Psychometric Properties and Hidden Dimensionality of the Sinhala Version of End Stage Renal Disease Adherence Questionnaire (SINESRD-AQ) Among Patients Receiving Haemodialysis in a Selected Hospital in Sri Lanka

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Abstract

Background

Adherence to a complex therapeutic regimen is crucial to maintain the quality of life of patients receiving haemodialysis. End Stage Renal Disease Adherence Questionnaire (ESRD-AQ) is a valid and most widely used instrument to assess all dimensions of treatment adherence among patients receiving in-center haemodialysis. Though the precise evaluation is fundamental, availability of valid and reliable instruments to evaluate treatment adherence is limited in Sri Lanka. Therefore, the purpose of this study was to evaluate the psychometric properties of Sinhala translated version of ESRD-AQ.

Methods

The translation and cultural adaptation of ESRD-AQ underwent forward and back translation, expert committee consolidation and pretesting among patients (n=10). Face and content validity were evaluated with a panel of experts (n=6) and group of patients (n=10). Confirmatory Factor Analysis (CFA) was performed to evaluate construct validity of two subscales of SINESRD-AQ. Subsequent Categorical Principal Component Analysis (CATPCA) was performed to identify a more parsimonious dimensionality to assess treatment adherence behaviors among patients. Ethical approval was obtained from the Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura and Teaching Hospital, Kurunegala, Sri Lanka.

Results

A total of 150 patients with mean age of 54.08±10.78 (±SD) years were included. Majority were males (72.7%). Excellent face and content validity of SINESRD-AQ was reported. The CFA of two subscales of ESRD-AQ demonstrated barely acceptable model fit (SRMR=0.120, CFI=0.913, GFI=0.997, AGFI=0.996, NNFI=0.896). Subsequent CATPCA revealed new dimensionality with five components explaining 74% of the total variance. Convergent validity of new dimensionality was confirmed with Composite Reliability (CR) and Average Variance Extracted (AVE) with the values greater than 0.7 and 0.5 respectively. According to the Fornell Larcker criterion (1971), the square root of AVEs of components were greater than the inter component correlations and heterotrait-monotrait values were less than the threshold of 0.85 demonstrated the discriminant validity of new dimensionality.

Conclusion

SINESRD-AQ is a valid and a reliable instrument to assess treatment adherence behaviors among Sinhala speaking patients receiving haemodialysis in Sri Lanka. A follow-up CFA is to be performed to confirm the revised dimensionality of SINESRD-AQ.

Background

End Stage Renal Disease (ESRD) is caused by progression of chronic kidney disease (CKD) to its terminal stage with severely declined glomerular filtration rate (GFR<15ml/min) [1] is a global public health concern.
Renal replacement therapy including long term dialysis or kidney transplantation is needed for patients with ESRD for survival [3]. Though the Kidney transplantation is the best of choice in management of patients with ESRD, resource constraints and shortage of kidney donors has made haemodialysis as most efficient and practical treatment modality in Sri Lanka [3]. The statistics of National Hospital of Sri Lanka demonstrate that the number of dialysis sessions carried out has dramatically increased from approximately 3000 in 2003 to more than 11600 in the year 2013 with approximately thousand haemodialysis sessions per month carried out in the hospital [4].

The increase of patients with ESRD necessitates management on dialysis for better outcomes, thus the adherence to prescribed treatment regimen is essential [5]. Patients receiving haemodialysis are required to adhere to a complex treatment regimen consisting of regular haemodialysis attendance, prescribed medications, recommended diet and fluid restrictions [5]. Although the health care team fosters adherence, the ability to comply with treatment regimen depends on the understanding and motivation of the patients with ESRD. Nevertheless, recently published literature revealed that approximately 50% of individuals with ESRD undergoing haemodialysis did not adhere to their prescribed treatment regimen [6]. In fact, non-adherence has been associated with increased morbidity and mortality among patients resulting in high cost for the health care system and substantial burden on their family [7].

Wide variations in the reported non-adherence rates have been observed due to lack of reliable measurement tools that address all the facets of treatment adherence behavior of the patients on maintenance haemodialysis. Adherence to haemodialysis treatment regimen is measured by a variety of methods including clinical measures such as biological markers (interdialytic weight gain) and biochemical markers (serum creatinine, blood urea nitrogen, serum potassium and phosphate levels etc.). In general, biological and biochemical markers can be viewed as objective measures while a valid and reliable tool to assess subjective phenomenon was in dearth in literature [8]. Few self-reported adherence scales have been developed and tested for use with patients with ESRD. Assessment of treatment adherence among patients receiving haemodialysis favors the use of multidimensional instrument to evaluate all the dimensions of adherence to the treatment regimen.

End Stage Renal Disease Adherence Questionnaire (ESRD-AQ) is one of the widely accepted multidimensional instruments designed by Kim et al. in Los Angeles, California to assess self-reported treatment adherence behavior in patients receiving haemodialysis [8]. ESRD-AQ has been culturally adapted and validated into different languages and used to assess treatment adherence among patients receiving haemodialysis in Portugal, United states, Spain, Brazil, Egypt and Palestine [3, 7, 8, 9, 10, 11]. In each language version, ESRD-AQ demonstrated acceptable validity and reliability. The content validity of the ESRD-AQ was assessed by calculating the Content Validity Index (CVI) for each item based on the ratings of an expert panel according to the degree of relevance of each item. Construct validity has been assessed by employing a known group analysis comparing adheres group with a group of non-adheres. Reliability of the instrument was evaluated with test-retest reliability using intraclass correlation coefficient (ICC) in a random sample. The original study conducted by Kim et al., demonstrated good Item level Content Validities for the forty-six items of the questionnaire ranged between 0.86-1.00, which resulted in average of I-CVI of 0.99. ICCs were ranged from
The mean scores from the directly measuring adherence behaviors on four different areas (haemodialysis attendance, prescribed medications, recommended diet and fluid restrictions) of treatment adherence indicated that the ESRD-AQ clearly distinguished adheres and non-adheres [8]. The validity and reliability indices (CVI = 0.97 - 0.99, Average CVI= 0.98 and ICC= 0.82 to 1.00) of the Spanish version (SESRD-AQ) were also within an acceptable range [9]. The Portuguese version of ESRD-AQ (PESRD-AQ) showed strong test-retest reliability across all the items and I-CVI ranging from 0.94-1.00 with an average I-CVI of 0.98 [7]. The Brazilian version showed I-CVI for all the items greater than 0.8 and average I-CVI of 0.96. It also showed high reliability with ICC of 0.98 and 0.91 for direct adherence behavior subscale and attitude/perception subscale respectively. The study further evaluated kappa statistic coefficient for each item of the two subscales of ESRD-AQ which were greater than 0.8 except two items presenting 0.45 and 0.79. Internal consistency (Cronbach's alpha) was 0.57 considered not satisfactory. Acceptable level of Cronbach's alpha is not necessarily important for the instrument as the six questions measuring adherence evaluate different aspects of treatment regimen and no homogeneity between items [10].

With the growing CKD problem and increasing number of patients receiving haemodialysis in Sri Lanka, a valid and reliable instrument is required to determine the degree of adherence to the haemodialysis treatment regimen among Sinhala speaking patients. It enables to address any deficiencies identified with treatment adherence among patients to prevent the occurrence of adverse events. Among the previous studies conducted in Sri Lanka, none have used ESRD-AQ to assess self-reported adherence to haemodialysis treatment regimen and no other Sinhala version of instruments measuring adherence are available for use among Sinhala speaking patients. Thus, availability of an instrument from Sinhala language is immensely worth to measure self-reported adherence in patients receiving haemodialysis in Sri Lanka. Therefore, the aim of the study was to evaluate psychometric properties of Sinhala translated version of ESRD-AQ for use among patients receiving haemodialysis in Sri Lanka.

**Methods**

**Study design and setting**

The study was a validation study which consisted of translation, cultural adaptation and evaluation of psychometric properties (face, content, consensual and construct validity) of the instrument (Figure 1). A descriptive cross-sectional study was conducted among Sinhala speaking patients receiving haemodialysis in Teaching Hospital, Kurunegala, Sri Lanka to evaluate construct validity of the instrument. Teaching Hospital, Kurunegala which is located nearly 100 km away from the capital city of Sri Lanka, has one of the main government sector haemodialysis units. It provides haemodialysis treatment to approximately forty-fifty patients daily during morning, afternoon and evening shifts.

The **procedure of translation and cultural adaptation of original English version of ESRD-AQ into Sinhala Language**

The translation process was conducted according to the recommended guidelines provided by Beaton et al. on cross-cultural adaptation of self-reported measures [12]. The translation process included five steps-forward translation, synthesis of common version, back translation, expert committee consolidation and
pretesting. The initial translation of ESRD-AQ from the original English language to the Sinhalese language was done by two independent professional bilingual translators (language expert and subject expert).

Both translations were compared, and discrepancies were resolved with the addition of an unbiased bilingual translator who was not involved in the forward translation process and synthesized a common Sinhala version of the instrument. The forward translated common Sinhala version of the instrument was independently back translated to the original English language by two other independent professional bilingual translators (language expert and subject expert). Both translations were compared, and discrepancies were resolved with the addition of an unbiased bilingual translator who was not involved in the back-translation process and produced a common English version of the instrument. A committee consisted of experts who were familiar with the constructs of interest, questionnaire designing and subject experts in the field of nephrology reviewed all versions of the translations and checked whether the translated and original versions achieve semantic, idiomatic, and conceptual equivalence. The committee discussed and resolved the discrepancies of the instruments and reached the consensus on all forty-six items to retain in the instrument. A pre final version of the SINESRD-AQ was produced. Proof reading of the questionnaire was done by a multidisciplinary panel of experts in the field of Community Medicine, Nephrology, Nursing and Language.

**Evaluation of psychometric properties of SINESRD-AQ**

The face, content, consensual and construct validity were assessed in order to determine whether the questionnaire measures what it intends to assess. Content validity was evaluated by obtaining opinion of experts (n=6) in the research field and having extensive clinical background of treating and caring the patients with ESRD and haemodialysis (Nephrologist, Clinician, University lecturers, Nutritionist and Haemodialysis nurse) using modified Delphi technique. To ensure that the questionnaire had appropriate items or domains to represent the construct of interest, the expert panel assessed content relevance of each question, appropriateness of the words, their cultural relevance and domain coverage of adherence by each question. Based on expert opinion, Item-level Content Validity Index (I-CVI), Average Item-level Content Validity Index for the whole scale (S-CVI) [13], Item-level Content Validity Ratio (I-CVR) [14] and Modified Kappa statistic coefficient (k) [15] for each item were calculated.

The resulting version was administered to a purposively selected group of patients (n=10) receiving haemodialysis to evaluate face validity. The patients were asked to comment on each item of the instrument to determine any difficulty in understanding the words of the items or answer the items. In fact, their feedback was used to improve comprehensibility of the items of the instrument. Based on comments of the participants, no further modifications were indicated in the instrument. The final SINESRD-AQ was produced, and proof reading was carried out to eliminate the spellings, grammatical and formatting errors.

**Sample and sample size calculation**

The study included all the patients above the age of 18 years, diagnosed with ESRD, receiving haemodialysis at least for six months and able to speak Sinhala language from all ethnic groups attending haemodialysis at Teaching hospital, Kurunegala, Sri Lanka. Patients who were critically ill were excluded from the study. The
sample size was calculated considering the rule of thumb 5-10 subjects per each item [16]. Considering 14 items in two subscales measuring adherence in ESRD-AQ, calculated sample size for the current study was 140 (1:10). Considering nonresponse rate of 5%, the final calculated sample size for the study was 150. Participants who fulfilled selection criteria were recruited for the validation study until the sample size was achieved.

**Measurements**

ESRD-AQ is an instrument consisting of 46 items designed to measure self-reported treatment adherence behavior in four dimensions: haemodialysis attendance (14 items), medication use (9 items), fluid restrictions (10 items) and diet (8 items). The remaining 5 items assess patient’s clinical history. ESRD-AQ is comprised of two subscales measuring direct adherence behavior (6 items- 14,17,18,26,31 and 46) and patients’ knowledge and perceptions about treatment (8 items – 11,12,22,23,32,33,41 and 42). Responses of the ESRD-AQ utilize a combination of Likert type, multiple choice and binary responses (yes/no) [10].

**Data collection procedure**

Data collection was carried out from November 2019 to April 2020. Patients who were willing to participate in the study were recruited after obtaining written informed consent. Subsequently, data were collected using interviewer administered SINESRD-AQ and using a self-designed questionnaire for socio-demographic characteristics regularly by the principal investigator without disturbing the haemodialysis treatment they received. An independent sample of ten patients receiving hemodialysis completed the questionnaire twice with a retest interval of one week in order to assess test-retest reliability of the instrument.

**Data analysis**

Descriptive statistics were analyzed using IBM SPSS Statistics version 25.0 software for windows. The indices evaluating content validity of the instrument were calculated with Microsoft office excel.

Construct validity of the SINESRD-AQ was assessed by Confirmatory Factor Analysis (CFA) using LISREL 11.0 software for windows.

Prior to perform factor analysis, the data set was assessed for suitability, quality, missing data and for violations of the assumptions of analytical techniques of CFA. No missing data were observed. The sample data assumed univariate marginal distribution. Both Shapiro-Wilk test and Kolmogorov–Smirnov test were involved in assessing univariate normality of data as the sample size is greater than 50 [17]. The p value was 0.000 (p<0.05) for all the variables in the data set which rejects the null hypothesis for the normality for the sample at a 5% level of significance assuming non-normality of data. Considering total adherence score and perception score yielded from two subscales of SINESRD-AQ, standardized values (z scores) were computed to identify univariate outliers. Any Z score above +3.29 or below -3.29 is considered as an outlier case [18]. Five extreme outliers (case 55,81,86,88 and 101) were detected and removed prior to performing CFA. The raw data set was checked for errors in data entry. Since the absence of errors, no adjustments were made to the data set prior to perform CFA. The sampling adequacy was assessed using the Kaiser-Meyer-Olkin (KMO)
test. A value 0.663 indicating that the sample is barely adequate to perform factor analysis. Bartlett's test of sphericity was less than 0.001 indicating an adequate amount of collinearity between items [19].

Robust unweighted Least Squares (RULS) estimation method in LISREL 11.0 which was especially designed for ordinal data and adjusted to non-normality was used to estimate model parameters as it yields better results in lower sample sizes and estimates parameters with less standard error compared to the other estimation methods [20].

Several model fit indices such as absolute fit indices [Root Mean Squared Error of Approximation (RMSEA), Standardized Root Mean square Residual (SRMR), Goodness of Fit Index (GFI) and Adjusted Goodness of Fit Index (AGFI)] and relative fit indices [Comparative fit index (CFI), Non-normed fit index (NNFI/Tucker-Lewis Index] were used to evaluate the goodness of fit of the CFA model of two subscales of ESRD-AQ and to examine the adequacy of the model fit to the data. RMSEA index less than 0.06 and SRMR less than 0.09 [21,22] were considered as an acceptable model fit. For the GFI, AGFI, CFI and NNFI [22], values greater than 0.95 were considered as good fit to the data. While no threshold levels have been recommended for parsimony fit indices (PNFI and PGFI), Mulaik et al. suggested that it is possible to obtain values within the 0.50 region while other goodness of fit indices achieve values over 0.90 [23].

Non-linear Principal Component Analysis (CATPCA) which is specifically designed for categorical (ordinal/nominal) variables in SPSS was performed on same data set to identify a hidden or more parsimonious dimensionality to assess treatment adherence behaviors among patients receiving haemodialysis in Sri Lanka. “Non-linear PCA discovers nonlinear relationships between items and doesn't have classical statistical assumptions as in PCA and it converts every category of the variables into numeric value by optimal scaling” [24]. Further, convergent validity of new dimensionality was evaluated with Composite Reliability (CR) and Average Variance Extracted (AVE) by each component. Discriminant validity was confirmed with Fornell and Larcker criterion (examining whether the square root of AVEs is higher than the inter construct correlations) [25] and Heterotrait-monotrait (HTMT) ratio of correlation [26].

Ethical considerations

The study was approved by the Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura (ERC No.06/19) and Committee of Ethics Review on Scientific Research, Teaching hospital, Kurunegala (THK/CERSR/2019/12).

Results

Socio-demographic characteristics of the participants

The mean age of the study participants was 54.08±10.78 (±SD years) (Age range 18-74 years). Majority were males (72.7%), married (96.0%), Sinhalese (98.0%) and not employed (86.0%). More than 70% (71.3%) of patients were diagnosed to have chronic kidney disease for less than five years and majority (64.7%) were receiving hemodialysis for less than one year (Table 1).
| Variable                      | Category                          | Frequency | Percentage % |
|------------------------------|-----------------------------------|-----------|--------------|
| Gender                       | Male                              | 109       | 72.7         |
|                              | Female                            | 41        | 27.3         |
| Age                          | Less than 40                      | 19        | 12.7         |
|                              | 41-60 years                       | 90        | 60.0         |
|                              | More than 60 years                | 41        | 27.3         |
| Civil status                 | Married                           | 144       | 96.0         |
|                              | Unmarried/Single                  | 6         | 4.0          |
| Race                         | Sinhala                           | 147       | 98.0         |
|                              | Muslim                            | 3         | 2.0          |
| Educational level            | Not attended school               | 3         | 2.0          |
|                              | Primary education (Up to grade five) | 34       | 22.7         |
|                              | Up to Ordinary Level              | 79        | 52.7         |
|                              | Up to Advanced Level              | 30        | 20.0         |
|                              | University education              | 4         | 2.7          |
| Current employment           | Yes                               | 21        | 14.0         |
|                              | No                                | 129       | 86.0         |
| Monthly income of the family (Rs.) | Less than 10,000           | 70        | 46.7         |
|                              | 10,001-20,000                     | 46        | 30.7         |
|                              | 20,001-40,000                     | 22        | 14.7         |
|                              | 40,001-60,000                     | 6         | 4.0          |
|                              | 60,001-100,000                    | 4         | 2.7          |
|                              | More than 100,000                 | 2         | 1.3          |
| Availability of co-morbidities | Yes                             | 116       | 77.3         |
|                              | No                                | 34        | 22.7         |
| Duration of CKD              | Less than 5 years                 | 107       | 71.3         |
|                              | 5-10 years                        | 29        | 19.3         |
|                              | More than 10 years                | 14        | 9.3          |
| Duration of haemodialysis    | Less than 1 year                  | 97        | 64.7         |
| Variable | Category       | Frequency | Percentage % |
|----------|----------------|-----------|--------------|
|          | 1-3 years      | 39        | 26.0         |
|          | More than 3 years | 14      | 9.3          |

Psychometric properties of SINESRD-AQ

Reliability analysis

Strong test-retest reliability existed across all the items measuring adherence in SINESRD-AQ with Intra Class Correlation Coefficients ranging from 0.53-0.96 [Average ICC=0.861 (p<0.01)]. Cronbach's Alpha for direct adherence behavior subscale and attitude/perception subscale were 0.205 and 0.767 respectively. Cronbach's Alpha for whole two subscales was 0.649.

Face and Content validity

I-CVIs for the forty-six items of the final SINESRD-AQ were ranged between 0.83 – 1.00. Average I-CVI for the whole SINESRD-AQ (S-CVI) was 0.93. I-CVR were ranged between 0.67 – 1.00. Modified Kappa statistic were ranged between 0.81-1.0.

Construct validity

Evaluation of subscale validity of SINESRD-AQ with Confirmatory factor analysis

The goodness-of-fit indices of the CFA model for two subscales of ESRD-AQ yielded chi-squared statistic (Satorra–Bentler scaled) value of 157.691 (df= 76) (p=0.0000). The Authors used two index presentation strategy suggested by Hu and Bentler et al. [21] in combination with SRMR (0.120) and CFI (0.913) to evaluate model fit. The other fit indices considered were as follows – GFI = 0.997; AGFI=0.996; NNFI/TLI=0.896; RMSEA=0.212, PNFI=0.708 and PGFI =0.722.

Non-linear Principal Component Analysis (CATPCA) of SINESRD-AQ

Thirty-two items of SINESRD-AQ were included in CATPCA except the items with yes/no answer format and supplementary questions. The overall value of Kaiser-Meyer-Olkin (KMO) test for selected thirty-two items was 0.726 indicating that the sample size and factorability are met for conducting factor analysis. The significant value of Bartlett’s test of sphericity was noted (<0.001) [19]. Eight Outliers (case 5,9,11,20,32,87, 92 and 101) were detected in the data set after performing initial CATPCA analysis by looking at objects scores that roughly exceeding the range of -3.5 - + 3.5 [27]. Then the analysis was re-run after removing those outliers with a Ten preset number of components. In addition to CATPCA, O’Connor parallel analysis (2000) was performed to determine the exact number of components to be extracted for further analysis [28]. Considering the eigenvalues obtained from both CATPCA and O’Connor parallel analysis, five components were extracted with eigenvalues greater than 1 (Figure 2). The Cattell’s (1966) scree plot also revealed a clear break in the slope after the 5th factor suggesting that five components to be retained for further analysis (Figure 3).
The analysis was re-run with five preset number of dimensions/components. Values of Variance Accounted For (VAF) each item was obtained by CATPCA analysis to determine the number of items to be retained in final analysis considering the communality of each item. Average value of 0.5-0.6 communality is acceptable for sample sizes between 100-200 [29]. Therefore, ten items with communality less than 0.5 were removed and final analysis was performed with twenty-two items. After performing final CATPCA, five components with eigenvalue greater than 1 were extracted and approximately 74% of total variance was explained by those five components. Eigenvalues for extracted components ranged between 6.455 - 1.741 (Table 2). All twenty-two items had communality greater than 0.5 and factor loadings greater than 0.6 (Table 3).

**Reliability analysis - Internal consistency**

Internal consistency reliability of new dimensionality was assessed with Cronbach’s Alpha and composite reliability. Cronbach’s Alpha for three components were greater than 0.6 and two were demonstrated 0.45. Composite reliability (CR) values were greater than 0.7 for all the components.

|                | Component 1 | Component 2 | Component 3 | Component 4 | Component 5 |
|----------------|-------------|-------------|-------------|-------------|-------------|
| **Eigenvalue** | 6.455       | 3.632       | 2.685       | 1.765       | 1.741       |
| **% Variance Accounted For (VAF)** | 29.341 | 16.510 | 12.204 | 8.023 | 7.916 |
### Table 3
Final Dimension/component solution of Sinhala version of ESRD-AQ

| Component                                                                 | Item                                                                 | Factor weights/ loadings | Cronbach’s Alpha |
|---------------------------------------------------------------------------|----------------------------------------------------------------------|--------------------------|------------------|
| **1. Regularity of health education by the health care staff**           | b29: When was the last time a medical professional talked to you about the importance of not missing your dialysis treatment? | .835                     | .885             |
|                                                                           | b210: How often does a medical professional talk to you about the importance of staying for the entire dialysis time during your dialysis treatment? | .860                     |                  |
|                                                                           | b320: When was the last time a medical professional spoke to you about your medicines? | .695                     |                  |
|                                                                           | b321: How often does a medical professional talk to you about the importance of taking medicines as ordered? | .785                     |                  |
|                                                                           | b429: When was the last time a medical professional spoke to you about your fluid restrictions? | .859                     |                  |
|                                                                           | b430: How often does a medical professional talk to you about the importance of fluid restriction? | .838                     |                  |
|                                                                           | b539: When was the last time a medical professional talked to you about your diet? | .841                     |                  |
|                                                                           | b540: How often does a medical professional talk to you about the importance of following a proper diet? | .848                     |                  |
| **2. Patient’s knowledge about the treatment regimen**                    | b212: Why do you think it is important to follow your dialysis schedule? | .882                     | .759             |
|                                                                           | b323: Why do you think it is important to take your medicines as scheduled? | .901                     |                  |
|                                                                           | b433: Why do you think it is important for you to limit your fluid intake? | .841                     |                  |
|                                                                           | b542: Why do you think it is important for you to watch your diet daily? | .838                     |                  |
| **3. Barriers to follow dietary recommendations**                         | b544: How much difficulty have you had following your dietary recommendations? | .922                     | .657             |
|                                                                           | b545: What type of difficulty have you had keeping your dietary recommendations? | .950                     |                  |
|                                                                           | b546: During the past week, how many times have you followed the diet recommendations? | .856                     |                  |
| **4. Patient’s perceptions and attitudes towards the treatment regimen** | b211: How important do you think it is to follow your dialysis schedule? | .753                     | .454             |
b322: How important do you think it is to take your medicines as scheduled?  .750
b432: How important do you think it is to limit your fluid intake?  .776
b541: How important do you think it is to watch the types of food you eat each day?  .652

5. Barriers to follow fluid restriction recommendations
b431: During the past week, how many times you followed the fluid restriction recommendations?  .709  .446
b435: How much difficulty have you had following your fluid restriction recommendations?  .860
b436: If you had difficulty following your fluid restriction recommendations, what type of difficulty have you had?  .929

Convergent and discriminant validity of new dimensionality of SINERSRD-AQ

The calculated AVE for each component was greater than 0.5 and CR was greater than 0.7. According to Fornell and Larcker criterion, the square root of AVEs of components are higher than the inter construct correlations (Table 4) and Heterotrait-monotrait (HTMT) ratio of correlations were less than 0.85 (Table 5).

| Component/ dimension | AVE  | CR   | Cronbach’s Alpha | Health Education | Knowledge | Diet | Perception | Fluid |
|----------------------|------|------|------------------|------------------|-----------|------|------------|-------|
| Health Education     | 0.675| 0.943| 0.885            |                  |           |      |            |       |
| Knowledge            | 0.750| 0.750| 0.759            | 0.238            |           |      |            |       |
| Diet                 | 0.828| 0.935| 0.657            | 0.040            | 0.044     |      |            |       |
| Perception           | 0.539| 0.823| 0.454            | 0.286            | 0.302     | 0.062|            |       |
| Fluid                | 0.702| 0.875| 0.446            | -0.193           | 0.100     | 0.170| 0.041      | 0.838*|

*Square root of AVE
Table 5

|                  | Health Education | Knowledge | Diet | Perception | Fluid |
|------------------|------------------|-----------|------|------------|-------|
| Health Education | -                |           |      |            |       |
| Knowledge        | 0.141            | -         |      |            |       |
| Diet             | 0.00196          | 0.049     | -    |            |       |
| Perception       | 0.338            | 0.595     | 0.183| -          |       |
| Fluid            | 0.210            | 0.284     | 0.357| 0.113      | -     |

Discussion

ESRD-AQ is one of the widely used instruments to determine self-reported adherence among patients receiving haemodialysis. It has been translated, culturally adapted and validated into different languages in different countries. The main objective of this study was to evaluate psychometric properties of Sinhala translated version of ESRD-AQ.

Several studies have been conducted to evaluate psychometric properties of ESRD-AQ with assessing face, content and construct validity and reliability with internal consistency reliability and test-retest reliability. Previous studies found in the literature have assessed construct validity of ESRD-AQ by employing known groups analysis by comparing the group of adheres with group of non-adheres. Adheres and non-adheres were distinguished based on the responses to the items directly measuring adherence in ESRD-AQ by the patients and respective clinical measures, i.e. “Patients were considered as non-adherent to their medications and diet if they have skipped or shortened their haemodialysis treatment more than once monthly and if their serum phosphorous level is higher than 7.5mg/dl” [8]. Although the several studies have proven scientific validity and reliability of ESRD-AQ with different methods, none of the studies have examined the validity and reliability of two subscales of ESRD-AQ measuring treatment adherence by employing factor analysis. Therefore, present study was intended to examine the validity and reliability of each aforementioned subscales to assess treatment adherence behaviors among patients receiving haemodialysis by employing CFA.

Firstly, the cultural adaptation process addressed both literal translation and verification of semantic and cultural adequacy of the words of SINESRD-AQ for use in Sri Lankan context. The reliability of the instrument was assessed with internal consistency (Cronbach's Alpha <0.6) and test-retest reliability (ICC>0.75) [30] and the values demonstrated acceptable reliability. Content validity of SINESRD-AQ was assessed as excellent by an expert panel with I-CVI>0.8, S-CVI=0.93, I-CVR>0.6 and modified kappa statistic>0.8 and face validity was confirmed with a group of patients. CFA evaluating construct validity of the model of two-subscases of ESRD-AQ came up with better indices closure to the desired values with relative chi-square (Satorra–Bentler scaled chi-square/df) (<3), GFI (>0.95), AGFI (>0.95), NNFI (>0.95) and CFI (>0.95). PNFI and PGFI also demonstrated acceptable values exceeding 0.5 [22]. Though, the SRMR was close to recommended threshold (<0.09), RMSEA indicated poor fit of the model (<0.08).
According to the Hu and Bentler's two index presentation strategy (1999), it is required to meet thresholds of combination of SRMR<0.09 with another model fit index including either NNFI (TLI)>0.96, RMSEA<0.06 or CFI>0.96. Considering the combinations of SRMR (0.12) and CFI (0.913), the model of two subscales came up with better indices closure to the threshold values indicating barely acceptable model fit [21, 22].

Even though CFA of current study, showed barely acceptable model fit according to the certain model fit indices, there were weak factor loadings (<0.3) of certain items in two subscales (especially in direct adherence behavior subscale) of SINESRD-AQ. Thus, the current study attempted to identify any hidden dimensionality unique to Sinhala speaking population receiving haemodialysis to assess treatment adherence behaviors.

Considering the categorical/ordinal nature of the variables, CATPCA was the most suitable method to extract hidden dimensions in the data, collected from the patients receiving haemodialysis in Sri Lanka. In CATPCA, five components unique to Sinhala speaking population were identified with approximately 74% of total variance (Component 1-29.3%; Component 2-16.5%; Component 3-12.2%; Component 4-8.0%; Component 5-7.9%). The five components extracted from CATPCA were named as considering the nature of the items consisted in each component as regularity of health education by the health care staff, patient’s knowledge about the treatment regimen, barriers to follow dietary recommendations, patient’s perceptions and attitudes towards the treatment regimen and barriers to follow fluid restriction recommendations. Factor loading of each item in each component was greater than 0.6. Internal consistency reliability (Cronbach’s Alpha) for each component was 0.885, 0.759, 0.657, 0.454 and 0.446 respectively. Three components indicated acceptable internal consistency while two showed internal consistency below the acceptable level (Cronbach’s Alpha<0.6). However, Cronbach’s Alpha is not a measure of dimensionality. It produces high Alpha coefficient for scales with similar length and variance. Highly correlated items or increasing the number of items of a scale will also produce high Alpha coefficient [33]. In the present study, new dimensionality has no similar length in the scales neither item of each scale are not assessing the similar content of adherence, i.e. barriers to follow fluid restriction recommendations – consists items relevant to frequency of following fluid restriction recommendations, the level of difficulty and type of difficulty in following fluid restriction recommendations. Therefore, the internal consistency reliability might not be an accurate method to assess reliability of this tool, whereas more valid reliability measures such as test-retest reliability can be assessed to determine the reproducibility and ability to provide consistent scores overtime with the scale [32].

The construct validity of new dimensionality was assessed by convergent and discriminant validity. Convergent validity was assessed by CR and AVE. According to the Hair et al., CR of constructs are required to be in the range 0.7-0.95 [33]. In the current study, both AVE and CR of new dimensionality were in the acceptable range which confirm convergent validity. The discriminant validity of new dimensionality was confirmed with Fornell-Larcker criterion. According to Fornell-Larcker criterion (1971), the square root of AVE of each construct in the diagonal were higher than the inter construct correlations (off diagonal) which shows discriminant validity. According to HTMT 0.85 criterion, current study confirmed discriminant validity of new dimensionality with values less than 0.85 which showed higher sensitivity and specificity rates in assessing discriminant validity [26].
The current study has a few limitations. The authors have not performed confirmatory factor analysis to confirm the construct validity of new dimensionality of SINESRD-AQ which gives more insight and confidence to assess treatment adherence behaviors among patients receiving haemodialysis. Test-retest reliability which is a more powerful measure to assess reproducibility of the instrument was also not evaluated on new dimensionality of SINESRD-AQ in the current study. It is recommended to conduct future studies with a larger sample size to examine validity and reliability of new dimensionality of ESRD-AQ using different settings and to check whether those findings are consistent with the results of the current study.

**Conclusions**

The current study concludes that the SINESRD-AQ is a scientifically and statistically valid and reliable instrument to assess treatment adherence behavior among Sinhala speaking patients receiving haemodialysis in Sri Lanka.

**Abbreviations**

SINESRD-AQ : Sinhala version of End Stage Renal Disease- Adherence Questionnaire; I-CVI: Item level content validity index; I-CVR: Item level content validity ratio; CFA- Confirmatory factor analysis; RMSEA: Root Mean Square Error of Approximation; GFI: Goodness of Fit Index; AGFI: Adjusted Goodness of Fit Index; SRMR: Standardized Root Mean Square Residual; CFI: Comparative Fit Index; NNFI: Non-Normed Fit Index; PGFI: Parsimony Goodness of Fit Index; PNFI: Parsimonious Normed Fit Index; HTMT: Heterotrait-Monotrait criterion; AVE: Average Variance Extracted; CR: Composite Reliability; CATPCA – Categorical Principal Component Analysis

**Declarations**

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**Authors’ contributions**

KW, UH, TDA and CSEG contributed to the concept and design of the study, assisted in writing and revising the manuscript. CL carried out data collection, data analysis, data interpretation and drafting of the manuscript. All authors have read and approved the manuscript to be published.
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Availability of data and materials

The raw data utilized to support the findings of the current study will be available from the corresponding author upon reasonable request.

Ethics approval and consent to participate

Ethical approval was granted from Ethics Review Committee, Faculty of Medical Sciences, University of Sri Jayewardenepura (ERC No.06/19) and Committee of Ethics Review on Scientific Research, Teaching hospital, Kurunegala (THK/CERSR/2019/12) before commencement of the study. All the procedures of the study were performed in accordance with the recommended guidelines and regulations of the Declaration of Helsinki. Written and verbal informed consent was obtained from all the patients prior to commencement of data collection of the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

References

1. Benjamin O, Lappin SL. End-stage renal disease. StatPearls [Internet]. 2021 Feb 4.
2. Thurlow JS, Joshi M, Yan G, Norris KC, Agodoa LY, Yuan CM, Nee R. Global epidemiology of end-stage kidney disease and disparities in kidney replacement therapy. American journal of nephrology. 2021;52(2):98-107. https://doi.org/10.1159/000514550
3. Deif HI, Elsawi K, Selim M, NasrAllah MM. Effect of an Educational Program on Adherence to Therapeutic Regimen among Chronic Kidney Disease Stage5 (CKD5) Patients under Maintenance Hemodialysis. Journal of Education and practice. 2015;6(5):21-33.
4. The National Hospital of Sri Lanka [Internet]. 2015. Available from:<http://www.nhsl.health.gov.lk>
5. Naalweh KS, Barakat MA, Sweileh MW, Al-Jabi SW, Sweileh WM, Sa’ed HZ. Treatment adherence and perception in patients on maintenance hemodialysis: a cross-sectional study from Palestine. BMC nephrology. 2017 Dec;18(1):1-9.
6. Mukakarangwa MC, Chironda G, Bhengu B, Katende G. Adherence to hemodialysis and associated factors among end stage renal disease patients at selected nephrology units in Rwanda: A descriptive
7. Poveda V, Amado L, Filgueiras M, Teixeira L, Miranda V, Santos-Silva A, Paúl C, Costa E. End-stage renal disease adherence questionnaire: translation and validation to the Portuguese language. Renal failure. 2016 Nov 25;38(10):1633-8. http://dx.doi.org/10.1080/0886022X.2016.1209063

8. Kim Y, Evangelista LS, Phillips LR, Pavlish C, Kopple JD. The End-Stage Renal Disease Adherence Questionnaire (ESRD-AQ): testing the psychometric properties in patients receiving in-center hemodialysis. Nephrology nursing journal: journal of the American Nephrology Nurses' Association. 2010 Jul;37(4):377.

9. Kim Y, Evangelista LS. Development and cultural adaptation of the Spanish version of the End Stage Renal Disease Adherence Questionnaire (SESRD-AQ). Nephrology nursing journal: journal of the American Nephrology Nurses' Association. 2013 Nov;40(6):493.

10. Lins SM, Leite JL, Godoy SD, Fuly PD, Araújo ST, Silva ÍR. Validation of the adherence questionnaire for Brazilian chronic kidney disease patients under hemodialysis. Revista brasileira de enfermagem. 2017 May; 70:558-65.

11. Hassan RM, Mohamed HS, Rahman AA, Khalifa AM. Relation between Therapeutic Compliance and Functional Status of Patients Undergoing Hemodialysis. American Journal of Nursing. 2020;8(6):632-40.

12. Beaton DE, Bombardier C, Guillemín F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 2000 Dec 15;25(24):3186-91. https://doi.org/10.1097/00007632-200012150-00014

13. Lynn MR. Determination and quantification of content validity. Nursing research. 1986 Nov.

14. Lawshe CH. A quantitative approach to content validity. Personnel psychology. 1975 Dec 1;28(4):563-75. https://doi.org/10.1111/J.1744-6570.1975.TB01393.X

15. Shrotryia VK, Dhanda U. Content validity of assessment instrument for employee engagement. Sage Open. 2019 Feb;9(1):2158244018821751. https://doi.org/10.1177%2F2158244018821751

16. Tabachnick BG, Fidell LS, Ullman JB. Using multivariate statistics. Boston, MA: Pearson; 2007 Mar 3.

17. Mishra P, Pandey CM, Singh U, Gupta A, Sahu C, Keshri A. Descriptive statistics and normality tests for statistical data. Annals of cardiac anaesthesia. 2019 Jan;22(1):67.

18. Mowbray FL, Fox-Wasylyshyn SM, El-Masri MM. Univariate outliers: A conceptual overview for the nurse researcher. Canadian Journal of Nursing Research. 2019 Mar;51(1):31-7. https://doi.org/10.1177%2F0844562118786647

19. Kaiser HF. A second generation little jiffy. Psychometrika. 1970 Dec 1;35(4):401-15.

20. KOĞAR H, KOĞAR EY. Comparison of different estimation methods for categorical and ordinal data in confirmatory factor analysis. Journal of Measurement and Evaluation in Education and Psychology. 2015;6(2). https://doi.org/10.21031/epod.94857

21. Hu LT, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. Structural equation modeling: a multidisciplinary journal. 1999 Jan 1;6(1):1-55. https://doi.org/10.1080/10705519909540118
22. Hooper D, Coughlan J, Mullen MR. Structural equation modelling: guidelines for determining model fit. Electron J Bus Res Methods 6: 53–60.

23. Mulaik SA, James LR, Van Alstine J, Bennett N, Lind S, Stilwell CD. Evaluation of goodness-of-fit indices for structural equation models. Psychological bulletin. 1989 May;105(3):430.

24. Jamali-Dolatabad M, Sarbakhsh P, Sadeghi-Bazargani H. Hidden patterns among the fatally injured pedestrians in an Iranian population: application of categorical principal component analysis (CATPCA). BMC public health. 2021 Dec;21(1):1-9.

25. Fornell C, Larcker DF. Structural equation models with unobservable variables and measurement error: Algebra and statistics. https://doi.org/10.2307/3151312

26. Ab Hamid MR, Sami W, Sidek MM. Discriminant validity assessment: Use of Fornell & Larcker criterion versus HTMT criterion. InJournal of Physics: Conference Series 2017 Sep 1 (Vol. 890, No. 1, p. 012163). IOP Publishing. https://doi.org/10.1088/1742-6596/890/1/012163.

27. Linting M, van der Kooij A. Nonlinear principal components analysis with CATPCA: a tutorial. Journal of personality assessment. 2012 Jan 1;94(1):12-25. https://doi.org/10.1080/00223891.2011.627965

28. O’connor BP. SPSS and SAS programs for determining the number of components using parallel analysis and Velicer’s MAP test. Behavior research methods, instruments, & computers. 2000 Sep;32(3):396-402. https://doi.org/10.3758/bf03200807

29. Samuels P. Advice on exploratory factor analysis.

30. Portney LG, Watkins MP. Foundations of clinical research: applications to practice. Upper Saddle River, NJ: Pearson/Prentice Hall; 2009.

31. University of Virginia Library [Internet].2021.Available from:https://data.library.virginia.edu/using-and-interpreting-cronbachs-alpha/

32. Jhangiani RS, Chiang IC. Research methods in psychology-2nd Canadian Edition.

33. Schuberth F. Confirmatory composite analysis using partial least squares: setting the record straight. Review of Managerial Science. 2021 Jul;15(5):1311-45. https://link.springer.com/article/10.1007/s11846-020-00405-0

**Figures**
Figure 1

Flow chart of the procedure
Figure 2

Extraction of components based on O'Connor parallel analysis

Figure 3

Cattell’s (1966) scree plot