ORIGINAL ARTICLE

Cross-cultural Adaptation of the Paediatric Epileptic Medication Self-Management Questionnaire (PEMSQ) in Malay Version.

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Abstract

Introduction: Effective self-management in children with epilepsy can optimize treatment efficacy and clinical outcomes, and reduce unnecessary healthcare utilization and costs. The Paediatric Epileptic Medication Self-Management Questionnaire (PEMSQ) for caregivers was developed by Modi et al. in 2010 to measure the elements of self-management in children newly diagnosed with epilepsy between the age of 2 to 14 years old. In this study, we attempted to cross-culturally adapt the PEMSQ into Malay as well as to determine its validity and reliability among caregivers of children with epilepsy. **Materials and methods:** Forward-backward translation was carried out by two groups of independent translators (experts in content and language). The content validation for the translated PEMSQ was performed by a panel of five experts with the cut-off point of 1.00, while the face validation was conducted among 10 targeted respondents with the threshold of 0.80. Finally, the reliability test was done in a pilot study amongst 65 caregivers of children with epilepsy with the minimum acceptable Cronbach's alpha values of 0.60 and inter-item correlations of between 0.15 to 0.50. All data were analysed using Statistical Package for Social Sciences (SPSS) version 20. **Results:** The content validity indexes for all items were 1.00, indicating good relevancy. The face validity indexes were within the range of 0.80 to 1.00, suggesting that the questionnaire was easily understood by the targeted respondents. In the pilot study, the Cronbach's alpha coefficient of the overall questionnaire was calculated to be 0.877. All domains except for Belief about Medication Efficacy managed to score Cronbach's alpha values of more than 0.60. The average inter-item correlations for all domains were within the range of 0.15 to 0.50, demonstrating acceptable internal consistency. **Conclusion:** The Malay version of the PEMSQ is found to be a valid and reliable self-administered questionnaire to measure self-management among caregivers of children between 2 and 14 years old with epilepsy. Further refinement of the research instrument can be considered, including confirmatory factor analysis.

Keywords: *Paediatric Epileptic Medication Self-Management Questionnaire (PEMSQ), Malay, cross-cultural adaptation, translation questionnaire, validation questionnaire*

Introduction

Epilepsy is a prevalent form of neurological disorder in all populations and is mostly developed during childhood. Basically, it is a repetition of spontaneous and recurrent seizures due to brain dysfunction [1]. To date, childhood epilepsy, in particular, remains a challenge to treat [2].

In children and adolescents, epilepsy can be debilitating. It can heavily impact their daily functioning and quality of life [3], [4]. In these patients, the illness is primarily managed in the home environment and not in clinic settings [5]. Thus, having supportive families are essential in order for them to lead as normal a life as possible [2].

As an important aspect of patient care, this is where the concept of self-management comes from. It revolves around a patient or family's active participation and responsibility in the daily routine to mitigate the illness and managing it in later life [4]. For epilepsy, it focuses on the activities required to curb the frequency of seizures and decrease their effects, including taking antiepileptic drugs, adopting healthy behaviours, as well as engaging in healthcare decision-making [5]. Effective self-management can optimize treatment efficacy and clinical outcomes, reduce unnecessary healthcare utilization and costs [6] .

The Pediatric Epileptic Medication Self-Management Questionnaire (PEMSQ) for caregivers was developed to measure the elements of self-management in children newly diagnosed with epilepsy between the age of 2 to 14 years old [5]. Apart from its comprehensive content, which covers knowledge, expectations, and beliefs of epilepsy treatment to barriers that affect medication adherence, it has been reviewed as a brief measure with strong psychometric properties. In addition to that, it is also easy to perform and interpret [7].

Due to these reasons, it is widely used in researches across the United States, either alone or in combination with other questionnaires to aid in clinical practice [8], [9]. Aside from that, it has been translated into other languages such as Korean [10] and Turkish [11] to be adapted into their own population. In Malaysia, a recent study in the city of Kuala Lumpur also utilized the PEMSQ to evaluate self-management issues in epilepsy therapy among parents of children with epilepsy. In the report, the investigators described the process of translating the instrument into Malay language by forward-backward translation and pre-testing. However, there was no further information on the validity and reliability aspects of it [12].

In view of the limited studies in this country pertaining to epilepsy self-management [12], it is proposed that a validated Malay version of the PEMSQ should be performed to ensure that the tool is reliable and valid to be used among the Malaysian population. To address this need, we attempted to cross-culturally adapt the PEMSQ into Malay as well as determine its validity and reliability among caregivers of children with epilepsy. The outcome of this study is hoped to provide a tool that is accurate and consistent in the assessment of epilepsy management, which in the long run, can be useful in guiding both caregivers and healthcare providers in the best interest of the patients.

Materials and Methods

Research Instrument

The PEMSQ was developed in English in 2010 by Modi et al. and has four domains with a total of 27 items; 8 items in Disease and Treatment Knowledge and Expectations; 8 items in Adherence to Medications and Clinic Appointments; 3 items in Barriers to Medication Adherence and 8 items in Beliefs about Medication Efficacy. Adding up the scores for all four domains would give the Total Self-Management score. The Disease and Treatment Knowledge and Expectations domain assesses the caregivers' adeptness regarding epilepsy and its management as well as their willingness to cooperate with the healthcare teams. The

Adherence to Medications and Clinic Appointments domain evaluates their propensity of therapeutic compliance. The Barriers to Medication Adherence domain determines their views of the obstacles that refrain their child from taking the medications as prescribed. The final domain, which is Beliefs about Medication Efficacy explores their perceptions on the effectiveness of the medication in treating epilepsy. The first 18 items are rated using a 5-point Likert scale which is (1) strongly disagree to (5) strongly agree, while the rest of them have a response of (1) never to (5) always. All items in the Barriers to Medication Adherence domain are negatively phrased and must be reverse scored for consistency. The score ranges according to each domain: Disease and Treatment Knowledge and Expectations (8 to 40), Adherence to Medications and Clinic Appointments (8 to 40), Beliefs about Medication Efficacy (3 to 15), Barriers to Medication Adherence (8 to 40). When combined, the Total Self-Management score should be in the range of 27 to 135. Higher scores represent better self-management [5].

Phase 1: Questionnaire Translation

Permission to translate the PEMSQ to Malay version was obtained from the authors before translating it using forward-backward translation. The PEMSQ was forward-translated into Malay by two independent translators; an expert in content (medical personnel) and a language expert (linguistic teacher). One common forward translation of the PEMSQ was produced and agreed upon by both translators. Subsequently, it was backward-translated to English by another two independent translators (a medical personnel and a linguistic teacher) who were not involved in the forward translation of the questionnaire. A single backward translation of the PEMSQ was then assembled and agreed upon by both translators. An open discussion between the two groups of translators and the researchers was held to consolidate the forward and backward translation versions by comparing them with the original PEMSQ. All discrepancies were reconciled and words or phrases that were not relevant within the Malaysian context were replaced. The whole questionnaire translation procedure was carried out from February to April 2019. The initially translated PEMSQ in Malay was prepared for the use in the later phase of the study [13], [14].

Phase 2: Validation Processes

Content Validation

Content validation of the initially translated PEMSQ was assessed by a panel of five experts who were familiar with the construct of the questionnaire. The panelists consisted of a consultant paediatric neurologist, a paediatric nurse, a clinical pharmacist, an outpatient pharmacist and a drug information pharmacist. The relevancy of the items to each domain were evaluated using the content validity index (CVI) approach. Each independent expert gave a rating based on a 4-point Likert scale which is (1) not relevant to (4) very relevant. The CVI for each item (I-CVI) was defined as the proportion of experts giving a rating of either 3 or 4. The cut-off point was set at 1.00 [15] and the calculations were made with Microsoft Excel [16]. The questionnaire was then modified based on the expert reviews to produce the revised version.

Face Validation

Ten targeted respondents were enrolled for face validation on the revised version of the translated PEMSQ. The clarity and comprehensibility of the wording used were evaluated based on their personal experience with epilepsy self-management. Using the face validity index (FVI) approach, each item was given a rating based on a 4-point Likert scale ranging from (1) not clear and not understandable to (4) very clear and understandable. The FVI for each item (I-FVI) was defined as the proportion of respondents giving a rating of either 3 or 4. The threshold was set at 0.80 [17] and the values were calculated with Microsoft Excel [16]. The final version of

the translated PEMSQ was assembled based on the comments from the respondents.

Pilot Study

The final version of the translated PEMSQ was self-administered to 65 respondents by convenience sampling to determine the internal consistency of the questionnaire. The inclusion criteria were primary caregivers of children between 2 and 14 years of age on antiepileptic drugs for at least 3 months under follow-up at Paediatric Clinic, Hospital Raja Perempuan Zainab II, Kelentan. The 10 respondents who were involved in the face validation process were excluded from the pilot study. Those who voluntarily gave consent after they were informed about the purpose and study procedures were recruited. Based on a sample size calculator for reliability studies [20], by assuming a minimum acceptable Cronbach's alpha of 0.60, an expected Cronbach's alpha of 0.76, significance level (alpha) of 0.05, power of 80% (β=0.2) and number of items of 27 [5], a minimum of 65 respondents were required for the pilot study. The entire second phase of the study took place from May to July 2019.

Statistical Methods

The internal consistency of the final Malay version of the PEMSQ was evaluated using Cronbach's alpha coefficient and average inter-item correlation. The construct validity or otherwise the correlations among the four domains and the Total Self-management scores were determined using Pearson's correlation test. The domains were deemed to be independent of each other if the degree of correlation between them was not high [18]. The data analysis was performed in Statistical Package for Social Sciences (SPSS) version 20 [19].

Ethics

This study was registered with National Medical Research Registry (NMRR-19-267-45663) and approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia. The permission to conduct the study at the site was obtained from the Director of Hospital Raja Perempuan Zainab II. All subjects were not identified and no personal information were disclosed to ensure their privacy and confidentiality. The entire study procedures were conducted according to the ethical principles outlined in the Declaration of Helsinki and Good Clinical Practice.

Results

The CVIs for all domains in the translated PEMSQ were calculated to be 1.00 (Table 1). As for the FVIs, they were computed to be between 0.80 to 1.00 (Table 2). Both CVIs and FVIs were within or above the cut-off points of 1.00 and 0.80; respectively, indicating that the items in the questionnaire were relevant and could be easily understood by the targeted respondents.

The psychometric properties of the translated PEMSQ were further tested in a pilot study. The majority of respondents, the caregiver of the patients, were Malay (n=64, 98.5%), parents (n=61, 93.9%) aged between 20 to 40 years old (n=55, 84.6%) with tertiary education (n=48, 73.9%). As for the patients, they were mostly male (n=43, 66.2%) and aged between 2 to 5 years old (n=57, 87.7%). They were mainly diagnosed with epilepsy for less than one year (n=63, 96.9%) and had two types of medications (n=38, 58.5%) (Table 3). The duration of time to complete the questionnaire was around 15 minutes.

The mean (SD) total score of PEMSQ for the respondents was 117.4 (7.7) out of 135 which suggested good self-management. The Cronbach's alpha coefficient of the overall questionnaire was calculated to be 0.877. All domains except for Beliefs about Medication Efficacy managed to meet the minimum acceptable Cronbach's alpha values of 0.60 (Table 4). Having said that, the average inter-item correlations for all domains were within the range

of 0.15 to 0.50, demonstrating acceptable internal consistency.

As for the total-items statistics, it was found that removing any item from the domains would not significantly increase the Cronbach's alpha values (Table 5).

For the construct validity, it was noted that most of the domains were correlated with each other ($p<0.05$). Only two of the Pearson's correlation coefficients were not statistically significant involving Beliefs about Medication Efficacy domain (Table 6).

Discussion

In this study, the forward-backward translation of PEMSQ from English to Malay language was first employed before the validation processes were carried out. The validation aspects attempted were content validity, face validity as well as internal consistency and construct validity. For content validation, all 27 items from the translated PEMSQ had obtained excellent level of agreement among the expert panels. We manage to achieve I-CVI and CVI average of 1.00, which indicated that the contents were highly relevant to be used in the targeted respondents [17]. It is suggested that the I-CVI must be 1.00 when there are five or fewer experts. This means that all experts must agree that the item is content valid [15].

In terms of face validity, the FVI scores for all items were satisfactory as the values were more than 0.80, showing good and clear understanding of the respondents towards the language used and the contents of the questionnaire [17]. Hence, all of the items in the translated PEMSQ were able to be retained.

Following the validation process, the reliability testing for the internal consistency was conducted. Cronbach's alpha was used considering it is one of the most common measures of internal consistency or reliability. It describes the inter-correlations of the items within the questionnaire whereby the coefficient generally improves as the inter-correlations among test items increase [21]. A reliable instrument is usually cited as having a value of more than 0.70 [22]. However, in some literature, the acceptable value is set at minimum 0.60 and lowest at 0.50 [23]. However, we decided that the minimum value should be 0.60, similar to the development of the original PEMSQ [5]. All domains managed to achieve more than 0.60 except for Beliefs about Medications Efficacy (0.550). As Cronbach's alpha is heavily influenced by the number of items in a scale, this problem was anticipated since that domain consisted of only 3 items. It should always be interpreted cautiously, as relying on just Cronbach's alpha is not sufficient to judge if a scale in a questionnaire is well-designed [24].

A close inspection on the correlation matrix of all items in a scale can reveal a more concerning scale quality. It refers to the degree of correlation among all of the items on a scale [24], [25]. The average inter-item correlation was found to be a more appropriate statistic to determine the internal consistency of a scale with a small number of items. Its ideal range is said to be between 0.15 to 0.50 [26], [27]. The average inter-item correlation for Beliefs about Medication Efficacy was within the range, and thus, should be considered as reliable despite its low Cronbach's alpha value.

Another way to improve the Cronbach's alpha value is by assessing the total-item statistics. This can be done by dropping the items with low correlations to shorten a scale without going below a certain level of reliability [21]. However, we found that none of the items removed can significantly raise the reliability for Beliefs about Medications Efficacy. Moreover, it is recommended that a domain should consist of at least 3 items to exhibit sufficient reliability [28]. Due to these reasons, it was decided to keep all of the items in Beliefs about Medications Efficacy. Moreover, a thorough discussion with the panellists suggested that the domain was to be remained as it was. There was no need to add

more questions as it managed to achieve the targeted inter-item correlation.

In the present study, we noted that there was a degree of correlation between the domains in the translated PEMSQ. This is by considering that the majority of correlation coefficients were significant except for two which involved Beliefs about Medication Efficacy. According to previous publications, Pearson's correlation was among the tests used for construct validity [5], [18], [29]–[31]. A very high degree of correlation is a sign that the domains are measuring the same aspect of an item. Because of the weak to moderate degree of correlations obtained in this study, the domains could be said as independent of each other but still owned a relationship between them. This was expected as all four domains contributed to the same dimension of epilepsy self-management [18].

This study represented the initial psychometric evaluation of the PEMSQ and had some limitations. Due to the small number of sample size, the test-retest reliability was unable to be executed as it might increase further chances of drop out. Because of the same reason, factor analysis was also not possible. Pearson's correlation may not be the ultimate test for construct validity as it is proposed that measures of psychological constructs are validated using factor analysis. Also, the construct validity was assessed within the domains only and was not compared with clinical parameters such as self-reported adherence and frequency of seizures.

Conclusion

The Malay version of the PEMSQ is found to be a valid and reliable self-administered questionnaire to measure self-management among caregivers of children between 2 and 14 years old with epilepsy. It has been cross-culturally adapted and evaluated for use in this specific patient population with satisfactory levels of validity and internal consistency. Hence, it is proposed to be used within the clinical setting to guide decision-making and improve the outcomes of children with epilepsy. Further refinement of the research instrument can be considered, including a confirmatory factor analysis.

Table 1. The CVIs calculated from five experts.

Items	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	I-CVI
Disease and Treatment Knowledge and Expectations						
Q1	4	4	4	4	3	1.00
Q2	4	3	3	4	4	1.00
Q3	4	4	3	4	3	1.00
Q4	3	4	4	4	3	1.00
Q5	3	3	4	4	4	1.00
Q6	4	3	3	4	4	1.00
Q7	4	4	3	4	4	1.00
Q8	3	4	3	4	3	1.00
CVI average						1.00
Adherence to Medications and Clinic Appointments						
Q9	4	3	4	4	4	1.00
Q10	4	4	3	4	4	1.00
Q11	4	3	3	4	4	1.00
Q12	3	4	3	4	4	1.00
Q13	3	3	4	4	4	1.00
Q14	3	4	3	4	4	1.00
Q15	3	4	3	4	4	1.00
Q16	3	4	4	4	4	1.00
CVI average						1.00
Beliefs about Medication Efficacy						
Q17	4	4	4	3	4	1.00
Q18	4	4	3	4	4	1.00
Q19	4	4	3	3	3	1.00
CVI average						1.00
Barriers to Treatment						
Q20	4	3	4	4	4	1.00
Q21	4	4	3	4	4	1.00
Q22	4	4	3	4	3	1.00
Q23	4	4	3	4	4	1.00
Q24	4	4	4	4	4	1.00
Q25	3	4	3	4	4	1.00
Q26	3	4	3	4	4	1.00
Q27	4	4	4	4	4	1.00
CVI average						1.00

*I-CVI: Item content validity index; Q: Question; Scale 1 to 4 range: Not relevant to very relevant; CVI average across the five experts = 1.00

Table 2. The FVIs calculated from 10 respondents.

Items	Rater 1	Rater 2	Rater 3	Rater 4	Rater 5	Rater 6	Rater 7	Rater 8	Rater 9	Rater 10	I-FVI
Disease and Treatment Knowledge and Expectations											
Q1	3	3	4	4	4	2	1	3	4	3	0.80
Q2	2	4	4	4	4	4	4	3	3	3	0.90
Q3	3	4	4	4	3	4	3	4	4	3	1.00
Q4	3	4	4	4	4	4	4	3	4	2	0.90
Q5	4	3	4	4	4	4	3	3	3	4	1.00
Q6	3	4	4	3	4	4	4	3	4	3	1.00
Q7	4	4	3	2	4	4	4	3	3	3	0.90
Q8	3	4	2	4	3	4	4	3	3	2	0.80
FVI average											0.90
Adherence to Medications and Clinic Appointments											
Q9	4	4	4	4	4	4	4	3	4	4	1.00
Q10	4	4	4	4	4	4	4	3	4	4	1.00
Q11	4	4	4	4	4	4	4	3	4	4	1.00
Q12	4	4	4	4	4	4	4	3	4	4	1.00
Q13	4	4	4	4	4	4	4	3	4	3	1.00
Q14	4	4	3	4	3	4	3	3	4	4	1.00
Q15	4	4	4	4	4	4	4	3	4	3	1.00
Q16	3	4	4	4	4	4	4	3	4	4	1.00
FVI average											1.00
Beliefs about Medication Efficacy											
Q17	3	4	4	3	4	4	4	3	4	4	1.00
Q18	3	4	4	4	4	4	4	3	4	4	1.00
Q19	3	4	4	4	4	4	4	3	4	4	1.00
FVI average											1.00
Barriers to Treatment											
Q20	4	4	3	2	4	4	2	3	3	4	0.80
Q21	3	4	1	2	3	3	3	3	4	4	0.80
Q22	4	4	1	3	4	3	3	3	4	4	0.90
Q23	1	4	1	3	4	4	4	3	4	4	0.80
Q24	4	4	1	3	4	3	3	3	3	4	0.90
Q25	1	4	1	4	4	4	3	3	3	4	0.80
Q26	3	4	4	3	4	2	4	3	4	4	0.90
Q27	3	4	1	3	4	4	4	2	4	4	0.80
FVI average											0.80

†I-FVI: Item face validity index; Q: Question; Scale 1 to 4 range: Not clear and not understandable to very clear and understandable; FVI average across the 10 respondents = 0.80 to 1.00

Table 3. Characteristics of the respondents and their child in the pilot study (n=65)

Characteristics	n (%)
Gender	
Male	26 (40.0)
Female	39 (60.0)
Age (years old)	
20 to 40	55 (84.6)
41 to 60	10 (15.4)
Ethnicity	
Malay	64 (98.5)
Non-Malay	1 (1.5)
Level of education	
Secondary	17 (26.2)
Tertiary	48 (73.9)
Relationship	
Parents	61 (93.9)
Grandparents	4 (6.1)
Gender of the child	
Male	43 (66.2)
Female	22 (33.8)
Age of the child (years old)	
2 to 5	57 (87.7)
6 to 14	8 (12.3)
Duration of epilepsy (year)	
< 1	63 (96.9)
> 1	2 (3.1)
Number of antiepileptic medication(s)	
1	27 (41.5)
2	38 (58.5)

Table 4. The descriptive statistics and reliability of the Malay version of the PEMSQ

Domains	Mean (SD)	Cronbach's Alpha	Average inter-item correlation
Disease and Treatment Knowledge and Expectations	32.8 (4.0)	0.882	0.485
Adherence to Medications and Clinic Appointments	34.9 (3.1)	0.802	0.362
Beliefs about Medication Efficacy	12.5 (1.0)	0.550	0.289
Barriers to Treatment	37.8 (4.3)	0.622	0.274
Total Self-Management	117.4 (7.7)	0.877	0.379

Table 5. The internal consistency of total-item statistics

Items	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Disease and Treatment Knowledge and Expectations				
Q1	28.65	10.795	0.842	0.845
Q2	28.92	12.635	0.600	0.873
Q3	28.29	13.898	0.401	0.890
Q4	28.54	13.034	0.653	0.868
Q5	29.06	12.715	0.598	0.873
Q6	28.82	12.872	0.617	0.871
Q7	28.51	12.598	0.746	0.859
Q8	28.49	12.473	0.769	0.857
Adherence to Medications and Clinic Appointments				
Q9	29.80	7.194	0.768	0.747
Q10	30.25	7.782	0.389	0.799
Q11	29.95	7.951	0.500	0.783
Q12	29.97	8.187	0.413	0.794
Q13	30.45	7.063	0.471	0.792
Q14	30.02	7.765	0.418	0.794
Q15	29.78	7.234	0.751	0.750
Q16	29.83	6.799	0.551	0.776
Beliefs about Medication Efficacy				
Q17	8.03	0.468	0.454	0.284
Q18	8.55	0.595	0.380	0.424
Q19	8.46	0.627	0.262	0.596
Barriers to Treatment				
Q20	33.08	3.228	0.409	0.562
Q21	33.29	3.648	0.161	0.640
Q22	33.09	2.741	0.653	0.471
Q23	32.82	4.309	0.000	0.635
Q24	33.15	3.288	0.340	0.585
Q25	33.32	3.253	0.256	0.621
Q26	33.05	3.545	0.365	0.580
Q27	32.91	3.804	0.369	0.591

Table 6. The correlations among the domains of the Malay version of the PEMSQ

Domains	Disease and Treatment Knowledge and Satisfaction	Adherence to Medications and Clinic Appointments	Beliefs about Medication Efficacy	Barriers to Treatment	Total Self-Management
Disease and Treatment Knowledge and Satisfaction	1.00	0.524 (<0.001)	0.181 (0.150) ‡	0.254 (0.041)	0.828 (<0.001)
Adherence to Medications and Clinic Appointments	0.524 (<0.001)	1.00	0.433 (<0.001)	0.455 (<0.001)	0.857 (<0.001)
Beliefs about Medication Efficacy	0.181 (0.150) ‡	0.433 (<0.001)	1.00	0.135 (0.283) ‡	0.438 (<0.001)
Barriers to Treatment	0.254 (0.041)	0.455 (<0.001)	0.135 (0.283) ‡	1.00	0.604 (<0.001)
Total Self-Management	0.828 (<0.001)	0.857 (<0.001)	0.438 (<0.001)	0.604 (<0.001)	1.00

‡p-value >0.05

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