beliefs, fears and attitudes towards the harm and benefits of their medications, so that their concerns about medications can be appropriately addressed.

In Malaysia, the Diabetes Medication Therapy Adherence Clinic (DMTAC) is implemented by pharmacists from the government sector since 2004 with the aim of improving medication adherence among diabetic patients as well as glycemic control⁶. The Modified Morisky Medication Adherence Scales (MMMAS) was used in DMTAC to measure patients' medication taking behaviour. However, this tool does not incorporate psychosocial elements which may address patients' point of view and beliefs towards their medical conditions particularly on medicine use⁵.

A more holistic approach towards patients' care can be achieved by considering the point of view from both the patients and healthcare providers. Beliefs about Medicine Questionnaire (BMQ) was developed to obtain a better understanding of patients' perceptions about medicine. BMQ which was originally developed in English is a novel method for assessing cognitive representations of medications. It is an 18-item questionnaire comprising of two sections, the BMQ-specific and BMQ-general⁷.

BMQ has been translated into various languages, including, Italian, German, Japanese, French, Spanish and Arabic^{2,8,9,10,11,12,13}. The Turkish translation of BMQ-T reported acceptable internal consistency with consistent psychometric properties as the original BMQ¹⁴. The Spanish version of BMQ reported with identical factor loadings as the original four constructs and is considered as a reliable tool to measure beliefs in medicine among Type 2 Diabetes Mellitus (DM) patients¹². Similarly, BMQ which has been adapted and validated on different sets of diseased populations and resulted in similar construct as in the original version^{15,16,17,18}. However,

to our knowledge there is no Malay version of BMQ to date. Thus, the purpose of this study was to translate the BMQ questionnaire into Malay and validate it in the Malaysian population particularly among DM patients.

Materials and methods

Subjects and study design

The study subjects consisted of male and female outpatients conveniently sampled from 13 health clinics in Johor Bahru district of Johor state, Malaysia between October 2015 and April 2016. Type 2 DM patients who received medications for at least two months and 18 years and above were considered as eligible for the study. However, non-Malaysian patients were excluded. The study was conducted in three phases of Malay translation, pre-testing and validation of the translated Malay BMQ.

Phase 1: BMQ was translated into Malay by using an internationally accepted translating process¹⁹. The translation process was conducted by a group of experts: the first group consists of language experts (teachers in *Sekolah Dalam Hospital*) and the second group consists of subject matter expert (medical personnel) with two parallel sets of forward and backward translations. The forward translation from the source language (English) into the target language (Malay) was performed by the first and second groups of expert independently. Two different sets of Malay BMQ questionnaire were produced. Another of first and second groups of expert blindly (without referring to the original version) and independently back translated the Malay version to English. Subsequently, another two different English-translated versions were produced. The process was carefully done to ensure preservation of contents and the meanings of the original questionnaire. Following reconciliation of the two forward and backward translations, revisions and amendments were made by the expert committee accordingly to produce a pre-final Malay BMQ.

Phase 2: In the first pre-test, face validity was done on ten diabetic patients at the out-patient setting. A single individual interview was conducted after ensuring the bilingual competency in order to assess respondents' comprehension of the translated questionnaire. Initially, the participants were required to read a short passage from the local English daily newspaper and translate it into Malay. Participants who passed the fluency test were given the pre-final Malay version of BMQ. The second pre-test was conducted on another 30 diabetic patients at the out-patient setting to further test the questionnaire to be finalized into Malay BMQ. In this part, participants were not tested for their bilingual competency, and no interviews were done.

Phase 3: Patients (n=180) were self-administered with the finalized Malay BMQ and were required to repeat the same procedure after four weeks. Data collection was performed by 5 pharmacists in the health clinics following an official training to ensure minimal risk of assessment bias.

Sample size was estimated using an assumption of Malay BMQ to have moderate construct validity with a minimal of 5 to 7 respondents required for each item in the questionnaire²⁰. Considering a 30% drop-out rate, 180 respondents were required for the questionnaire validation. The sample size for every health clinics were distributed based on the proportion of

patients reported in previous year in each health clinic in the district.

Ethical issues

Ethical clearance was obtained from Medical Research Ethics Committee (MREC) (NMRR-15-869-25888) while the permission for data collection was obtained from the Johor Bahru District Health Office, Malaysia. The study was conducted in compliance to Malaysian Good Clinical Practice (GCP) Guideline and Malaysian Data Protection Act. Written informed consents were obtained from all patients prior to their participation.

Study instrument

BMQ was originally developed in English by Horne R. (1999). BMQ-Specific consisted of two 5-item factors which assess beliefs on the necessity of prescribed medications (*Specific-Necessity*) and concerns about prescribed medications based on beliefs about the danger of dependence, long term toxicity and the side effects of medications (*Specific-Concerns*). BMQ-General comprised of two 4-item factors assessing the beliefs that medicines are harmful, addictive and poisons which should not be taken on a continuous basis (*General-Harm*) and that medicines are overused by doctors (*General-Overused*). The answers were 5-point Likert Scale, ranging from 5-strongly agree, 4-agree, 3-uncertain, 2-disagree to 1-strongly disagree. The original version of BMQ was reported with good internal consistency and test-retest reliability as well as discriminant validity⁷.

Statistical analysis

Construct validity

Construct validity was performed by using an Exploratory Factor Analysis (EFA) which utilises Principle Axis Factoring extraction method with Promax rotation²¹. An eigenvalue greater than 1 was used for constructs extraction. A factor loading Kaiser-Meyer-Olkin (KMO) and Bartlett's test were used to justify the sampling adequacy. Analysis was performed using IBM SPSS version 21.0²³.

Further analysis was performed using a Confirmatory Factor Analysis (CFA) with Structural Equation Modelling (SEM) using AMOS (Amos Development Corporation) to test the fit of the EFA model in Malay BMQ-General and BMQ-Specific. Fitness of the model were accessed based on X^2/df ratio <3 , Comparative Fit Index (CFI) > 0.95 , Tucker Lewis Index (TLI) > 0.95 and Root Mean Square Error (RMSEA) < 0.06 ^{24,25}.

Feasibility

A floor effect occurs when several of the patients score the lowest possible score, whereas a ceiling effect occurs when several of the patients score the highest possible score. The amount of ceiling and floor effects present determine the quality of the content validity. Ceiling and floor effects were evaluated to be satisfactory by analyzing the percentages of the scores at the extremes of the response scale to be less than 15%²⁶.

Reliability

Internal consistency and test-retest reliability were considered for reliability testing. Cronbach's alpha of more than 0.5 was acceptable while 0.7 or more was considered as good^{27,28}.

Intra-class correlation coefficient (ICC) with value of ≤ 0.40 was considered as poor to fair, 0.41–0.60 moderate, 0.61–0.80 good and >0.80 excellent^{29,30}. Corrected item to total correlation of more than 0.2 was acceptable³¹.

A total of 166 (out of 180) respondents completed the Malay BMQ. The majority of respondents were female (51.2%) and of Malay ethnicity (74.1%) having at least a secondary education (59.6%). The mean age of the respondents was 51.2 (SD: 10.1) years. The majority of the diabetic respondents were patients who received oral treatment (49.4%) (Table 1).

Results

Demographic characteristics

Table 1: Socio-demographic characteristics of the respondents (n=166)

Socio-demographic characteristics	n (%)	
Gender		
Female	85	(51.20)
Male	81	(48.80)
Race		
Malay	123	(74.10)
Indian	20	(12.05)
Chinese	19	(11.45)
Others	4	(2.41)
Education		
Primary	31	(18.67)
Secondary	99	(59.64)
Tertiary	33	(19.88)
Treatment		
Oral only	82	(49.40)
Both oral and injectable (insulin)	58	(34.94)
Injectable (insulin) only	25	(15.06)
Age, (years) [mean (SD)]	51.2	(10.10)
Duration of DM, (years) [mean (SD)]	7.5	(6.10)

Content validity

The BMQ was translated into Malay by two groups of subject-matter experts and non-subject-matter experts using forward and backward translations. The translated versions were reviewed by language experts and pharmacists. Several items in both BMQ-Specific and BMQ-General created major confusion among the respondents where the words *mystery*, *protective*, *additive* and *poisons* were deemed as confusing. Language experts were approached for opinions and suggestions of substitute questions with different terms but with similar meaning were employed. The opinions and

suggestions by the respondents were considered in selecting the appropriate question for the four items having the confusing words with no item being removed from the Malay BMQ.

Construct validity

Exploratory factor analysis using a Promax rotation resulted in two constructs for BMQ-Specific and a single construct for BMQ-General with 19.5% variance for Need, 31.6% variance for Concern and 35.1% variance for Overuse and Harm. The sample was adequate for constructs extraction [BMQ-Specific (KMO=0.77) and BMQ-General (KMO=0.82)]. Bartlett’s test was statistically significant (p -value <0.001). Construct-Need has four items that were similar to the original BMQ-Specific but with an additional item of factor loading of 0.545. Other items were extracted into Construct-Concern. However, all eight items which were distributed into two constructs in the original BMQ-General were gathered into a single construct for Malay BMQ-General. The loading factors for the items ranged from 0.522 to 0.791 (Table 2) and the items seemed to be well correlated within the constructs.

Table 2: Exploratory factor loading on Promax rotated solution of Principle Axis Factoring of Malay BMQ

Items in constructs	Concern	Need	Harm/Overuse
BMQ-Specific (KMO: 0.769; Bartlett’s test $p<0.001$)			
I sometimes worry about becoming too dependent on my medicines.	0.776		
My medicines disrupt my life.	0.756		
Having to take my medicines worries me.	0.689		
I sometimes worry about the long term effects of my medicines.	0.659		
My medicines are mystery to me.	0.639		
My health in the future will depend on my medicines.		0.791	

My life would be impossible without my medicines.	0.771
Without my medicines I would be very ill.	0.755
My health, at present, depends on my medicines.	0.640
My medicines protect me from becoming worse.	0.543

BMQ-General

(KMO: 0.815; Bartlett's test $p < 0.001$)

Natural remedies are safer than medicines.	0.665
All medicines are poisons.	0.664
Medicines do more harm than good.	0.626
Doctors use too many medicines.	0.607
Most medicines are additive.	0.569
If doctors had more time with patient, they would prescribe fewer medicines.	0.542
Doctors place too much trust in medicines.	0.528
People who take medicines should stop their treatment for a while every now and again.	0.522

Explained variance after extraction (%)	31.600	19.500	35.100
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Feasibility and reliability

The floor effects ranged from 0.6% to 1.6% while ceiling effects ranged from 0.6% to 2.4% across the construct which preserved the realistic measure to detect any significant observation and responsiveness of respondents. Skewness and kurtosis for all three constructs were in the acceptable range with no severe normality violations (Table 3).

The internal consistency of the constructs was measured using Cronbach's alpha with the values ranging from 0.74 to 0.75. Test-re-test reliability testing using ICC resulted in fair and moderate correlation whereas item-total correlation of the constructs ranged from 0.35 to 0.64 (Table 3).

Table 3: Internal consistency and reliability of Malay BMQ

Statistical parameters	Constructs		
	Concern	Need	Harm/Overuse
Skewness, kurtosis	0.08, 0.62	-0.02, -0.10	0.12, 0.36
Cronbach's α	0.75	0.75	0.74
ICC* (95% CI)	0.75 (0.68, 0.81)	0.75 (0.68, 0.81)	0.74 (0.69, 0.79)
Test ^a [mean (SD)]	16.6 (3.2)	17.1 (3.2)	24.1 (4.1)
Re-test ^a [mean (SD)]	16.4 (3.3)	17.3 (3.1)	24.2 (3.9)
Floor effect [n (%)]	1 (1.6)	2 (1.2)	1 (0.6)
Ceiling effect [n (%)]	2 (1.2)	4 (2.4)	1 (0.6)
Item-total correlation (range)	0.44, 0.60	0.35, 0.64	0.37, 0.49

*Mean measure,

ICC-Intra-class correlation, SD-Standard deviation

^a Paired t-test: Need: p -value=0.517; Concern: p -value=0.615; Overuse & Harm: p -value:0.797

CFA analysis using AMOS was performed to justify the goodness of fit of the Malay BMQ. The Malay BMQ-General revealed a good fit with X^2/df of 1.41 which is lower than 3. RMSEA was lower than 0.08 and CFI was reported as 0.952 which is greater than 0.9. However, TLI and NFI values were lower than the proposed cutoff of 0.95 which

reflected the model's failure to improve the fit by 95% relative to a null model. Similarly, Malay BMQ-Specific was also fit with X^2/df of 1.81, RMSEA of 0.067, CFI of 0.923 and failed to improve model fit by 95% relative to a null model since the TLI and NFI values were lower than 0.95 (Figure 1).

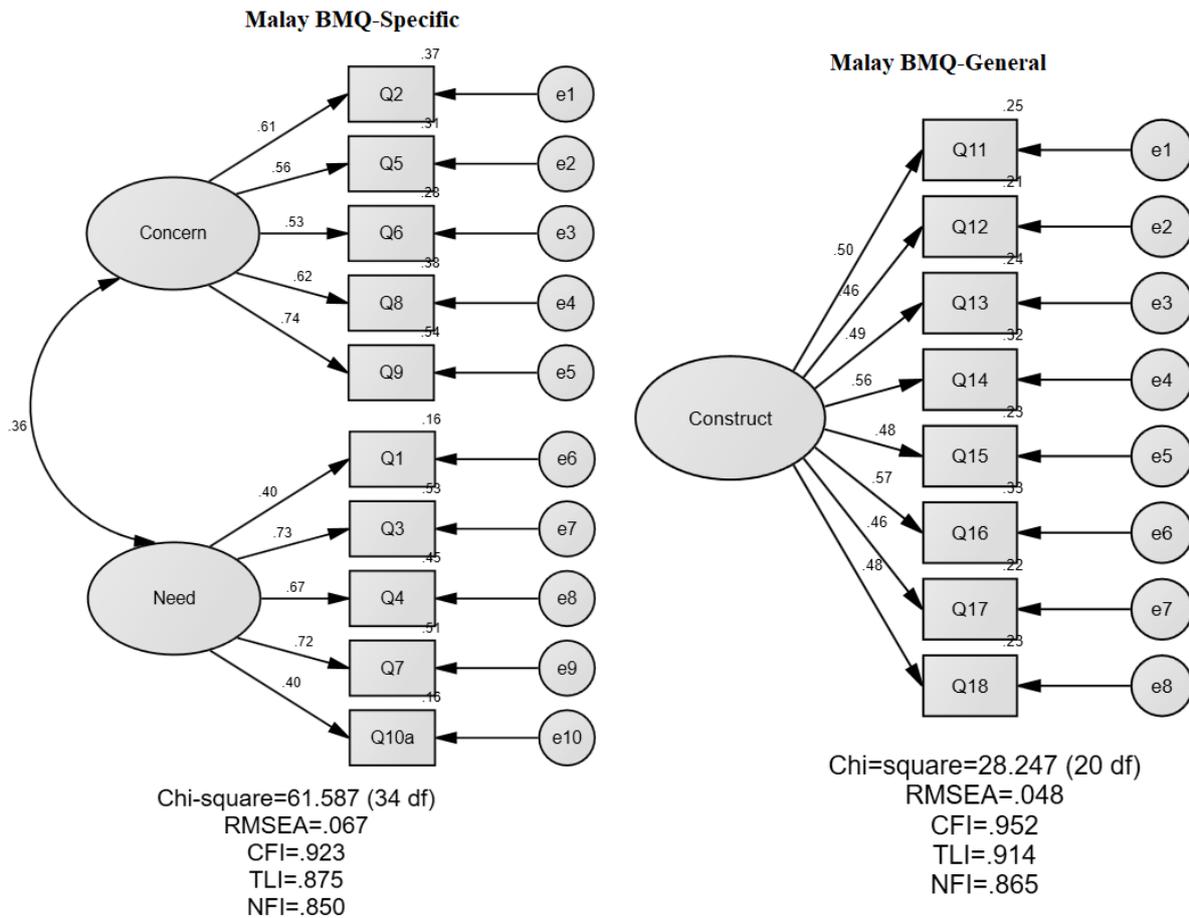


Figure 1: Path diagram of standardized parameters of SEM in the Malay BMQ

Discussion

Our study is the first to translate the BMQ questionnaire into Malay and validate it in the Malaysian population particularly among DM patients. The Malay BMQ questionnaire was found to be a reliable and valid survey tool for Malaysian DM population. The study finding discovered that the Malay BMQ questionnaire has a good internal consistency and validity for DM population in Malaysia. Comparison with previous studies (Table 4) which has translated BMQ indicated similar patient criteria where the average patient's age is within the range of 44-56 years similar to the present study with an average of 51 years and an average of 50% of patients were male. The original BMQ was translated into Portuguese, Persian, French, Maltese and other versions^{11,15,16,17,32,33,34}. The translated BMQ has been validated among hypertensive, psychiatric, mental illnesses, asthmatic and diabetic patients^{11,15,16}.

The Malay BMQ was successfully validated on Type II diabetes mellitus patients who were on oral and/or insulin medications for a period of at least 2 months. Gatt (2017) has also reported that Maltese BMQ has been translated and validated among 25% of diabetic patients from the total number of samples¹⁵. Cronbach alpha was within a range of 0.50-0.67 similar to the present study with Cronbach alpha between 0.74-0.75. Both studies have shown that measurement of the medication beliefs among diabetic patients can be successfully conducted by using the translated version of BMQ.

The present study of Malay BMQ presented with two constructs for BMQ-Specific and a single construct for BMQ-General but the original BMQ was reported with only two constructs for BMQ-General⁷. However, the present study successfully replicated the findings reported by Samalin (2017) with a single construct for BMQ-General - validated the French BMQ among mental illness patients which resulted with 42% variance with factor loading in a range of 0.49 to 0.78 for BMQ-General with similar findings as in the Malay BMQ with 35% variance with factor loading in a range of 0.52 to 0.67¹¹. Both studies reported good and reliable internal consistencies. Similarly, Salgado (2013) and Mostafavi (2016) also reported good internal consistencies with Cronbach's alpha value that was greater than 0.6 but with two constructs extracted for BMQ-General as in the original BMQ^{16,17}.

In order to preserve the meaning and contents of the original BMQ, the translation process was carried out carefully by subject matter and language experts. Words such as *mystery*, *protective*, *additive* and *poisons* were among the words that pose difficulties in understanding among respondents in Malay BMQ. Subsequently, the words *mystery* and *additive* were maintained while *protective* and *poisons* were substituted with words which suit the local diabetes patient population context. Salgado (2013) also reported that the word *mystery* was a challenge in the translation of Portuguese BMQ¹⁷. Meanwhile, Mahler (2012) reported that *natural remedies* was an issue in the translation of German version of BMQ and the word was replaced with *conventional medicine* which was considered as appropriate to the German population⁹.

Factor loading was not smooth enough for Malay BMQ-Specific as the item “my medicines protects me from becoming worse” was extracted into Need instead of Concern with marginal difference in the loading factor within the two constructs. The original BMQ extracted this item with factor loading 0.670 into Concern⁷. Nevertheless, in the present study the item was extracted with factor loading 0.543. Removal of the item does not improve the model fit in Malay BMQ-Specific. Therefore, it is hypothesized that that the type II DM patients tend to perceive the fact the “diabetic medicine protects me from becoming worse” as a necessity rather than a concern. Thus, it was remained to be extracted in Need. Similar factor loading issues were reported in other versions of BMQ^{12,15}.

The findings from the confirmatory factor analysis of Malay BMQ were similar to the ones reported by Mostafavi (2016)

for Persian BMQ. Persian BMQ which was validated among hypertensive patients produced a fit model with CFI values of 0.958 and RMSEA of 0.073¹⁶. Similarly, in the present study, the Malay BMQ was reported with good construct validity, having a CFI value of greater than 0.9 and RMSEA as high as 0.067. Meanwhile, Fall (2017) also reported CFI of 0.89 and RMSEA of 0.08 for French BMQ. The reported results indicated that the construct validity was good for a fit model for both BMQ-General and BMQ-Specific questionnaires².

The present study achieved the estimated sample with 92.2% response rate among Type II diabetic patients. However, the discriminant validity was not considered in the study which limits the generalisability of the findings into other groups of patients apart from diabetes. Researchers intended to further validate Malay BMQ may consider to use a wide variety of patients groups so that the generalisability can be improved.

Table 4: Comparison of other studies

Author	Year of study	Sample	Criteria	Findings			
				BMQ-Specific		BMQ-General	
				Need	Concern	Harm	Overuse
Horne R. et al., 1999	March-May 1994 (Original BMQ) ⁷	n=524 (asthmatic, diabetic, psychiatric, renal dialysis, cardiovascular & general medical)	Gender	48% male			
			Age (years)	Mean: 50.75 (SD: NA)			
			Cronbach's α	0.55-0.86	0.63-0.80	0.47-0.83	0.60-0.80
			Variance				
Salgado et al., 2013	March-June 2010 (Portuguese BMQ) ¹⁷	n=300 (NA)	Gender	30.3% male			
			Age (years)	Mean: 62.0, SD: 14.4			
			Cronbach's α	0.76	0.67		
			Variance	44%			
Mostafavi F, et al, 2016	NA (Persian BMQ) ¹⁶	n=612 (hypertension)	Gender	44% male			
			Age (years)	Mean: 44.08, SD: 10.38			
			Cronbach's α	0.89	0.90	0.93	0.85
			Variance	10.85%	18.52%	11.43%	16.50%
Samalin L, et al, 2017	NA (French BMQ) ¹¹	n=150 (schizophrenia, bipolar disorder, major depression disorder)	Gender	44.7% male			
			Age (years)	Mean: 51.3, SD: 16.6			
			Cronbach's α	0.83	0.68	0.80	
			Variance	31.59%	22.88%	41.91%	
Gatt I, et al, 2017	June-September 2013 (Maltese BMQ) ¹⁵	n=400 (asthmatic, diabetic, cardiovascular, depression)	Gender	48% male			
			Age (years)	Mean: 56.0, SD: 18.13			
			Cronbach's α	0.73	0.66	0.56	0.48
			Variance				
Present study	October 2015-April 2016 (Malay BMQ)	n=166 (diabetic)	Gender	48.8% male			
			Age (years)	Mean: 51.2, SD: 10.1			
			Cronbach's α	0.75	0.75	0.74	
			Variance	19.50%	31.60%	35.10%	

*NA-Information not available

Conclusion

The Malay BMQ-General and BMQ-Specific questionnaire was found to be a valid and reliable survey instruments to be used for Malaysian patients with DM. Items in Malay BMQ were extracted into 2 constructs in BMQ-Specific (Need and

Concern) and a single construct for BMQ-General (Harm/Overuse).

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Conflict of interest

Researchers declared that there is no conflict of interest.

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All the authors were involved in study conceptualization and study methodology. PS, AA, WYL and YPW were involved in the translation of the questionnaire. CLY, CPY, AS, NHK, SJY and TKM were involved in the field data collection. PS and AA performed statistical analyses and interpretation. PS and AA were involved in drafting the manuscript. The manuscript was reviewed by all authors.

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Legal requirement and ethics approval

The study has been reviewed and approved by the Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-15-869-25888). This committee is responsible for reviewing and approving research studies to ensure that research studies are planned ethically and pose no harm to the participants.