

Translation and Validation Study of Eustachian Tube Dysfunction

Questionnaire (ETDQ-7) Into Bahasa Malaysia

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Dissertation Submitted in Partial Fulfilment Of the Requirements of

the Degree of Master of Medicine

(Otorhinolaryngology – Head and Neck Surgery)



SCHOOL OF MEDICAL SCIENCES

UNIVERSITI SAINS MALAYSIA

MAY 2022

ACKNOWLEDGEMENT

I would like to thank my supervisor, Associate Prof. Ramiza Ramza Bin Ramli, a Senior Consultant in our department, Department of Otorhinolaryngology – Head and Neck Surgery, for his guidance and unfailing support. I would like to extend my appreciation and gratitude to my co-supervisor, Dr Nik Adilah Binti Nik Othman for her invaluable advice and guidance throughout this dissertation process. Special thanks to Nurzulaikha PhD student Biostatistics and Research Methodology Unit, Universiti Sains Malaysia. Kubang Kerian, Kelantan for her expertise in the area of statistical analysis in this study.

I would like to acknowledge the original author of the ETDQ-7 questionnaire, Professor Vijay Anand MD FACS, Clinical Professor of Otolaryngology-Head and Neck Surgery, Weill Cornell Medical College, New York Presbyterian Hospital Weill -Cornell Medical Centre for giving permission to translate this questionnaire.

I would like to thank my beloved wife Neoh Hui Pheng, and my parents for providing me all the mental and emotional support throughout my course work and making this work a reality.

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ABSTRAK (BAHASA MELAYU)

Pengenalan: Disfungsi tiub eustachian kronik (DTE) merupakan patofisiologi kepada banyak penyakit di telinga tengah. Namun masih terdapat kekurangan kelengkapan diagnostik untuk keadaan ini. ETDQ-7 merupakan satu soal selidik yang terdiri daripada 7 soalan telah dikaji secara konsisten dan terbukti boleh dipercayai dan sah untuk penilaian disfungsi tiub eustachian. Kami berhasrat untuk menterjemah ETDQ-7 ke dalam versi Bahasa Malaysia (BM) dan menentukan kesahihannya.

Methodologi: Kajian ini dijalankan di Jabatan Otorinolaringologi, Pembedahan Kepala dan Leher Universiti Sains Malaysia dari Mac 2020 hingga Januari 2021. Penterjemahan ETDQ-7 ke versi Bahasa Malaysia telah dihasilkan berikutan translasi "forward" dan "backward". BM-ETDQ-7 menjalani ujian "Face Validity" (FV) dalam 10 pesakit. Berikutan indeks FV yang memuaskan, 126 peserta, termasuk 60 peserta dengan DTE dan 66 peserta kawalan sihat telah diambil untuk melengkapkan BM-ETDQ-7. Peserta yang dikumpulkan dalam DTE adalah mereka yang mempunyai aduan DTE positif dan tympanogram yang tidak normal. Subset peserta daripada kedua-dua kumpulan mengulangi BM ETDQ-7 dalam jangka masa 2 minggu

Keputusan: BM-ETDQ-7 menghasilkan nilai Cronbach α sebanyak 0.878. Kebolehpercayaan ujian-ujian semula menunjukkan pekali ICC yang baik (>0.9), dan korelasi yang baik ($r > 0.8$). BM-ETDQ-7 menunjukkan diskriminasi yang baik antara kedua-dua kumpulan dengan individu dan jumlah skor min lebih tinggi. Skor 17.5 didapati sebagai nilai optimum untuk membezakan kedua-dua kumpulan.

Kesimpulan: Kajian ini menunjukkan kebolehpercayaan dan kesahihan BM-ETDQ-7 yang baik apabila digunakan untuk peserta ETD dan peserta yang sihat. Kami mengesyorkan penggunaan BM- ETDQ-7 dalam amalan klinikal di kalangan penduduk Bahasa Malaysia.

ABSTRACT (ENGLISH)

Introduction: Chronic eustachian tube dysfunction (ETD) is the pathophysiologic basis of many middle ear diseases. Unfortunately there is a lack of diagnostic tool for this condition. The ETDQ-7 is a 7-item questionnaire which has been consistently studied and proven reliable and valid for the evaluation of eustachian tube dysfunction. We aim to translate ETDQ-7 into Bahasa Malaysia (BM) version and determine its validity.

Methods: This cross-sectional study was carried out in the Otorhinolaryngology , Head and Neck Surgery Department of University Sains Malaysia from March 2020 until January 2021. Translated Bahasa Malaysia version of ETDQ-7 was produced following rigorous forward and backward translation. The BM-ETDQ-7 undergo Face Validity (FV) testing in 10 patients. Following satisfactory FV index, 126 participants, including 60 participants with ETD and 66 healthy control participants were recruited to complete the BM-ETDQ-7. Participants grouped in ETD were those who have positive ETD complains and abnormal tympanogram. A subset of participants from both group repeated the BM ETDQ-7 in time frame of 2 weeks

Results: Internal consistency testing of translated ETDQ-7 yielded a Cronbach α value of 0.878. Test- retest reliability showed good ICC coefficient (>0.9), and good correlation ($r > 0.8$). The BM-ETDQ-7 showed good discrimination between both groups with a significantly higher individual and total mean score. A score of 17.5 were found to be the optimal value to differentiate both groups.

Conclusion: The present study showed good reliability and validity of BM-ETDQ-7 when applied to both ETD and healthy participants. We recommend the use of BM-ETDQ-7 in clinical practice among Bahasa Malaysia- speaking population.

Chapter 1

INTRODUCTION

CHAPTER 1: INTRODUCTION

The eustachian tube (ET) plays an important role to maintain equilibrium of the pressure of the middle ear (ME) with regards to the environmental pressure changes. The human ET measures about 3-4 cm and can be divided into the bony part and the fibrocartilaginous part (1). Basic function of Eustachian tube are pressure equalization and ventilation of the middle ear, mucociliary clearance of secretions from the middle ear, and protection of the middle ear from sounds and from pathogen and secretions from the nasopharynx (2).

Eustachian tube dysfunction (ETD) affects roughly up to 1-5% of adult population and this condition can have significant impact on the quality of life (3). Participant may present with a wide variety of symptoms such as aura fullness, tinnitus, popping discomfort and occasionally ear pain and discomfort, autophony and muffled hearing.

The clinical assessment of participant with suspected ET dysfunction is subjective based on a wide variety of clinical complains, physical examination and some ancillary test such as tympanometry, tuning fork test, pure tone audiometry and nasopharyngoscopy. In a recent consensus regarding ETD by Schilder et al, the authors agreed that individual signs and symptoms cannot be used reliably to diagnose ETD (4). Only by using a combination of clinical symptoms and signs supported by ancillary test are clinicians able to diagnose and classify the subtypes of ETD. Tympanometry is a good tool to demonstrate ETD by revealing a negative ME pressure or Jerger type C pattern. However it should be noted that this test is made at a single point, and a normal ME pressure may

not exclude obstructive or patulous ETD (5). Furthermore, tympanometry is not a tool that is readily available in primary care.

Nasopharyngoscopy are helpful in the case of inflammatory or dilatory ET dysfunction, where examination may reveal an inflamed Eustachian tube orifice or identifying obstructive masses in the area of the ET as in the case of nasopharyngeal carcinoma, enlarged adenoid tissues or other tumours encroaching the tubal orifice. Again however, this tool is not readily available in primary setting. Imaging technique such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) are not recommended for routine use for diagnosing ETD outside of research setting (6).

Considering the impact of ETD to the quality of life, and taking into consideration that diagnosis is mainly clinical and there are many emerging new techniques for the treatment of ETD such as eustachian tuboplasty or balloon dilatation, Mc Coul et al (7) developed a questionnaire to assess ETD known as the Eustachian Tube Dysfunction Questionnaire-7 (ETDQ-7) which consists of 7 items related with symptoms of ETD and a scale of response ranging from 1 to 7 with "1" corresponding to absence of symptoms, and "7" corresponding to maximum symptom severity. The questionnaire is modelled on other popular questionnaire such as the Otitis Media 6-Item Quality-of-Life Survey (OM-6) and 20-Item Sino-Nasal Outcomes Test (SNOT-20). The author has found that the total item score cut point of ≥ 14.5 versus < 14.5 or a mean score of ≥ 2.1 (for categorizing a participant as having ETD) provided 100% sensitivity and 100% specificity of differentiating participant with or without ETD. ETDQ-7 has been extensively validated

not only in other English study (8) but has also been translated and validated in other languages such as German (9), Brazil (3), Turkish (10), Danish (11) and Portuguese (12) all of these studies reporting a valid and reliable tool after translation.

The main advantage of ETDQ-7 is that it allows for quantitative measurement of symptoms rather than getting a clinical history alone. Quantification of symptom score allow for assessment of disease severity, follow-up and monitoring of treatment outcome. As the questionnaire was originally published in English, there is need to translate it into Bahasa Malaysia so that it can be culturally adapted to our country and to compare the translated questionnaire with existing standards for diagnosing ETD which is via a combination of history, clinical examination and supportive ancillary test (4). The translated and validated Bahasa Malaysia version of ETDQ-7 will facilitate early detection and early treatment to help in preventing sequelae of ETD.

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Chapter 2

OBJECTIVES OF THE STUDY

CHAPTER 2: OBJECTIVES OF THE STUDY

2.1 GENERAL OBJECTIVES

To translate and validate ETDQ-7 questionnaire into Bahasa Malaysia version.

2.2 SPECIFIC OBJECTIVES

The specific objectives for this study are as the following:

- i) To forward and backward translate the ETDQ-7 into Bahasa Malaysia
- ii) To determine face validity of the BM- ETDQ-7.
- iii) To determine the internal consistency and test-retest reliability of BM- ETDQ-7
- iv) Assess discriminant validity of translated questionnaire by comparing mean score of ETD vs non-ETD group and using Receiver Operating Curve analysis to determine optimal area under the curve (AUC) and cut-off point between the 2 groups.

Chapter 3

MANUSCRIPT

3.1 TITLE PAGE

Translation and Validation Study of Eustachian Tube Dysfunction Questionnaire (ETDQ-7) Into Bahasa Malaysia

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3.2 ABSTRACT

Introduction: Chronic eustachian tube dysfunction (ETD) is the pathophysiologic basis of many middle ear diseases. Unfortunately there is a lack of diagnostic tool for this condition. The ETDQ-7 is a 7-item questionnaire which has been consistently studied and proven reliable and valid for the evaluation of eustachian tube dysfunction. We aim to translate ETDQ-7 into Bahasa Malaysia (BM) version and determine its validity.

Methods: This cross-sectional study was carried out in the Otorhinolaryngology , Head and Neck Surgery Department of University Sains Malaysia from March 2020 until January 2021. Translated Bahasa Malaysia version of ETDQ-7 was produced following rigorous forward and backward translation. The BM-ETDQ-7 undergo Face Validity (FV) testing in 10 patients. Following satisfactory (0.83) FV index, 126 participants, including 60 participants with ETD and 66 healthy control participants were recruited to complete the BM-ETDQ-7. Participants grouped in ETD were those who have positive ETD complains and abnormal tympanogram. A subset of participants from both group repeated the BM ETDQ-7 in time frame of 2 weeks

Results: Internal consistency testing of translated ETDQ-7 yielded a Cronbach α value of 0.878. Test- retest reliability showed good ICC coefficient (>0.9), and good correlation ($r > 0.8$). The BM-ETDQ-7 showed good discrimination between both groups with a significantly higher individual and total mean score. A score of 17.5 were found to be the optimal value to differentiate both groups.

Conclusion: The present study showed good reliability and validity of BM-ETDQ-7 when applied to both ETD and healthy participants. We recommend the use of BM-ETDQ-7 in clinical practice among Bahasa Malaysia- speaking population.

Keywords: *Eustachian tube dysfunction; ETDQ-7; translation; Bahasa Malaysia; validation*

3.3 INTRODUCTION

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3.4 MATERIAL AND METHODS

Ethical approval

The study protocol was approved by Human Research Ethics Committee of Universiti Sains Malaysia (USM/JEPeM/20010027) and the written informed consent was obtained from all participants.

Sample size calculation

Face validity testing was used as the choice of our initial pilot testing, with minimal sample size of 10 participants based on study by Yusof MSB et.al (13). For internal consistency testing, minimal sample size calculation were based on general rule- of thumb of 10 subjects per variable (14). Minimal sample size in our 7 item questionnaire were 70 samples. For discriminant validity testing, minimal sample size taken were based on sensitivity and specificity formula (15) for obtaining a Receiver Operator Curve. We estimated a sensitivity and specificity of are 0.950 and 0.950, respectively. Local study on the prevalence of otitis media effusion is 18.3% (16) were taken to reflect the prevalence of ET dysfunction in our local. Type I error probability and precision were taken as 0.05 and 0.1, with an additional of 20% dropout rate, the minimal sample size were 125 samples. Preceding translational studies of ETDQ-7 (7,10–12) used sample sizes ranging from 30-50 subjects in the ETD group and 20-60 in control group. We use a minimal sample size of 50 for both groups. Therefore, a minimal sample of 125 required for sensitivity and specificity testing.

Subjects, Location and Time

Participants were prospectively enrolled from Otorhinolaryngology Clinic in Hospital University Sains Malaysia. All subjects recruited presented to the clinic from March 2020 till January 2021.

Inclusion and Exclusion Criteria

For inclusion criteria, all participants in this study were at least 18 years old and were able to read in Bahasa Malaysia. They are included into 2 groups. Participants included in the ETD group were those who presented with a history of at least two of the following symptoms in one or both ears over the previous 1 month period: aural fullness or pressure, a sensation of clogged or muffled hearing, recurrent or persistent middle ear effusion (defined as an effusion present on examinations at least 1 month apart), or the inability to rapidly self-equilibrate middle ear pressure following changes in ambient atmospheric pressure and had a retracted or poorly mobile tympanic membrane on pneumatic otoscopy. This group must have abnormal tympanograms. Another group of participant whom did not fulfil the inclusion criteria for the ETD group are those who presented to the clinic with complains not related to ET. They were enrolled as non ETD group. They presented with other complains chiefly recurrent tonsillitis, voice disturbance, cervical node swelling, laryngopharynx masses, snoring, parotid and submandibular masses. This control group of are those that have normal tympanic membrane, nasal cavity findings and normal tympanograms. Participants excluded from the study are those who have recent surgery of the head or neck within 3 months; history of radiotherapy at the head and neck region; evidence of acute upper respiratory infection, including uncontrolled

allergic rhinitis, acute sinusitis, acute otitis media, active chronic suppurative otitis media; cleft palate or history of cleft palate repair; craniofacial syndrome, including Down syndrome.

Procedures : Translation of ETDQ-7 into Bahasa Malaysia

Forward translation from English to Bahasa Malaysia was done by a professional translator from School of Languages, Literacy and Translation USM. The forward Bahasa Malaysia draft were then back translated to English by a different professional translator from School of Languages, Literacy and Translation USM. The forward and backward translated draft was reviewed by a panel of experts of consist of a Rhinologist, Otologist and Audiologist and reconciled before producing the final translation of ETDQ-7 (Table 1).

Grouping Criteria

Participants included in the ETD group are those that have positive ETD complains as previously described, with objective signs of ET dysfunction based on otoscopic or nasoendoscopic findings and supported by abnormal tympanogram either Type B or C. For the non ETD group, are participants who do not present with symptoms pertaining to ETD dysfunction as previously described, and must have a normal otoscope and nasoendoscopic finding and must have normal tympanogram. All grouping between ETD and non-ETD participants in the study was consulted with the attending Otorhinolaryngologist.

Participants grouped for the test-retest reliability were those who agreed to withhold their medication such as usage of antihistamine, nasal decongestants such as oxymetazoline, nasal douching for a duration of two weeks. All participants who fail to be complete the questionnaire in two weeks duration were excluded from this analysis.

Statistical analysis

The statistical calculation and evaluation were performed via IBM SPSS version 26 (IBM, Armonk, NY, USA). Descriptive statistics were employed for selected variables. The findings were presented based on the types and distribution of the data. Categorical data were presented as frequencies and percentages, while numerical data were presented as means and standard deviations or as medians and interquartile ranges if not normally distributed.

Face validity testing of the translated questionnaire was adapted from another study of similar design by Zakaria et al (17). A face validity questionnaire was distributed to 10 participants who were fluent in Bahasa Melayu. Feedback were obtained in a score of 1 to 4 regarding clarity and comprehension of the questionnaire with higher score indicating questions increasing clarity and comprehension. The face validity index for Item and Scale (I-FVI and S- FVI) were calculated respectively. The acceptable index cut-off point were 0.83 based on a study by Mohamad et.al (18).

Internal consistency reliability was assessed by calculating Cronbach α value. Internal consistency was generally considered adequate if Cronbach α was above 0.7.

Test-retest reliability, respondents for the questionnaire were followed up in a time frame of two weeks to reassess the symptoms score. The analysis was performed using the Intraclass Correlation Coefficient (ICC) as well as Pearson Correlation Coefficient. All probability values are two-sided, and a level of significance of less than 0.05 were considered as statistically significant.

For discriminant validity, the difference in mean scores of each item and difference in mean total scores between the ETD and Non-ETD groups were compared using independent sample T- test and a level of significance of less than 0.05 were considered as statistically significant.

Estimates of sensitivity and specificity were measured using a ROC curve with the larger area under curve (AUC) indicating better sensitivity and specificity. Optimal score cut-off point differentiating ETD and non-ETD group were then analysed.

3.5 RESULTS

Subject Demography

Demographic characteristic of participants for the study were presented in Table 2. A total of 126 participants were enrolled for discriminant validation study. Of the 126 participants, 60 were diagnosed with ETD while 66 were non ETD group. The ETD group consisted of 37 female (61.7%) and 23 male (38.3%) while the non ETD group consisted of 39(59.1%) female and 27(40.9%) male. The mean age group in the ETD group was 39 ± 14 while the mean age group in the Non ETD group was 44 ± 16 . In the ETD group, 37 participants (61%) have type B tympanogram while 23 participants (39%) have type C tympanogram. All non ETD participants (100%) have type A tympanogram.

Face Validity

A total of 10 recruits were enrolled for Face Validity testing. They were aged between 35 to 66 years (6 females and 4 males). The I-FVI (Table 3) for ETDQ-7 were found to be ranged from 0.90 to 1.00. Of 7 items in the translated ETDQ-7 questionnaire, 6 items rated 1.00 while only 1 item rated 0.90 for I-FVI. The S-FVI/ Average is 0.98.

Reliability Testing

Internal consistency testing of translated ETDQ-7 yielded a Cronbach α value of 0.878 (very high) for the entire study with the ICC 0.878 (95% CI of 0.842-0.908).

For test- retest reliability, a total of 66 participants fulfilled our criteria suitable for withholding medication was followed up in 14 days. However 4 participants did not fulfil the 14 day timeline were excluded from this part of analysis. A final total of 62 participants were included in statistical analysis. Of these participants, 37 were in the ETD group, while 25 were in the non ETD group (Table 2). The ICC coefficient value of all items were scored above 0.9. Strong correlation between the first and second evaluations for each item of the questionnaire was shown by Pearson correlation coefficient above 0.80; $p < 0.001$ in Table 4.

Discriminant Validity

Mean score and the total mean score for the ETD group versus the Non ETD group were generally significantly different shown in Table 5. Those in the ETD group scored higher with the average difference between the two groups ranged from 6.27 to 15.25 for total mean score and the differences were statistically significant ($p < 0.001$).

ROC analysis shown in Figure 1 shows Area Under the Curve (AUC) of 97.3% (95% CI= 0.943-1.00); $p < 0.001$. The accepted cut-off point of 14.5 in the original study only yielded a sensitivity of 96.5% and specificity of 72.5% in our study. A more optimal cut-off point was found at 17.5 with a sensitivity of 96.5% and specificity of 84.1% (Table 6)

3.6 DISCUSSION

Our work described the process of translation and validation of the ETDQ- 7 into Bahasa Malaysia being the lingua franca of Malaysia. ETDQ-7 remains the only validated disease-specific instrument for ETD used worldwide founded by Mc Coul et.al (7). There remains a notable need to translate this tool in our local setting in the absence of a compelling diagnostic test as an alternative participant-reported outcome measure of ETD. An early diagnosis of ETD potentially prevents severe middle ear pathology.

Previous study on translation and validation of the ETDQ-7 had been undertaken into German, Turkish, Portuguese and Danish and all yielded results similar of the original North American version. Hence the ETDQ-7 is now widely used as an adjunct method for diagnosis and management of ETD participants and is recommended as pre- and post-operative assessment of participants undergoing tuboplasty (9). We follow the method of translation used in other similar local translational and validation study (19) and similar guidelines (20) for medical questionnaire using forward and backward translation with a panel of expert review.

Face validity as a form of response process validation is a systematic and evidence-based approach (13). The overall I-FVI of 0.90 and S-FVI of 0.98 reflects high clarity rating judge by individual rater. This form of face validation has also been adopted in other local study an alternative for measuring content validity (17). Of note could only obtained quantitative assessment as the qualitative assessment was not recorded.

We found good internal consistency with a Cronbach α value of 0.878 with ICC 0.878 (95% confidence interval of 0.842 to 0.908). The Cronbach alpha could suggest that questions are inter-related, and the overall construct is homogeneous. Similar high internal consistency has also been reported in other studies (9-12). Test-retest reliability of Bahasa Malaysia ETDQ-7 demonstrated excellent ICC above 0.9 between repeated measurements after 14 days. The duration of 14 days was chosen similar to other translational studies (10,12) to enable comparison made. We also adopted the protocol by the original study where only participants who did not receive any medical or surgical intervention were chosen for retest as we believed that continuing symptomatic relief medication could improve the score especially in the ETD group. It is arguable that a time frame of two weeks could provide possibility of modification status between two evaluation however, our study showed that the mean test- and retest score were not found to be significantly different.

Overall individual item for translated ETDQ-7 score and total score were significantly higher in the ETD than the non-ETD group reflecting consistency with the overall construct of this questionnaire. Of note, item 1 which translated for "Rasa tekanan dalam telinga?" and item 6 for "Bunyi berdengung dalam telinga?" were found to have significantly higher mean score (10.23 and 11.51 respectively) in the ETD group compared to the non ETD group, which may imply that these two symptoms were more often experienced in ETD participants.

The original English study by Mc.Coul et al yielded a AUC of 100% and a German translation study also shown a good AUC of 98.8% (9). We demonstrated an AUC of 97.3% providing outstanding discrimination score. The generally accepted cut-off point of 14.5 in other studies showed a 100% sensitivity and 100% specificity (7,9). In our study, this cut-off point yielded a sensitivity of 96.5% but a specificity of 72.5%. A cut-off point of ≥ 17.5 was found to provide better balance of sensitivity(96.5%) and specificity (84.1%) in the Bahasa Malaysia ETDQ-7. The specificity in our present study were lower than the specificity reported by Mc Coul et al and this findings were also similarly reported by Hansen et al (11). The author proposed that this low specificity could be due to recruitment of patient with known sensorineural hearing loss in the control group which in some cases complaints of tinnitus in item 7.

Some limitation to the ETDQ-7 are worth mentioning. Response items are focused on the severity of the symptoms. The nature of the events whether it is intermittent, continuous or worsen during certain time of day are not represented in the questionnaire. We have also not assess the concurrent validity with other questionnaire such as the SNOT-22 as was done by Mc Coul et al because a local Bahasa Malaysia version is yet to be adapted.

3.7 CONCLUSION

In conclusion, this study found the translated Bahasa Malaysia version of ETDQ-7 is reliable and valid. Bahasa Malaysia version of ETDQ-7 can provide a simple and valuable alternative for screening ETD participants in our primary health care setting and is useful for screening, and guiding appropriate intervention. The Bahasa Malaysia version of ETDQ-7 may perhaps be utilised further in assessment of intervention outcomes.

3.8 Acknowledgements

We would like to acknowledge the original author of the ETDQ-7 questionnaire, Professor Vijay Anand MD FACS, Clinical Professor of Otolaryngology-Head and Neck Surgery, Weill Cornell Medical College, New York Presbyterian Hospital Weill -Cornell Medical Centre for giving permission to translate this questionnaire. Special thanks to Nurzulaikha PhD student Biostatistics and Research Methodology Unit, Universiti Sains Malaysia, Kubang Kerian, Kelantan for her expertise in the area of statistical analysis in this study.

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