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Research Article

Validation of The Self-administered Version of The International Restless Leg Syndrome Severity Scale (sIRLS)

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Abstract

Aims: Restless Legs Syndrome (RLS) is a neurological sensorimotor disorder that causes a person to feel the need to move their lower extremities due to uncomfortable sensations. This condition can be monitored to minimize and cure the symptoms. One of the monitoring instrument is The Self-administered version of The International Restless Legs Syndrome Rating Scale (sIRLS). In Indonesia, the sIRLS instrument has not been culturally adapted. This research aims to translate and to test the content validity the Indonesian version of the sIRLS, so that it can further contribute to subsequent psychometric research on this instrument.
Methods: The sIRLS were translated through forward translation, synthesized translation, back-translation, synthesized back-translation, and expert committee by five translators and three expert judges. Content validity was tested through CVR, I-CVI, and S-CVI for the essentiality, relevancy, and clarity of each item.
Results: The first validity test showed a significant value for essentiality and relevancy of all the items (1,00). However the first test showed an insignificant value for the clarity of the seven items (0,33 and 0,66). Therefore the researcher should revise the seven items based on the suggestions from the expert judges and then carry out a second content validity test. Consequently, the final values of the CVR, I-CVI, and S-CVI showed significant values (1,00) for the essentiality, relevancy, and clarity.
Discussions: Many Adaptation and modification on a few terms were required to achieve both meaning and cultural equivalence and also to facilitate understanding of the respondents.
Conclusion: The Indonesian Version of self-administered version of The International Restless Legs Syndrome Rating Scale (sIRLS) is validly reviewed from the essentiality, relevancy, and clarity of the items.

Keywords:
Bahasa Indonesia, content validity, cross-cultural adaptation, restless legs syndrome instrument

INTRODUCTION

Restless Legs Syndrome (RLS) is a sensorimotor disorder caused by a neurological abnormality that causes the patients to always tend to move their arms or legs (1). The cause of this syndrome is still yet to be researched further. However, previous research found a correlation between dopamine imbalance, decreased

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iron in the brain, and impaired iron regulation with the involuntary movement (twitch or muscle spasm) that often occurred in RLS patients (2).

RLS populations are two to three times higher in the chronic kidney disease (CKD) patients population than the general population (3). RLS is primarily found in CKD patients with End Stage Renal Disease (ESRD) who undergo dialysis treatment (4). Studies showed that 30% of patients who undergo Hemodialysis are experiencing RLS symptoms (5). Another study found that 40,7% of patients who undergo Hemodialysis also experience RLS symptoms (6). A case-control study conducted in Taiwan reported that the long duration of Hemodialysis was also one of the driving factors in the occurrence of RLS in patients (7).

According to the Indonesian Renal Registery (IRR), in 2015, it was estimated that the prevalence of CKD would increase by 10% each year. The number is estimated to reach 400 people per population, with the prevalence of CKD patients undergoing Hemodialysis reaching 15,424 patients. In 2016 it was reported that 98% of patients with CKD in Indonesia also undergo Hemodialysis. In 2017 it was estimated that the number of patients with CKD who undergo Hemodialysis was 77.892 patients (8). With the prevalence of CKD increasing every year, this could affect the number of patients undergoing Hemodialysis. This phenomenon could also increase the prevalence of RLS in Indonesia.

However, RLS is often neglected by the healthcare worker because patients have difficulty expressing the symptoms that they are experiencing. Therefore, RLS is often misdiagnosed, and patients are handled too late (9). RLS can cause a person to feel the extreme need to move their upper or lower extremities due to discomfort sensations such as pain, itching, or burning sensation (1). In severe cases, RLS can cause discomfort and anxiety in patients undergoing dialysis therapy, which can potentially cause the patients not interest to continue the dialysis and thus hinder the therapy (10). Therefore, RLS needs to be monitored so that it can be treated and minimized.

The Self-administered Version of The International Restless Leg Syndrome Severity Scale (sIRLS) is a modified version of the International Restless Legs Severity Rating Scale (IRLS) that allows RLS patients to be monitored from the comfort of their own homes. Differ from the IRLS, The sIRLS can be administered with or without the presence of both the patient and examiner, which makes it easier for healthcare workers to assess the patient's condition. The sentence "In the past week" was added to 10 of the modified items to guide the patients to know the time frame of which the items were asked. The sIRLS consists of 11 questions that are valid according to the construct validity test between IRLS and sIRLS which showed the value of 0,80 – 0,94. The sIRLS is also reliable according to the Cronbach Alpha that showed the value of 0,93 (11).

In Indonesia, the sIRLS instrument has not been culturally adapted. Translation of a questionnaire is essential if the instrument is not available in a language spoken by the target population (12). Translating one instrument into another language is also cheaper and faster than developing a new instrument (13).

Besides translation, content validation is also playing a crucial part. Content validity provides information on the representativeness of the content domain and clarity of the items according to the judgment of the expert panel (14). Content validity focuses on the extent to which items represent an adequately prepared definition of a concept (15).Rather than developing new instruments, validating a pre-existing instrument is less complicated and is cost-effective (16).

Previous Indonesian researchers used the IRLS instrument to measure the severity of RLS. However, this research did not adequately explain the translation process

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or the validity test. Therefore, seeing the effect of RLS in patients, the convenience offered by sIRLS instrument, and an absence of the RLS severity scale that has been translated properly, the researcher decided to do a translation and content validation of The International Restless Leg Syndrome Severity Scale (sIRLS). The objective of this research is to do the translation on the sIRLS and test the content validation that comprises the essentiality, relevancy, and clarity of the instrument. The translation of the sIRLS to Indonesia can provide a translated and valid instrument to add to the number of instruments that have been translated. This translation could also provide the following research regarding the instrument's psychometric study.

METHODS

Translation Process

This study uses Gjersing (2010) guideline for cross-cultural adaptation for the translation process. The process includes synthesizing two forward and two back translations and comparing them by a committee of experts (17). Four translators and One linguist were required for this process. To be considered as a translator, the individual must have a nursing education background (master's or doctoral degree) and have studied abroad as an indicator that they are fluent in both English and Indonesian. In the other hand, a linguist does not have to had a nursing education background. The translation process comprise:

1. **Forward Translation**: Two independent translators are required to translate the original sIRLS (English) to Indonesian.
2. **Synthesized translation**: One linguist is required to synthesize the two versions of the forward translations.
3. **Back-translation:** Two independent translators are required to translate the synthesized version (Indonesian), back into English.
4. **Synthesized Back-translation**: The two back-translation results were then discussed with all of the authors regarding the conversion of words and sentences from the forward translation process to synthesized back-translation. As a result, one single synthesized version of the back-translation was obtained.
5. **Expert Committee:** This process provides an expert panel to judge the translated version of the intruments. Three experts judge who have a background in nursing education especially in Medical-surgery nursing and who have an understanding of RLS and GGK topics as well as an understanding of patient characteristics and culture are required (Minimum of one year clinical).This process is conducted to assess few categories from each item of the Indonesian Version of The sIRLS instrument, such as essentiality, relevancy, and clarity. The judges were sent instructions along with the translated version of the instrument. The judges then assessed each items according to three categories, essentiality, relevancy and clarity using a Likert Scale. A likert scaled from 1 to 3 was used to assess essentiality and clarity ; (1) not essential, (2) useful but not essential, and (3) essential; and 1) not clear, (2) the item need revision, and (3) clear. A Likert Scale from 1 to 4 was used to assess relevancy; (1) not relevant, (2) somewhat relevant, (3) quite relevant, and (4) relevant. The judges were asked to write their suggestion and recommendation for the items which rated below 2.

Content Validation

Content validation of the instruments was analyzed with CVR, I-CVI, and S-CVI (18). The assessments results were then analyzed descriptively for each category.The Content Validity Ratio (CVR)

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formula was used to analyzed the essentiality of the items.

CVR = (ne – N/2) / (N/2)

Where ne is the number of experts who gives a rating of 3 and N is the total number of the expert judges (19).

In terms of relevancy and clarity, the value of each category was calculated using the Item-Content Validity Index (I-CVI) and Scale- Content Validity Index (S-CVI). The I-CVI value for each item was calculated by the number of expert judges that rated 4 or 3 divided by the total number of expert judges. The S-CVI was divided into two categories. The Universal Agreement (S-CVI/UA) and the average (S-CVI/Ave). The S-CVI/UA is calculated by summing all item with the I-CVI value equal to 1,00 and then dividind by the total number of items. The S-CVI/Ave calculated by the total value of I-CVI divided by the total number of items. The minimum acceptable S-CVI is considered to be any value between 0.80 to 0.90 (20). The value of CVR and I-CVI should be equal to 1,00 if the number of expert judges is less than five people (13)

Ethical Clearance

The Universitas Achmad Yani (Unjani) ethic committee (044/KEPK/FITKes-Unjani/I/2024) approved this study. All the subjects were informed about the study before they participated. The subjects were given the freedom to decline or withdraw from this study. The author protected the confidentiality of the subjects, including their names.

RESULTS

Translation

In the translation process, differences in translation results or interpretation of each items can occur all of the translators. For example, there were different translations for the terms, “severe” and “in the past week”. Therefore, a thorough discussion is needed to make sure that all of the items meet the accurate translation equivalent to the original version of sIRLS and also match the habitual form and use of the Indonesian Language. After thorough discussion of the translation result provided by all five translator we decided on one final form of a few terms (Table 1).

Table 1. Comparisson of the original terms of sIRLS and translations results.

Item	Original sIRLS	Indonesian Translation	English Translation	Final Indonesian Translation
Q1-Q11	In the past week	*Dalam seminggu terakhir*	In the past week	*Dalam seminggu terakhir*
		Kondisi yang Anda alami minggu lalu	Conditions Experienced in the Last Week	
Q1-Q11	Severe	*Parah*	Severe	*Parah*
		Berat	Heavy	

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The term "In the past week" was translated in to two meaning by two translator. One translator interpreted them as "*Kondisi yang Anda alami minggu lalu*" or "Conditions experienced in the last week" in English. We rated this translation was too complicated and had the potential to confuse and and to be misunderstood by the participants. Therefore, we agreed to choose the term "*Dalam seminggu terakhir*" which was more simple and straight forward. There were also different interpretations of the term "severe". One translator interprated them as "*berat*" or "heavy" in English. We rated that the term was slightly deviated from the original sIRLS form. We also consider habitual form and use of the term "*berat*" which is commonly used to represent the weight of an object by Indonesian's population. Therefore, we agreed upon the terms "*parah*" which was also the literal translation of the term "severe".

Content Validation

First Assessment of Content Validation

The First assessment showed a significant value for essentiality and relevancy category (Table 2). The value of both categories met the minimum value for CVR and I-CVI of three expert judges, which is 1,00 and the S-CVI minimum values are >0,80 (S-CVI/UA) and >0,90 (S-CVI/Ave). The CVR value for essentiality was 1,00 for all items. The I-CVI value for relevancy was 1,00, with only two expert judges rated somewhat relevant in item 2 and one expert judges rated somewhat relevant in item 3. The S-CVI/UA and S-CVI/Ave was also 1,00. However the clarity category showed an insignificant value (Table 2). Only four items were rated as clear and the remaining seven items need to be revised because the value of both I-CVI and S-CVI did not meet the minimum value.The I-CVI for two items were 0,33 and I-CVI for five other items were 0,66. Therefore the S-CVI values were 0,36 (S-CVI/UA) and 0,72 (S-CVI/Ave).

Revision of the items

With the value of I-CVI and S-CVI in the clarity category have not reached the specified minimum value (1,00), changes were needed. The expert committee made changes to seven items of the Indonesia Version of The sIRLS: 1,2,3,4,8,9, and 11 that have not reached the minimum value for I-CVI in clarity category. The changes were done with input from the judges and supporting journals The changes consisted of rewording, replacements, removal, and restricting of the items to facilitate the respondents.. Table 2 showed the revised version of the seven items.

Table 2. Revision of Items That Have Not Met The Minimum Value of I-CVI (Clarity)

No. Item	Items of Instrument	I-CVI	Input	Revised Version
1	*Dalam seminggu terakhir..* *Secara umum, bagaimana Anda menilai Ketidaknyamanan akibat RLS/ Sindrom Kaki Gelisah pada kaki atau lengan Anda?*	0,66	1 out of 3 judges suggested to just use the "RLS" abbreviation	*Dalam seminggu terakhir..* *Secara umum, bagaimana Anda menilai Ketidaknyamanan akibat RLS pada kaki atau lengan Anda?*
2	*Dalam seminggu terakhir..* *Secara umum, bagaimana Anda menilai keinginan untuk bergerak karena RLS yang Anda alami?*	0,33	2 out of 3 judges suggested to give a specification of which body part that wants to be moved	*Dalam seminggu terakhir..* *Secara umum, bagaimana Anda menilai keinginan untuk menggerakkan bagian tubuh, baik kaki atau lengan*

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				akibat RLS yang Anda alami?
3	*Dalam seminggu terakhir.. Secara umum, seberapa banyak rasa tidak nyaman pada tangan dan kaki akibat RLS berkurang setelah bergerak?*	0,66	1 out of 3 judges suggested to replace the word "*banyak*" with "*parah*" to match the answer options	*Dalam seminggu terakhir.. Secara umum, seberapa parah rasa tidak nyaman akibat RLS pada tangan dan kaki berkurang setelah bergerak?*
4	*Dalam seminggu terakhir.. Secara umum, seberapa parah gangguan tidur akibat gejala RLS yang Anda alami?*	0,66	1 out of 3 judges suggested to add the example of sleep disturbances	*Dalam seminggu terakhir.. Secara umum, seberapa parah gangguan tidur Seperti contoh kesulitan tidur, pola tidur berubah, kelelahan karena kekurangan tidur, ketidakpuasan tidur akibat gejala RLS yang Anda alami?*
8	*Dalam seminggu terakhir.. Ketika Anda mengalami gejala RLS, seberapa parah gejala tersebut rata-rata setiap harinya?*	0,66	1 out of 3 judges suggested to reword the items to facilitate understanding from the respondents	*Dalam seminggu terakhir.. Berapa jam rata-rata, dalam sehari anda mengalami gejala RLS?*
9	*Dalam seminggu terakhir Secara umum, seberapa parah dampak RLS terhadap kemampuan Anda melakukan kegiatan harian, sebagai contoh menjalani kehidupan keluarga, kegiatan rumah, sosial, sekolah atau pekerjaan yang menyenangkan?*	0,66	1 out of 3 judges suggested to add example to the activities mentioned in the question	*Dalam seminggu terakhir Secara umum, seberapa parah dampak RLS terhadap kemampuan Anda melakukan kegiatan sehari-hari, sperti menjalani peran dalam keluarga, melakukan tugas rumah, berinteraksi sosial, belajar di sekolah atau menjalani pekerjaan kantor dengan semestinya?*
11	*Pertanyaan Tambahan. Bagaimana gejala RLS yang biasa Anda alami selama setahun terakhir dibandingkan dengan gejala RLS selama 7 hari terakhir ini yang sesuai dengan yang anda*	0,33	1 out of 3 judges suggested to remove the sentence, *"yang sesuai dengan yang anda laporkan di atas*	*Pertanyaan Tambahan. Bagaimana gejala RLS yang biasa Anda alami selama setahun terakhir dibandingkan dengan gejala RLS selama 7 hari terakhir ini (lingkari kata-kata / poinnya*
	Gejala yang biasa menjadi lebih buruk *(1) Sangat buruk* *(2) Jauh lebih buruk* *(3) Agak lebih buruk* *(4) Hampir sama* *Gejala biasa menjadi lebih*		1 out of 3 judges suggested to add (:) punctuation and underline on the instructions of the answer options	*Gejala yang biasa menjadi lebih buruk:* *(1) Sangat buruk* *(2) Jauh lebih buruk* *(3) Agak lebih buruk* *(4) Hampir sama* *Gejala biasa menjadi lebih*

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baik: *(5) Agak lebih baik* *(6) Jauh lebih baik* *(7) Sangat lebih baik*	*baik:* *(5) Agak lebih baik* *(6) Jauh lebih baik* *(7) Sangat lebih baik*

Reassessment of The Revised Version

The revised instrument was then sent back to the three expert judges to be reassessed. The reassessment result showed a significant result, with all three categories showing a CVR, I-CVI, and S-CVI value of 1,00 (Table 3). Therefore, all items were finally considered essential, relevant, and clear.

Table 3. Assessment and Reassessment of Content Validity

———————	First Assessment	Reassessment
Essentiality		
1,00	11	-
CVR	1,00	-
Relevancy		
1,00	11	
I-CVI	1,00	-
S-CVI/ UA	1,00	-
S-CVI/ Ave	1,00	-
Clarity		
0,33	2	-
0,66	5	-
1,00	4	11
———————	**First Assessment**	**Reassessment**
I-CVI	0,72	1,00
S-CVI/ UA	0,36	1,00
S-CVI/ Ave	0,72	1,00

DISCUSSION

Translation of Indonesian Version of sIRLS

The translation process should not only focus on translating the meanings of each item but also on how the translation is acceptable in the local tongue and settings (12). This study aimed to translate the sIRLS and assess the content validation of the Indonesian version of the sIRLS. The final result of the translated and validated instrument, should meet the linguistic and cultural equivalent of the habitual form and use of the Indonesian language while still reflects the same meaning as the original sIRLS instrument.

Researchers must consider several steps when translating an instrument from a foreign language to a local language. One of them is forward/backward translation, which is the most common step used to translate an instrument (21). This process allows an instrument to be translated into a local language without shifting the meaning from the original sIRLS .

At the translation stage, there will be several differences in the translation results, both in the use of terms and in the

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sentences. This can happen in the forward/back-translation process due to different interpretations between translators. Therefore, a discussion process is needed to analyze the translation results with the original instrument form to obtain the correct composition of the final version of the translated instrument (16).

It is also essential for the sentence/ word to be easily understood by the participants according to their educational level and their culture (12). For example the term "In the past week" was translated to "*Dalam seminggu terakhir*" which was rated much easier to understand by the participants..

Adaptation and modification on a few terms were also needed to achieve both meaning and cultural equivalence. These modifications classified into different category, a vocabulary equivalence, grammatical-syntactical equivalence, and idiomatic equivalence (22). This study provides the example of idiomatic equivalence modification in a few terms. This modification can be applied when the original terms are replaced with terms that are more appropriate to the target context. . For example the word "need" in item 2 was translated *"kebutuhan"* in Indonesia. According to *Kamus Besar Bahasa Indonesia* (KBBI), the word the word "*kebutuhan*" indicates an object or a service that is necessary to fulfil the human needs. We rated the word as too extreme to define the meaning of that item. Therefore, we decided to change them into "*Keinginan*". The word indicates someone's desire that came from within someone. Another example was the term "severe" was first translated to "berat" (heavy). But According to *Kamus Besar Bahasa Indonesia* (KBBI), the word "*berat*" indicates the size of an object compared the other objects and the word is commonly use to describe weight of an object by the Indonesian population. Therefore the word *"parah*" (severe) was chosen to represent "severe".

Revision on items of Indonesian Version of sIRLS

The expert committee assessment results in a few changes and revision. This assessments is important to obtain the cross-cultural equivalence and also substantially contributes to the understanding of the respondents candidate (23). Revisions and changes were needed to facilitate the respondents.

In this study, expert judges made suggestion for the use of global medical terms. On item number 1 expert judges suggested sticking with the RLS abbreviation and not translating it to "Gejala Kaki Gelisah" because it is not universal. The use of abbreviation in medical field should be universal and can be understood by all health workers (24).

Expert judges also suggested some modification to elaborate some items. For example on item number 2 expert judges suggested to add specific body part that was affected by RLS. Therefore we add "arms and leg" to specify the body part. This decision was taken based on the RLS theory, where the patients often feel the need to move their upper and lower extremities (legs and arms) (10). On item number 4, expert judges suggested to add the example of sleep disturbances that was caused by RLS. Therefore, we added example of sleep disturbances based on the subjective of the Nursing Diagnosis of Sleep disturbance from *Standar Diagnosis Keperawatan Indonesia* (SDKI). The example of the sleep disturbances are difficulty getting to sleep, changes in sleep time, fatigue caused by lack of sleep, and unsatisfactory sleep. It is also supported by research about Clinical Indicator of the sleep disturbance diagnosis, which found that the patients who were diagnosed with sleep disturbance often showed signs of waking up too early, difficulty getting to sleep, difficulty maintaining sleep, disturbed sleep patterns (changes in the amount and quality of sleep), changes in health status, sleep disturbances that impact the next day, no energy (fatigue, decreased sleep quality, mood swings, and unsatisfactory sleep(25).

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Another suggestions were to rewrite items number 8,9, and 11 to facilitate the respondents and clarify the meaning of items. Previous study found that lower education and lower income were correlated with lower health literacy (26). Assuming that the respondents candidate can come from various education level, researchers intend to keep the items as simple as possible to avoid any misunderstanding. On item number 8, expert judges suggested to elaborate the item because they rated that item 8 is similar to item 6. So we elaborated on the item by asking the average hour of RLS symptoms that happened in one day. On item number 9 expert judges suggested to specify the activities mentioned in item 9. Therefore we added; carry out a role in the family, doing housework, interacting socially, studying at school, and doing office work as the example of the activities. On items number 11 expert judges suggested adding the underline and (:) punctuation on the answer's instructions to differentiate the answer's choices from the instructions.

These changes and modification were made due to the very different language of the original instrument. The researcher intends to do this study to provide the first of the many steps of cross-cultural adaptation on sIRLS instruments. Therefore this study could open up the opportunities for future researchers to do the next steps until the instrument is reliable, valid, and effective for use in the local's country, in this case Indonesia.

STUDY LIMITATIONS

In the implementation of this study, there are several shortcomings, especially in the translation process. We had difficulty contacting the original instrument developer, so we skipped the synthesized back-translation process. Instead, all authors did a thorough discussion to analyze the sentence structure of each item match the linguistic and cultural equivalent of Bahasa Indonesia with the original instrument.

CONCLUSION

This study aims to translate the sIRLS instrument to the Indonesian version and test the content validity of it. During the translation process, several adjustments and modifications were made to match the linguistic and cultural equivalent of the habitual form and use of Bahasa Indonesia while still in line with the original version of the sIRLS.

The content validity test of the Indonesian version of sIRSL instrument, assesses the eleven items covering categories of importance, relevance and clarity. The CVR showed a value of 1.00 for each item, which means that 11 items of the Indonesian version of sIRLS are important. The I-CVI value for both categories, namely the relevance and clarity category, shows a value of 1.00 for each item, indicating that each item from the Indonesian version of sIRLS is relevant and clear. The S-CVI/UA and S—CVI/ Ave values which also show 1.00 mean that the entire Indonesian version of the sIRLS instrument is declared relevant and clear.

This study adds to the number of instruments that have been translated and contribute to subsequent psychometric study on this instrument. Suggestions for future researchers are to do validity tests using other methods such as construct validity tests, whether through Face Validity, Exploratory Factor Analysis, Confirmatory Factor Analysis, or RASCH Model. Apart from that, the Indonesian version of the sIRLS instrument would be better if a reliability test was carried out using Cronbach Alpha analysis so that later the reliability of this instrument can be tested and can be applied both for research and clinical purposes.

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