TRANSLATION AND VALIDATION OF MALAY LANGUAGE VERSION OF

THE PATIENT-PHYSICIAN RELATIONSHIP SURVEY (PPRS) (PATIENT

VERSION) AND DETERMINANTS OF AN EFFECTIVE PATIENT-PHYSICIAN

RELATIONSHIP IN THE MANAGEMENT OF IRRITABLE BOWEL SYNDROME

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LIST OF SYMBOLS

$<$	less than
$>$	more than
$\leq$	less than or equal to
$\geq$	more than or equal to
%	percentage

LIST OF ABBREVIATIONS

CBT	cognitive behavioural therapy
CSQ	Consultation Satisfaction Questionnaire
ENS	enteric nervous system
EFA	exploratory factor analysis
FBDSI	functional bowel disorder severity index
GI	gastrointestinal
IBS	irritable bowel syndrome
IBS-C	irritable bowel syndrome-constipation
IBS-D	irritable bowel syndrome-diarrhea
IBS-M	irritable bowel syndrome-mixed
IBS-U	irritable bowel syndrome-unclassified
IQR	interquartile range
MISS	Medical Interview Satisfaction scale
PPR	patient-physician relationship
PPRS	patient-physician relationship survey
SD	standard deviation
SKIP-11	Skala Kepuasan Interaksi Perubatan -11

ABSTRAK

Latar Belakang

Sindrom iritasi usus ialah sesuatu yang lazim dan terapinya melibatkan pendekatan pelbagai cabang. Hubungan pesakit-doktor yang berkesan (PPR) sering mempengaruhi hasil rawatan tetapi penentunya tidak sepenuh diketahui. PPR dapat dinilai dengan menggunakan borang soal selidik PPR yang baru dibuat, tetapi alat ini masih belum diterjemahkan dan disahkan dalam bahasa Melayu.

Kaedah

Kajian asal PPR berbahasa Inggeris (PPRS) (versi pesakit) terlebih dahulu dijemahkan kepada bahasa Melayu, dengan menggunakan pendekatan penjemahan yang standard. Selepas itu, untuk mengesahkan soal selidik PPRS yang diterjemahkan, ia diberikan kepada pesakit dengan sindrom iritasi usus (IBS) (berdasarkan kriteria Rome IV), yang direkrut secara berurutan menggunakan lakaran keratan rentas. Analisis faktor eksploratori (EFA) dan analisis kebolehpercayaan dilakukan untuk menentukan sifat psikometrik PPRS. Soal selidik SKIP-11 versi Bahasa Melayu (tinjauan untuk menilai kepuasan pesakit dan mungkin yang paling tepat dengan PPRS) yang disahkan telah diberikan secara serentak untuk menentukan kesahan perbandingan PPRS. Analisis min dan regresi perbandingan telah dilakukan untuk meninjau penentu PPRS yang berkesan dalam pengurusan IBS.

Hasil

EFA telah menghasilkan tiga faktor. Kaiser-Meye-Olkin ialah 0.798. Ujian sferisiti Bartlett adalah signifikan (P <0.001). PPRS yang telah dijemahkan kepada bahasa Melayu adalah terdiri daripada tiga domain bersamaan dengan 28 perkara. Domain tersebut adalah ciri-ciri interpersonal, jangkaan perawatan klinikal dan aspek komunikasi.

Ketekalan dalaman adalah memuaskan (Cronbach's alpha 0.932). Bagi penentu PPR yang berkesan, seramai 80 pesakit dengan sindrom iritasi usus yang rata-ratanya berumur 52 tahun, iaitu sebanyak 70% berbangsa Melayu dan 52.5% ialah wanita telah memberi maklum balas. Analisis faktor status bujang menunjukkan (median adalah 36, julat antara kuartil adalah 14; nilai-P 0.038) dan pendapatan isi rumah (pendapatan lebih tinggi) (37.67 skor min, 7.98 SD; Nilai-P 0.02) adalah penentu penting kepada PPR yang berkesan. Terdapat hubungan yang cukup signifikan antara PPRS dan SKIP-11iaitu (r=0.3, P =0.007).

Kesimpulan

Kajian mencadangkan bahawa PPRS terjemahan kepada bahasa Melayu (versi pesakit) adalah soal selidik yang sah dan boleh dipercayai untuk menilai PPR. Status perkahwinan bujang dan pendapatan isi rumah yang tinggi adalah penentu PPR yang berkesan dalam IBS.

ABSTRACT

Background

Irritable bowel syndrome is prevalent and its therapy involves multi-pronged approaches. An effective patient-physician relationship (PPR) often affects the treatment outcome but its determinants are not fully known. PPR can be assessed using a newly developed PPR questionnaire, but this tool has not been translated and validated in Malay language.

Method

The original English PPR survey (PPRS) (patient version) was first translated into Malay language, using a standard forward and backward translation approach. Subsequently, to validate the translated PPRS questionnaire, it was administered to patients with irritable bowel syndrome (IBS) (based on the Rome IV criteria), recruited sequentially using a cross-sectional design. Exploratory factor analysis (EFA) and reliability analysis were performed to determine the psychometric properties of PPRS. A validated Malay-version of SKIP-11 questionnaire (a survey to assess patient satisfaction and probably the closest to PPRS) was administered concomitantly to determine the comparative validity of PPRS. Comparative mean and regression analyses were conducted to explore the determinants of effective PPRS in the management of IBS.

Results

The EFA yielded three factors. The Kaiser-Meye-Olkin was 0.798. Bartlett's test of sphericity was significant (P <0.001). The final Malay-translated PPRS consisted of three domains with 28 items. The domains included interpersonal features, clinical care expectations and aspects of communication. The internal consistency was satisfactory (Cronbach's alpha 0.932). For the determinants of effective PPR, a total of 80 patients with irritable bowel syndrome with the mean age 52, 70% Malay and 52.5% female had

responded. Factor analysis showed marital status(single) (median36, interquartile range 14; P-value 0.038) and household income (higher income) (mean score 37.67, SD 7.98; P-value 0.02) were the significant determinants of effective PPR. There was a fair significant correlation between PPRS and SKIP-11(r=0.3, P =0.007).

Conclusion

The study suggested that the Malay-translated PPRS (patient version) is a valid and reliable tool to be used to assess PPR. Marital status of single and high household income are the determinants of effective PPR in IBS.

INTRODUCTION

Irritable bowel syndrome is a common chronic functional gastrointestinal (GI) disorder. The worldwide estimated prevalence is 11.2% and varies based on the geographical area, age, gender and diagnostic criteria. [1,2] The pathophysiology is a complex interaction between the brain, enteric nervous system, immune changes and hormonal dysregulation. [3,4]

The current gold standard diagnosis relies on symptom-based diagnostic criteria by ROME IV. [3,4] The common clinical feature is abdominal pain associated with abnormal or alternating bowel habits. This is a disorder with relapse and remitting history therefore it leads to a high economic burden.[1,4]

The management aims to treat the symptoms and improve the quality of life. The strategies included pharmacological, psychological, behavioural and complementary interventions. [5,6] Non-pharmacological approach is also important, including a good patient-physician relationship, identification of contributing factors and continuous care. [2]

Patient satisfaction is an important predictor of health outcomes and measures the quality of care. Satisfaction with the consultations has its implications in the effectiveness of therapeutic interventions. [7] The satisfaction of patients in patient-physician interaction is described as doctors showing interest in patient's health problems, able to provide descriptions of the disease and prognosis, giving them opportunities to talk about health and how the disease affects their life. [8]

The tools used to measure patient satisfaction had been validated and were found to be reliable, one of which is the SKIP-11 questionnaire.[9] A patient-centred approach with the analysis on effective interaction is essential when helping patients manage their chronic illness. [10]

However, these tools are not always suitable for a specific condition (for example, functional GI disease including irritable bowel syndrome.) Thus, there has been an interest to develop a more specific questionnaire targeting this group of patients, one of which is the recently developed Patient-Physician Relationship (PPR) questionnaire.

Many patients with irritable bowel syndrome have no satisfactory treatments. Researches have shown that patient-physician relationships impact patient satisfaction. Few validated questionnaires are available for the user to test patient-physician relationship in irritable bowel syndrome. However, none was done at a local level. The purpose of this research project is to translate the patient version of the patient-physician relationship questionnaire and study the perspective of the patients to learn the factors that affect the quality of the patient-physician relationship in the management of irritable bowel syndrome. These studies will fill this gap in knowledge and aim to explore determinants of patient expectations in physician interaction.

LITERATURE REVIEW

Current IBS consensus

The diagnosis is based on a new Rome IV criteria as recurrent abdominal pain related to two or more of the following: defecation–related, alteration in stool frequency, and changes in the stool form. The onset occurs at least six months before the diagnosis, and symptoms should be presented in the last three months. [11,12,13]

IBS classified by predominant bowel habit into diarrhea-predominant IBS (IBS-D; >25% Bristol Stool Scale form type 6 or 7 and <25% Bristol Stool Scale form type 1 and 2), constipation-predominant IBS (IBS-C; >25% Bristol Stool Scale form type 1 or 2 and <25% Bristol Stool Scale form type 6 and 7) or mixed form IBS (IBS-M; >25% Bristol Stool Scale form type 1 or 2 and >25% Bristol Stool Scale form type 6 and 7). [12]

The risk factors reported female gender, duration of acute diarrhea illness, and presence of life stressor.[13] The study showed that IBS impaired daily activity with social activity, quality of life, and psychosocial.[14]

The current literature proved that the choice of pharmacological treatments should be based on the nature and severity of the symptoms. The medication included laxative, antidiarrheal, antispasmodic, probiotic, serotonin receptor agonists and antagonists and anti-inflammatory therapies.[15] Non-pharmacological treatments recommendation are cognitive behavioral therapy (CBT), acupuncture and diet modification.[5,11]

The goal of treatment is relieving symptoms by education and support. The treatment process is important to maintain a therapeutic relationship towards eliminating the IBS symptoms and improve patients' quality of life. [16]

Patient and physician relationship

The patient-physician relationship is the foundation of medical care. The quality of this relationship is important for chronic illness management. [10] The challenges in the treatment, the interplay of psychosocial factors and the dependence of successful outcome on a positive doctor-patient relationship has been highlighted in the management of IBS. [17] Doctors are aiming to help patients with IBS in managing illness-related interpersonal problems as a way to improve patient care. A significant aspect of fostering this relationship provides effective patient-centred education about IBS.

Active listening, not interrupting, using empathy, setting realistic expectations, and using nonverbal techniques can help build this relationship. [18] The doctor must understand the patient's goal and avoid focusing only on the gastrointestinal symptoms. Many patients identify a caring physician performs a physical examination and provides education regarding the causes, natural history and treatment of IBS. [19]

Three major themes to determine IBS patients' illness experience are the feeling of frustration from the lack of control, a sense of isolation and dissatisfaction with available treatments, information received and the health care system in general. The

most commonly unmet patient expectations are for the doctor to show more empathy, to create rapport and to provide disease-related education. [10]

Studies have indicated that positive aspects of the therapeutic relationship may contribute to a decrease in the level of stress, depression, anxiety and severity of symptoms and improve the overall quality of life, subsequently long-lasting improvement has been demonstrated.[20]

Patient-physician questionnaire

There is an increasing number of survey instruments to provide feedback on doctors' practices from patients. The survey can be elicited using different methods of either an interview or open-ended questions. The patients' perceptions and suggestions for changes can address the experience and help to assess and improve the quality of medical care delivered.[20]

The mmeasurement of the patient-physician relationship to evaluate and follow-up the disease is important in the management of chronic illness. A structured approach such as using the multiple item questionnaire with Likert scale response categories produces data that are easier to handle but require validity and reliability. Validated questionnaires such as the Medical Interview Satisfaction Scale (MISS), Consultation Satisfaction Questionnaire (CSQ), Patient Experience Questionnaire and Patient Enablement Instrument exclusively address the patient's perspective. [21]

While a multiple-item questionnaire is a format that is commonly used, the difficulties that arise for researchers are choosing between particular questionnaires and assessing whether further psychometric testing is required and cultural differences re-evaluated before being applying in different settings. Many questionnaires have been developed for single studies and have not achieved widespread use. CSQ and MISS are two tools that are widely used to measure satisfaction. A study comparing MISS and CSQ showed neither questionnaire was superior to the other in psychometric terms while MISS focused more on physician's humaneness.[7] MISS was developed to look especially at satisfaction with individual consultations using four subscales (communication comfort, distress relief, compliance intent and rapport).

In Malaysia, Abd Aziz et al (2013) translated and validated the Malay version of MISS questionnaire.[22] "Skala Kepuasan Interaksi Perubatan -11 (SKIP-11)" is a modification of the Malay version of MISS-21 with three domains (distress relief, rapport and interaction outcome) and 11 items are acceptable for use in assessing patient satisfaction in patient-physician interaction. SKIP-11 questionnaire is a self-administered questionnaire that has been used in several studies to measure patient satisfaction in a primary healthcare setting on the topic of cardiovascular disease risk patients and type 2 diabetic patients. [23]

To study PPR among IBS, A. Halpert et al. (2011) used a method of expressive writing to elicit inpatient perspectives on their relationships with healthcare providers with the limitation of qualitative research, where the results are subject to interpretation

by the author. However, Kurlander et al. (2017) developed a questionnaire measuring patient expectation using PPRS.[24] PPRS was generated after a qualitative analysis through focus group and psychometrically valid to assess the level of expectations that patients with IBS have of their providers. It comprised 32 questions with three domains that were interpersonal features, clinical care expectation and aspects of communication. This questionnaire was developed through a multi-step process used for instrument development but at present, only the English version is available. The development and validation of PPRS can be used in medical training to enhance the quality of therapeutic communication and outcomes.

CHAPTER 2   **OBJECTIVE OF STUDY**

2.1 General objective

To translate and validate the English version of patient-physician relationship survey (PPRS) into Malay version and to evaluate the determinants of effective relationship among irritable bowel syndrome (IBS) patients

2.2 Specific objective

1. To translate the original English version of PPRS (patient version) into the Malay version

2. To perform an exploratory factor analysis of the newly translated Malay version of PPRS

3. To assess the determinants of effective relationship using the newly validated Malay version PPRS among IBS patients

4. To determine comparative validity of the newly translated PPRS scale with "Skala Kepuasan Interaksi Perubatan (SKIP- 11)"

2.3 Research Questions

1. What instrument can be used to measure the determinants of patient-physician relationship in the management of IBS in Malaysia?

2. What are the factors associated with an effective patient-physician relationship in IBS?

2.4 Research Hypothesis

1. The Malay version PPRS is a valid tool to assess Malaysian IBS patients'

expectation

2. The validated Malay version of PPRS is reliable to establish an expectation of IBS

patients in an effective patient-physician relationship

3. Social demographic and disease severity are significant associated factors for a

higher score on PPRS

CHAPTER 3   **MANUSCRIPT**

3.1 TITLE: Translation and validation of the Malay patient version patient-physician

relationship survey (PPRS) and determinants of an effective patient-physician

relationship in management of Irritable Bowel Syndrome

JOURNAL: International Journal of Environmental Research and Public Health

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Keywords: Patient-physician relationship, Irritable bowel syndrome

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3.4 METHODOLOGY

Study design and patient selection

This was a cross-sectional study conducted in a single-centre at Hospital Universiti Sains Malaysia between November 2020 to February 2021.

Patients diagnosed with IBS were recruited from the clinic of Hospital Universiti Sains Malaysia. A total of 120 patients were identified through the outpatient follow up list. All patients of age 18 years old and above, who follow up at least once in the past 6 months were included and invited to participate in this survey. Those with reduced mental capacity and who did not consent to participate in this survey were excluded.

Assessment and measures

The variables for this study were the participant's demographic, clinical background, PPRS and physician-patient interaction satisfaction score. The patient demographic details included age, sex, race, marital status, education level,

employment status and household income. The clinical data information included the frequency of clinic visits, days restricted to work in 6 months, severity and subtype. The patient-physician relationship survey score was measured using translated PPRS and the patient satisfaction in patient-physician interaction score was measured using SKIP-11.

Research tools

Two questionnaires, namely PPRS and SKIP-11 were used in this study. Permission from the authors was obtained. Permission to translate material was replied to emails after the request letter was sent.

These instruments are explained below.

PPRS questionnaire

PPRS was created and modified based on the feedback by patients, gastroenterologist, GI fellows and content experts. The PPRS was validated to be used to assess the level of IBS patients' expectations in PPR. The Patient-physician relationship survey questionnaire consisted of 32 questions in three domains and responses on a 7-item Likert scale. The domains included interpersonal features (trust, respect, honesty, empathy, humour, likeability and creating a sense of connectedness), clinical care expectations (being knowledgeable, perform a physical examination, provide education to the patient education, collaborate with other providers, spend adequate time with the

patient and provide a plan of care) and aspects of communication (not interrupting, not being rude, allowing the patient to feel heard, speaking in an understandable manner and creating a sense of comfort when the patients are talking about problems). Each component was rated ranging from "-3(very undesirable)" to "+3(very desirable)". The sum of the scores was ranged from -96 to +96.

SKIP-11 questionnaire

SKIP-11 is the translated and validated Malay version of the MISS-21 which was conducted to measure patient satisfaction on patient-physician interaction. This questionnaire consisted of 11 questions and responses on a 5-item Likert scale. Theme included distress relief (four items), rapport (four items) and interaction outcome (three items). The total score was within the range of 11 (minimum) and 55 (maximum).

Research Procedure

The original English patient PPR survey (PPRS) was first translated into Malay language, using a forward and backward translation approach. The forward translation involved translating the patient version PPRS into Malay language by two independent translators consisted of a bilingual researcher and a qualified linguistic expert. The Malay translated questionnaire was compared with the original and the discrepancies were discussed between translators and investigators to produce a reconciled version of the translated questionnaire.

The revised Malay translated patient version questionnaire was subsequently back-translated into English by another two independent translators with qualifications. They were completely blinded to the original version of the questionnaire. Two different versions of English questionnaires were discussed and reconciled for any discrepancies. Then, further revision or modification was made to the Malay version. All revisions and modifications were done with consensus among all translators, investigators and research team members. The revisions made to both forward and backward translation during the reconciliation process were documented in a table showing the source language version, the target language version, comments and modifications. In the subsequent validation study, the investigators added questions in the front part of the final translated questionnaire to assess the socio-demographic details and clinical backgrounds.

The name lists of the patients were obtained from the outpatient clinics at Hospital Universiti Sains Malaysia. A total of 120 potential patients who met the inclusion criteria were recruited. The research assistant was trained by the study investigator to explain the study and procedures by telephone. All the eligible subjects were then phone-interviewed by the researcher. Explanations on the study and procedures were given to the patients before the acquisition of informed consent. The researcher interviewed the patients who agreed to participate in this study after the consent was taken. To test the comparable validity, SKIP-11 questionnaire was conducted with PPRS.

Regarding the structural validity, the required sample size was at least five times the number of items, but with 100 individuals as an minimum. To identify the factors associated with PPRS, the calculation was made comparing two mean formula power of 80%, and the sample size was 123 after considering the 10% non-response.

Data and statistical analysis

All analyses were carried out using SPSS version 26 for windows. The structural validity of the final translated version of Malay PPRS questionnaire was evaluated using the exploratory factor analysis (EFA). Kaiser-Meyer-Olkin (KMO) and Bartlett's test of sphericity were computed to justify undertaking a factor analysis. The criterion for factor loadings was set at >0.30. The internal consistency reliability was tested using the Cronbach's alpha, in which a Cronbach's alpha value of 0.75-0.95 was acceptable for internal consistency. The comparative validity was examined using SKIP-11 with Pearson's correlation.

The results for sociodemographic and clinical characteristics, PPRS and SKIP-11 scores were described using descriptive statistics. The categorical variables were presented as frequency and percentages. The continuous variables were presented as the mean and standard deviation for parametric data and presented as median and interquartile range for non-parametric data. While the comparisons between two groups were made using independent t-tests and the comparisons of more than two groups were made by one-way ANOVA for parametric data. The two-group comparisons were made

by Mann-Whitney test and the ones for more than two groups were made by Kruskall Wallis test for non-parametric data. Simple linear regression was performed to assess the parametric correlations between two quantitative variables and P-value <0.05 was considered as statistically significant.

Ethical issue

The permission to conduct the study was obtained from Research and Ethics Committee of Universiti Sains Malaysia. (reference number: USM/JEPeM/20060313).

3.5   RESULT

Psychometric properties assessment

Bartlett's sphericity was significant(P<0.001). KMO was implied that factor analysis could be used to identify the factors. Three factors were extracted among 32 items in the patient-physician relationship scale. A number of four items were deleted in EFA model of Malay version of PPRS (item 18 'refers me to other providers when needed', item 28 'is dismissive', item 30 'seems rush' and item 31 'is not concerned about me'). These factors were clinical care expectation, communication aspect and interpersonal feature. For the clinical care expectation factor, the items were found to have commonalities ranging from 0.28-0.87. For the communication aspect factor, the items were found to have commonalities ranging from 0.42-0.82. Lastly for

interpersonal features, the items were found to have commonalities ranging from 0.28-

0.98. The factor loading ranges for clinical care expectation was 0.39-0.82, 0.55-0.93

for the communication aspect and 0.36-0.81 for the interpersonal feature.

Table 1 Exploratory factor analysis of Malay version of PPRS

Factor	Item	Factor loading	Communality
Clinical care expectation	Listen to me	0.612	0.643
	Provide educational information	0.653	0.799
	Will continue to care for me	0.479	0.631
	Spends adequate time with me	0.583	0.638
	Is empathic and caring	0.423	0.621
	Checks to make sure I understand	0.490	0.275
	Uses language I understand	0.778	0.869
	Accepts my feelings and point of view	0.368	0.706