

RESEARCH ARTICLE



Validation of two brief instruments (the SURE and CollaboRATE) to measure shared decision-making in patients with restless legs syndrome

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Summary

Restless legs syndrome (RLS) is a common neurological disorder characterised by an urge to move arms and legs, usually associated with discomfort, pain, motor restlessness, and sleep disturbance. An individually adapted treatment is needed but difficult to optimise, which makes shared decision-making (SDM) important. However, brief validated instruments on how patients with RLS perceive their involvement in treatment decisions are lacking. Therefore, the aim was to validate two instruments, SURE (Sure of myself, Understand information, Risk–benefit ratio, Encouragement, i.e., to assess decisional conflict) and CollaboRATE (brief patient survey focused on SDM, i.e., to assess SDM), in patients with RLS. A cross-sectional design, including 788 participants with RLS (65% females, mean [SD] age 70.8 [11.4] years) from a national patient organisation for RLS, was used. A postal survey was sent out to collect data regarding weight, height, comorbidities, demographics, and RLS-related treatment data. The following instruments were included: the SURE, CollaboRATE, Restless Legs Syndrome-6 Scale, and eHealth Literacy Scale. Confirmatory factor analysis and Rasch models were used to assess the validity and reliability of the SURE and CollaboRATE. Measurement invariance, unidimensionality, and differential item functioning (DIF) across age, gender, and medication groups were assessed. The SURE and CollaboRATE were both identified as unidimensional instruments with satisfactory internal consistency. No DIF across age and gender was identified, while significant DIF was observed for both the SURE and CollaboRATE regarding medication use categories. However, both the SURE and CollaboRATE are potential instruments to be used in research, but also as reflection tools by healthcare professionals, patients, and students to explore and assess SDM, and support its development in clinical care.

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Funding information

Familjen Kamprads Stiftelse, Grant/Award Number: 20223144; Forskningsrådet i Sydöstra Sverige, Grant/Award Number: 969214

KEYWORDS

confirmatory factor analysis, decisional conflict, restless legs syndrome, shared decision-making, sleep, validity

1 | INTRODUCTION

Restless Legs Syndrome (RLS) is a sensory-motor disorder often affecting sleep (Garcia-Malo et al., 2020; Khachatryan et al., 2022), with a worldwide prevalence of 3% (Broström et al., 2023), that impacts all aspects of everyday life (Harrison et al., 2021). The disease causes an urge to move the legs due to unpleasant sensations, pain, motor restlessness and a worsening of symptoms during rest (Guay et al., 2020; Winkelman et al., 2013). Experiences of disturbed sleep (Harrison et al., 2021), depressive symptoms and a lower quality of life (Svetel et al., 2015) are frequent. Even though diagnostic criteria exist (Allen et al., 2014), RLS is deemed as a difficult condition to both diagnose and treat (Fulda et al., 2021), partly due to varying anamnestic descriptions by patients (Holzknecht et al., 2022), but also due to gender differences in clinical, laboratory and polysomnographic features, where women seem to be more severely affected by symptoms than men (Holzknecht et al., 2020). However, women seem to have a significantly lower degree of periodic leg movements during sleep. The treatment regime is complex, with dopaminergic drugs being the most widely used pharmacological approach, but a multiple treatment strategy often needs to be considered, including for example, iron, $\alpha_2\delta$ channel ligands, and benzodiazepines (Silber et al., 2021). There are also various non-pharmacological therapies, but more studies are needed (Harrison et al., 2019). Unfortunately, there is no standardised treatment for RLS, and what provides relief for the often very distressing symptoms is individual (Guay et al., 2020). RLS treatment is also complicated by augmentation, a phenomenon related to dopaminergic drugs, where the RLS symptoms become more severe over time and when the suggested response is to taper the drug and replace it with another treatment (Heim et al., 2017). This is counterintuitive to many patients, and some healthcare professionals (HCPs) who are not experienced in RLS, as increasing the dose in the face of augmentation typically leads to a short-term beneficial effect (Winkelman, 2022). It might therefore be challenging to achieve treatment adherence in such situations. As the patient is an expert on his/her own symptoms and symptom relief, it is of the utmost importance to individualise the care and to listen to each patient's story and plan treatment together (Swanson, 1991).

Shared decision-making (SDM) is a two-way process that may help HCPs and patients with RLS to agree on interventions (Elwyn et al., 2012, 2013). It can be described as a communication process where the practitioner and the patient together focus on the patients' needs, beliefs and wishes (National Quality Forum, 2017) and both consider the practitioner's knowledge regarding the disease and its treatment (Coulter & Collins, 2011). Today, it is increasingly common for patients to search for information in relation to their diagnosis and treatment on the internet (Milos Nymberg et al., 2019). Consequently, the importance of ehealth literacy increases in the care encounter

(Nguyen et al., 2016). RLS is well known to be common among the elderly (Broström et al., 2023), who, when compared to younger patients, have had to learn to use computers during their adult life (Wang et al., 2013). Elderly patients with RLS may therefore have difficulties accessing and interpreting digital information about their care, which in turn may impact SDM, both from the patient's and practitioner's perspective. Consequently, ehealth literacy can be an important aspect to include when validating instruments for decisional conflict and SDM.

When using SDM, the practitioner needs to carefully take into consideration 'what the patient is saying' and not decide themselves 'what the patient's needs are' (Elwyn et al., 2015; Oerlemans et al., 2021), that is, the patient's role in making decisions regarding their health needs to be considered (Légaré et al., 2008). Interestingly, proposals have been made that patients' health improves when involved in SDM, and SDM has also proven to be especially useful for patients with long-term health conditions (Joosten et al., 2008), like RLS. In contrast to this, Harrison et al. (2021) described how patients with RLS often felt that HCPs' understanding of their RLS symptoms and management was lacking and they could leave the appointment feeling their concerns had not been acknowledged. If they had medications prescribed, they felt that side-effects or other treatment options were not discussed, which made them reluctant to seek further care as their trust in the practitioner had disappeared. Therefore, using SDM in clinical practice can be beneficial for the patient's health (Joosten et al., 2008).

Previous literature reviews have identified many different decision aids and instruments for measuring SDM (Scholl et al., 2011; Simon et al., 2007; Stacey et al., 2017). Although there are several instruments, they focus on different aspects of SDM and are in many cases lengthy. The four-item SURE (Sure of myself, Understand information, Risk-benefit ratio, Encouragement) instrument focuses on the task of making a decision, while CollaboRATE (a brief patient survey focused on SDM), contains three items, focuses on SDM. Neither of these two instruments has been used in patients with RLS. The advantages of the selected instruments are their widespread use and brevity (Brodney et al., 2019) both in research and clinical practice. Therefore, the aim of the present study was to validate two instruments, the SURE (i.e., to assess decisional conflict) and CollaboRATE (i.e., to assess SDM) in patients with RLS.

2 | METHODS

2.1 | Design, setting and participants

The study used a cross-sectional design. The study sample was derived from a nationwide patient organisation for RLS containing

~1500 members. All members of the organisation were invited to participate in a postal survey. Inclusion criteria were being aged ≥ 18 years, having been diagnosed with and treated for RLS, being able to speak and understand Swedish, and granting written informed consent. Ethical approval was obtained (Dnr 2022-01515-01).

2.2 | Demographic and clinical data

Demographic variables (e.g., age, gender, living conditions, employment) and data regarding clinical aspects (e.g., self-reported comorbidities), diagnostic procedures (e.g., time since symptom-debut, time since diagnosis, follow-up routines), and treatment of RLS (e.g., medication, follow-up routines) were collected in the postal survey to describe sample characteristics and to be used as covariates in the analyses.

2.3 | Instruments

2.3.1 | The SURE

The SURE (Légaré et al., 2010) is an instrument developed to measure decisional conflict, that is, the patient's uncertainty about actions to take regarding their health when the actions may involve risk, loss, regret or when they challenge their own values. SURE contains four items, where the participant is asked (1) 'Do you feel sure about the best choice for you?' (Sure of myself), (2) 'Do you know the benefits and risks of each option?' (Understand information), (3) 'Are you clear about which benefits, and risks matter most to you?' (Risk-benefit ratio), and (4) 'Do you have enough support and advice to make a choice?' (Encouragement). A response of 'yes' scores 1 and a response of 'no' scores 0. A score of ≤ 3 indicates decisional conflict (Légaré et al., 2010). The SURE has previously been validated in patients with obstructive sleep apnea (Broström et al., 2019) and patients with acute respiratory infection (Ferron Parayre et al., 2014).

2.4 | The CollaboRATE

The CollaboRATE (Elwyn et al., 2013) is an instrument developed to measure SDM, that is, the extent to which the patient is informed, and involved in health issues and treatment options. CollaboRATE contains three items, where the participant is asked (1) 'How much effort was made to help you understand your health issues?' (2), 'How much effort was made to listen to the things that matter most to you about your health issues?', and (3) 'How much effort was made to include what matters most to you in choosing what to do next?'. A 5-point Likert scale is used ranging from 1 = no effort was made to 5 = every effort was made (Elwyn et al., 2013). The CollaboRATE has been found to be a valid and reliable instrument in patients with obstructive sleep apnea (Broström et al., 2019) and psychiatric outpatients (De Las Cuevas et al., 2020).

2.5 | Restless legs Syndrome-6 scale (RLS-6)

The RLS-6 includes six items assessing RLS symptoms during the past week (Kohnen et al., 2016). The items focus on sleep quality (items 1 and 6); RLS during the night (items 2 and 3); manifestations of RLS during daytime relaxation (item 4); and RLS during activity (item 5, which mainly refers to discriminating RLS from non-RLS symptoms). All items are rated on a 0–10 scale, where symptoms and sleepiness are rated from none/not at all (0) to very severe (10), sleep satisfaction from completely satisfied (0) to completely dissatisfied (10). When evaluating the results, item 5 is left out, and no total score is derived (Kohnen et al., 2016). In general, higher scores indicate more severe symptoms.

2.6 | The eHealth literacy scale (eHEALS)

The eHEALS measures the individuals' perceptions of their own digital health literacy skills (i.e., their combined knowledge, comfort, and perceived skills at finding, evaluating, and applying electronic health information to health problems) (Norman & Skinner, 2006). All eight items use a 5-point Likert scale ranging from strongly disagree (1) to strongly agree (5) (Norman & Skinner, 2006). A higher score indicates a higher level of eHealth literacy meaning greater confidence in finding, evaluating, and using health information on the internet to make health-related decisions (Paige et al., 2017).

2.7 | Data collection

Contact was established with the Swedish nationwide patient organisation for RLS. The board of the organisation agreed that information about the survey could be dispatched by postal mailing to all members. Between June and August 2022, all listed members aged ≥ 18 years received written information about the study, a questionnaire consisting of the above-mentioned instruments, as well as a separate document informing them that the board of the organisation had approved the dispatch. Agreement to participate was indicated by returning a written informed consent, which was separate from the questionnaire, in a pre-stamped envelope.

2.8 | Statistical analysis

The psychometric properties of the SURE and CollaboRATE were examined regarding internal consistency, factor structure, concurrent validity, and measurement invariance. The internal consistency was measured using the Cronbach alpha coefficient and McDonald's omega coefficient. Values of ≥ 0.7 for Cronbach's alpha and McDonald's omega coefficients indicate acceptable internal consistency (Kalkbrenner, 2023; Nunnally, 1978). To conduct further examinations of internal consistency, average variance extracted (AVE) and composite reliability (CR) were calculated according to the standardised factor

loadings from confirmatory factor analysis (CFA). An AVE value of ≥ 0.5 and a CR value of ≥ 0.7 is acceptable (Hair Jr et al., 2014). Corrected item-total correlation was calculated to measure to which degree individual items in a scale contribute to the overall score. A corrected item-total correlation of ≥ 0.3 is acceptable (Wang et al., 2007).

Factor structures of the SURE and CollaboRATE were assessed using the CFA (Brown, 2015). The weighted least square mean and variance adjusted estimator was used because the SURE has dichotomous response options and the CollaboRATE has ordinal response options. Several model fit indices were used to test the unidimensionality, including: a comparative fit index (CFI) of > 0.9 , a Tucker–Lewis index (TLI) of > 0.9 , a root mean square error of approximation (RMSEA) of < 0.08 , and a standardised root mean square residual (SRMR) of < 0.08 . Measurement invariance across age, gender and medication use subgroups was examined using multigroup CFA. Measurement invariance is established if the differences in the CFI (Δ CFI) are ≥ -0.01 , the differences in the RMSEA (Δ RMSEA) are ≤ 0.02 , and the differences in the SRMR (Δ SRMR) are ≤ 0.01 between the models being compared (Cheung & Rensvold, 2002).

To further evaluate the psychometric properties of the SURE and CollaboRATE, a Rasch analysis using the partial credit model was conducted. This analysis provided information on the properties of the scales' items, including item difficulty, mean square (MnSq) infit and outfit. Values between 0.5 and 1.5 for the infit and outfit MnSq were considered to indicate acceptable fit (Andrich & Hagquist, 2012; Tennant & Conaghan, 2007). Differential item functioning (DIF) was conducted to investigate whether age, gender and medication use subgroups responded differently to specific items of the SURE and CollaboRATE. A DIF contrast of < 1 indicated no substantial DIF (Holland & Wainer, 1993).

To assess the concurrent validity of the SURE and CollaboRATE, a network analysis (Borgatti et al., 2009) was conducted that investigated the patterns of associations between the items in the SURE, CollaboRATE, eHEALS, and RLS-6. The network structure was assessed using the least absolute shrinkage and selection operator (LASSO) (Friedman et al., 2010) regularisation based on the extended Bayesian information criterion (Chen & Chen, 2008). The importance of nodes within the network was measured using betweenness (connectivity measure), closeness (proximity metric), and strength (degree centrality). A non-parametric bootstrap with 500 samples was used to estimate the confidence intervals of the network parameters.

3 | RESULTS

3.1 | Study population

A total of 788 patients (mean [SD] age 70.8 [11.4] years) responded to the survey (i.e., response rate 52%), of which 65% were females, 62% were married, 43% had university education, 73% were retired, and 43% consumed alcohol once or less per month. The most common comorbidity was iron deficiency, which was reported by 78 patients (10%), while only 12 patients (0.01%) reported depression.

TABLE 1 Characteristics of the population ($n = 788$).

Variable	Value
Gender, female, n (%)	510 (65)
Age, years, mean (SD)	70.8 (11.3)
Education, n (%)	
≤ 9 years	166 (21)
12–13 years	277 (35)
University	345 (44)
Civil status, n (%)	
Married/living together	582 (74)
Unmarried and living alone	45 (6)
Divorced/widower and living alone	150 (19)
Smoking	
Yes, n (%)	41 (5)
Alcohol, n (%)	
Never uses alcohol	158 (20)
Uses alcohol 2–3 times or more/week	226 (29)
Comorbidities, n (%)	
Renal disease	15 (2)
Parkinson's disease	5 (0.5)
Multiple sclerosis	9 (1)
Migraine	59 (7)
Iron deficiency	78 (10)
Pharmacological treatment, n (%)	
Dopamine agonists	625 (79)
Opioids	163 (21)
$\alpha_2\delta$ ligands	144 (18)
Dopa/derivates	105 (13)
Iron supplement	33 (4)

Use of dopamine agonists, opioids, $\alpha_2\delta$ channel ligands, and dopa/derivates was reported by 79%, 21%, 18%, and 13%, respectively. The mean (SD) number of drugs was 3.6 (2.88). One fifth of the participants were fully satisfied with their prescribed RLS treatment. A total of 44% and 37% of the participants indicated severe symptoms during the night and day, respectively, on the RLS-6, and 43% experienced excessive daytime sleepiness. Patient demographics and clinical characteristics are shown in Table 1.

3.2 | Unidimensionality

The results of the psychometric properties of the SURE and CollaboRATE are shown at item level (Table 2). The original unidimensional model of the SURE did not yield acceptable model fits: chi-squared (degrees of freedom [df]) of 17.989 (2), RMSEA of 0.104, CFI of 0.995, TLI of 0.985, and SRMR of 0.031. Adding an error term between item 1 and item 4 resulted in a chi-squared (df) of 3.621 (1), RMSEA of 0.060, CFI of 0.999, TLI of 0.995, and SRMR of 0.013 (Table 3). Factor loadings were all significant and ranged from 0.775

TABLE 2 Psychometric properties of the SURE and CollaboRATE in item level ($N = 788$).

Item	Factor loading ^a	Item-total correlation	Infit MnSq	Outfit MnSq	Difficulty	DIF contrast across gender ^{bc}	DIF contrast across age ^{bd}	DIF contrast across medication use ^{be}	DIF contrast across medication use ^{bf}
SURE 1	0.775	0.615	1.06	1.20	0.53	0.49	-0.04	-0.64	-0.45
SURE 2	0.895	0.617	1.07	1.20	-1.89	-0.13	0.13	0.24	0.21
SURE 3	0.964	0.701	0.77	0.76	-0.64	-0.40	-0.05	1.02	0.45
SURE 4	0.810	0.614	1.06	1.17	2.00	0.05	-0.02	-1.11	0.27
CollaboRATE 1	0.881	0.814	1.23	1.12	-0.14	0.35	-0.21	0.43	0.32
CollaboRATE 2	0.965	0.881	0.77	0.72	-0.25	-0.05	0.20	-0.53	-0.30
CollaboRATE 3	0.906	0.857	0.96	0.93	0.39	-0.03	0.01	0.13	0

Abbreviations: DIF, differential item functioning; MnSq, mean square error.

^aBased on confirmatory factor analysis.

^bDIF contrast >0.5 indicates substantial DIF.

^cDIF contrast across gender = Difficulty for females - Difficulty for males.

^dDIF contrast across age categories = Difficulty for patients aged >70.79 years - Difficulty for patients aged ≤70.79 years.

^eDIF contrast across medication use = Difficulty for patients with no medication use - Difficulty for patients with monotherapy.

^fDIF contrast across medication use = Difficulty for patients with monotherapy - Difficulty for patients with polytherapy.

TABLE 3 Psychometric properties of the SURE and CollaboRATE in scale level ($N = 788$).

Psychometric testing	SURE	CollaboRATE	Suggested cut-off
Internal consistency (Cronbach's α)	0.816	0.927	≥0.7
Internal consistency (McDonald's omega ω)	0.813	0.928	≥0.7
Average variance extracted	0.747	0.842	≥0.5
Composite reliability	0.921	0.941	≥0.7
Confirmatory factor analysis			
Chi-squared (df)	3.621 (1)	0 (0)	Non-significant
Comparative fit index	0.999	1	>0.9
Tucker-Lewis index	0.995	1	>0.9
Root mean square error of approximation	0.060	0	<0.08
Standardised root mean square residual	0.013	0	<0.08
Rasch analysis			
Item separation reliability	0.99	0.89	>0.7
Item separation index	9.71	2.87	>2
Person separation reliability	0.50	0.88	>0.7
Person separation index	0.99	2.67	>2

Abbreviation: df, degrees of freedom.

to 0.964 (Table 2). The item-total correlations between the SURE items were all significant and >0.6. The original unidimensional model of the CollaboRATE showed an excellent fit to the data with a chi-squared (df) of 0 (0), RMSEA of 0, CFI of 1.0, TLI of 1.0, and SRMR of 0. Factor loadings ranged from 0.881 to 0.9065 with significant levels. Factor loadings ranged from 0.881 to 0.906 and were found to be significant. Additionally, all three CollaboRATE items showed high collation with the total score.

3.3 | Internal consistency

Internal consistency was found to be satisfactory for both the SURE and CollaboRATE. Both exhibited AVE and CR values above the threshold of 0.5 and 0.7, respectively (Table 3).

The results of Rasch analysis (Table 2) indicate that all items for both the SURE and CollaboRATE showed a general fit to the Rasch model. The infit MnSq values for the SURE ranged from 0.77 to 1.07, while the outfit MnSq values ranged from 0.76 to 1.20. Similarly, for the CollaboRATE, the infit MnSq values ranged from 0.77 to 1.23, while the outfit MnSq values ranged from 0.72 to 1.2.

To explore whether the items had similar psychometric and discriminative properties independent of the respondents' age, gender, and medication use, a DIF analysis was conducted (Table 2). The results revealed no substantial DIF for either the SURE or CollaboRATE for gender (male and female participants) and age categories (patients aged >70.8 years and those ≤70.79 years). Regarding medication use categories (i.e., no medication use, monotherapy, and polytherapy), significant DIF was

observed for both the SURE and CollaboRATE. Specifically, for the SURE, substantial DIF was found for item 3 (i.e., focusing on risk-benefit ratio) and item 4 (i.e., focusing on encouragement) between participants without medication use and those with monotherapy. No substantial DIF was found across patients with monotherapy versus those with polytherapy. Notably, there was no significant DIF for items in the CollaboRATE across medication use (Table 2).

3.4 | Measurement invariance

Tables 4 and 5 present the measurement invariance analysis of the SURE and CollaboRATE across age, gender, and medication use groups using CFA. Partial invariance was found for the SURE across gender groups as the difference between the Configural model (M1) and Metric model (M2) exceeded the acceptable thresholds. However, the differences between the Metric model (M2) and Scalar model (M3) were within the acceptable thresholds. In the age group, the differences between the Configural model (M1), Metric model (M2) and Scalar model (M3) were within the acceptable thresholds. Therefore, the SURE demonstrates full measurement invariance across age groups. The measurement invariance of the SURE across medication use groups was not supported as the differences between the Configural model (M1), Metric model (M2) and Scalar model (M3) exceeded the acceptable thresholds. The CollaboRATE showed full measurement invariance across age and gender groups of patients. However, for medication use

groups, partial measurement invariance was observed. The differences in fit indices between the Configural model (M1) and Metric model (M2) exceeded the acceptable thresholds (Tables 4 and 5).

3.5 | Concurrent validity

The results of the network analysis are depicted in Figure 1. The network consisted of 21 nodes, and out of a possible 210 edges, 107 were non-zero, resulting in a sparsity value of 0.490. Item 3 in the CollaboRATE and item 4 in the SURE showed a significant edge intensity ($r = 0.198$). Item 1 and Item 4 in the SURE had a negative but significant edge intensity with Item 2 ($r = -0.267$) and Item 3 ($r = -0.119$) of the RLS-6, respectively. Item 2 of the SURE and Items 1 and 6 of the eHEALS showed a weak edge intensity ($r = 0.041$). Regarding the centrality measures (Figure 2), the CollaboRATE had limited influence within the network, while the SURE showed a moderate influence as a connector variable. The eHEALS had mixed centrality measures, and the RLS-6 scale emerged as a key information hub.

4 | DISCUSSION

The present study is the first study within an RLS context to validate two brief instruments, focusing on the feeling of decisional conflict (i.e., the SURE) and how individuals perceive their participation in

TABLE 4 Measurement invariance of the SURE across gender, age and medication use groups through confirmatory factor analysis ($N = 788$).

Model and comparisons	Fit statistics							
	Chi squared (df)	Δ Chi squared (Δ df)	CFI	Δ CFI	SRMR	Δ SRMR	RMSEA	Δ RMSEA
Gender								
M1: Configural	4.323 (2)		0.998		0.009		0.058	
M2: Metric	5.531 (5)		0.999		0.015		0.017	
M3: Scalar	9.468 (8)		0.998		0.020		0.023	
M2 – M1		1.208 (3)		0.001		0.006		-0.041
M3 – M2		3.937 (3)		-0.001		0.005		0.006
Age								
M1: Configural	4.652 (2)		0.997		0.009		0.062	
M2: Metric	8.470 (5)		0.996		0.023		0.045	
M3: Scalar	9.881 (8)		0.998		0.026		0.026	
M2 – M1		3.817 (3)		-0.001		0.014		0.017
M3 – M2		1.411 (3)		0.002		0.003		-0.019
Medication use								
M1: Configural	21.97 (3)		0.981		0.021		0.161	
M2: Metric	45.21 (9)		0.963		0.057		0.128	
M3: Scalar	66.37 (15)		0.948		0.060		0.118	
M2 – M1		23.24 (6)		-0.018		0.036		-0.033
M3 – M2		21.16 (6)		-0.015		0.003		-0.010

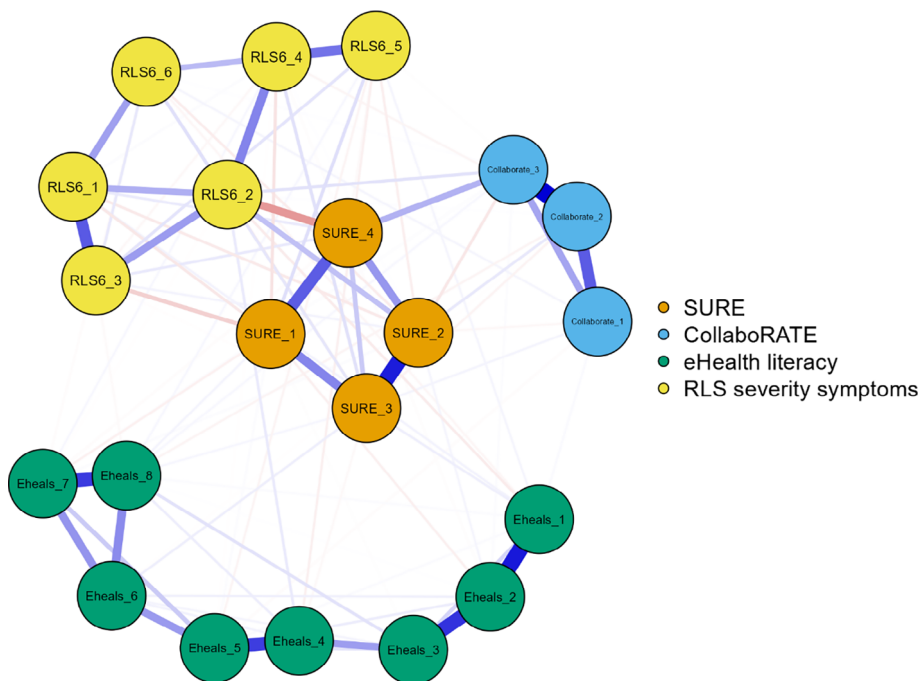
Abbreviation: df, degrees of freedom.

TABLE 5 Measurement invariance of the CollaboRATE across gender, age and medication use groups through confirmatory factor analysis (N = 788).

Model and comparisons	Fit statistics							
	Chi squared (df)	ΔChi squared (Δdf)	CFI	ΔCFI	SRMR	ΔSRMR	RMSEA	ΔRMSEA
Gender								
M1: Configural	0 (0)		1.0		0.0		0.00	
M2: Metric	0.635 (2)		1.0		0.003		0.00	
M3: Scalar	6.467 (10)		1.0		0.006		0.00	
M2 – M1		0.635 (2)		0.00		0.003		0.00
M3 – M2		5.576 (8)		0.00		0.003		0.00
Age								
M1: Configural	0 (0)		1.0		0.00		0.00	
M2: Metric	0.502 (2)		1.0		0.002		0.00	
M3: Scalar	7.776 (10)		1.0		0.011		0.00	
M2 – M1		0.502 (2)		0.00		0.002		0.00
M3 – M2		6.992 (8)		0.00		0.009		0.00
Medication use								
M1: Configural	0 (0)		1		0		0	
M2: Metric	5.92 (4)		0.999		0.044		0.044	
M3: Scalar	11.46 (8)		0.998		0.042		0.042	
M2 – M1		5.92 (4)		–0.001		0.044		0.044
M3 – M2		5.53 (4)		–0.001		–0.002		–0.002

Abbreviation: df, degrees of freedom.

FIGURE 1 Extended Bayesian information criterion GLASSO (graphical least absolute shrinkage and selection operator) model based on network analysis according to the SURE, CollaboRATE, eHEALS and RLS-6 (N = 788). SURE_1–SURE_4 = the SURE scale, Collaborate_1–Collaborate_3 = the CollaboRATE scale, Eheals_1–Eheals_7 = the eHealth Literacy Scale, RLS6_1–RLS6_6 = the Restless Legs Syndrome-6 Scale.



SDM (i.e., the CollaboRATE), using rigorous methods. Both demonstrated good validity, where age and gender did not influence the assessments made. Furthermore, the person's perceived ehealth literacy did not affect how they responded to the instruments measuring

decisional conflict and SDM in relation to their RLS treatment. Moreover, SDM has also proven to be especially useful for patients with long-term health conditions (Joosten et al., 2008) like RLS. Consequently, the two instruments can be used by physicians and other

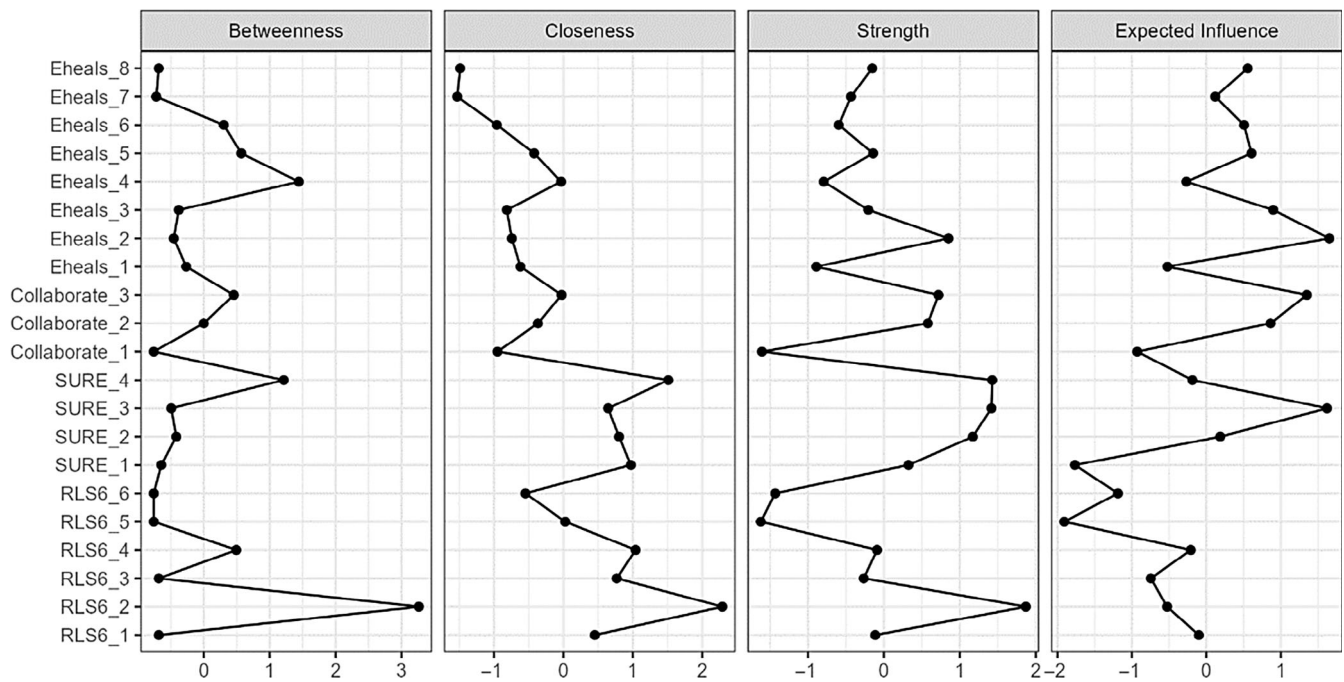


FIGURE 2 Standardised estimates of node centrality in according to the SURE, CollaboRATE, eHealth Literacy Scale (eHEALS), and Restless Legs Syndrome-6 (RLS-6) Scale ($N = 788$).

HCPs when learning to use SDM in clinical practice. The intention of the discussion is therefore to highlight the importance of validity aspects of the SURE and CollaboRATE and how they can be used in clinical RLS situations.

Both the SURE and CollaboRATE were identified as unidimensional with satisfactory internal consistency, meaning that they related only to the construct they were intended to measure. Initially, the SURE did not yield acceptable model fits, but when an error term was added between Item 1 and Item 4 it resulted in acceptable model fit indices. On the other hand, the CollaboRATE showed an excellent fit to the data. In an RLS context, both decisional conflict and SDM are important but complex constructs. A one-dimensional instrument can oversimplify the construct it is measuring. However, brief unidimensional instruments are important in clinical practice both for HCPs and patients. Another important aspect is DIF (Holland & Wainer, 1993), which occurs when patients with the same latent ability (e.g., the same level of experienced SDM), but from different groups defined by, e.g., age or gender, have different likelihoods of favouring a specific item response alternative on a multi-item scale (e.g., the CollaboRATE), after controlling for overall scale scores. The opposite occurs when patients with the same latent ability have an equal probability of getting a specific score on an item, regardless of group membership. Regarding age and gender, the results showed that no substantial DIF was identified for SURE or CollaboRATE (Table 2) meaning that age and gender did not affect answers to any of the items included in the instruments. RLS appears in almost all ages (Khachatryan et al., 2022), with a higher prevalence among older versus younger adults (Broström et al., 2023). Furthermore, previous literature emphasises a gender difference regarding

perceptions of RLS symptoms. For example, women have predominantly sensory symptoms, while men have predominantly motor symptoms. Furthermore, women assess their RLS severity as worse than men (Holzknecht et al., 2020). Interestingly, men and women also talk differently about their RLS, where men more frequently mention stable symptoms and successful attempts at relief than women (Holzknecht et al., 2022). Even though there seem to be gender differences in how RLS symptoms are described and experienced, the present study does not present gender-related DIF for the SURE or CollaboRATE.

Regarding medication use, a significant DIF was observed for both the SURE and CollaboRATE. The treatment of RLS is complex, and one treatment does not fit all (Didato et al., 2020; Lv et al., 2021; Winkelman, 2022). Current guidelines recommend initiating treatment for RLS when the symptoms impair the patient's function in everyday life. There are many factors to take into consideration when prescribing RLS treatment. The number of drugs prescribed did not affect the perceived SDM. When using SDM, HCPs must have faith and belief that the patient can make decisions about themselves and their care and must consider that the patient has the right to make decisions (Coulter & Collins, 2011). Different options and preferred outcomes are discussed, and optimal decisions are made in collaboration (Coulter & Collins, 2011; National Quality Forum, 2017). Informing the patient that their opinion is important is one way to invite the patient into a discussion on their health and care (Stibbelbout et al., 2015). However, dopamine treatment might influence the patient's decision-making ability. In two consecutive studies, Heim et al. (2017, 2018) investigated decision-making in patients with RLS with and without dopamine treatment using two distinct information sampling

tasks. All patients with RLS gathered significantly less information compared to healthy controls and made more irrational decisions. This could suggest that patients with RLS in general are more susceptible to making disadvantageous decisions. However, those treated with dopaminergic drugs had an even greater tendency to jump into conclusions than drug-naïve patients, regardless of whether they had had augmentation or not. Moreover, patients with dopaminergic treatment decided significantly more often to ignore the evidence they had at the time of their decision (Heim et al., 2017; Heim et al., 2018). Therefore, it is important to know the prescribed medications' effect on the individual patient. As part of quality improvement, or in tutoring sessions for students or less experienced HCPs, the SURE and CollaboRATE can be completed. This should be done after a consultation by both the patient and the HCP to facilitate reflection by the latter about the consultation to improve the latter's SDM competence.

Interestingly, the network analysis (Figure 1) showed Item 3 in the CollaboRATE and Item 4 in the SURE were related to each other. Moreover, Item 1 and Item 4 in the SURE had a negative but significant edge intensity with Item 2 (i.e., problems falling asleep) and Item 3 (i.e., problems during the night) of the RLS-6, respectively. In order to function effectively in everyday life and maintain overall well-being, sleep is a fundamental requirement for everyone (Tatinyen et al., 2020). Patients with RLS often exhibit symptoms at bedtime (Holzknecht et al., 2020). In the present study, the majority of the patients were elderly, and it is well known that elderly patients frequently encounter issues with insomnia (Tatinyen et al., 2020). Patients with RLS might feel they have lost faith in HCPs and medical treatment when they cannot control their sleep situation (Heim et al., 2017). A lesser focus on sleep-related problems and medical treatment might lead to patients trying to make their own corrections to their medical regime. The findings of the present study suggest that patients with RLS perceive a lack of support and advice in relation to their sleep situation and report serious symptoms that occur when falling asleep. Therefore, it is of the utmost importance that HCPs pay extra attention to patients experiencing this and invite them to the SDM. However, as patients might experience a lack of mutual language and faith in HCPs, it is important to be mindful of how consultations are carried out in different care settings in order to facilitate SDM (Coulter & Collins, 2011), as well as to follow up and evaluate the decisions made (Stibbelbout et al., 2015) to be able to support the patient to cope with symptoms and sleep problems.

Moreover, the network analysis displayed two clusters, one with items from the eHEALS and the other with items from the CollaboRATE, SURE and the RLS-6 Scale (Figure 1). There was also a weak association between Item 2 of the SURE (i.e., understanding of information) and Items 1 (i.e., knowledge to find health resources) and 6 (i.e., skills needed to evaluate health resources) of the eHEALS. Ehealth can be seen as an important improvement of the existing healthcare also for older adults (Milos Nymberg et al., 2019). However, when designing information materials and/or interventions, it is important to be mindful of the target population and use co-design (Sanders & Stappers, 2008). As many patients with RLS are older they

may be seen as 'digital immigrants' due to a potentially low digital literacy (Wang et al., 2013). When co-designing digital health information and/or an intervention regarding RLS, it might therefore be of great importance to include patients. The five 'As' of access (Sieck et al., 2021) could then be taken into consideration, namely: Availability (i.e., the relationship between existing health services provided by the system and resources to the patient's need and ability); Accessibility (i.e., the relationship between digital skills and literacy of the patient population and the support available); Accommodability (i.e., the relationship between requirements of, e.g., digital platforms and the patient's ability to navigate them); Affordability (i.e., the relationship between the costs of services and devices needed and the patient's ability to pay for them); and Acceptability (i.e., the relationship between the healthcare organisation's tools and workflows regarding the intervention and the patient's attitude toward and acceptance of the intervention) (Sieck et al., 2021). Given the limited resources in many healthcare organisations today, the utilisation of digital information materials, when tailored to age and digital literacy, has the potential to enhance accessibility and deliver crucial information. Additionally, it can empower patients to play an active role in SDM regarding their RLS.

4.1 | Limitations

Our sample was collected through a survey sent out to a nationwide patient organisation for RLS. The patients in the sample, response rate 52%, may have been more interested and engaged in their RLS diagnosis or dissatisfied with their care than persons not involved in a patient organisation or those who did not respond to the survey, which could have influenced the results in different ways. Comorbidities were self-reported, and some diagnoses such as depression might therefore be under reported. Furthermore, data regarding decisional conflict and SDM are self-reported from the perspective of the patient, and information about pharmacological treatment was not collected through medical records, nor was information regarding follow-up routines. The patients may have reported incorrectly about which drugs they were prescribed in relation to their RLS diagnosis. However, the sample was large and nationwide, which means that patients with varied symptom burdens and treatment regimens, who saw different doctors from different care settings, were included.

5 | CONCLUSIONS AND CLINICAL IMPLICATIONS

The instruments SURE and CollaboRATE showed good validity and reliability when used in an RLS context to measure SDM and decisional conflict. Even though previous literature highlights clinical gender differences, and how symptoms are communicated, there was no gender- or age-related DIF for either of the instruments. The significant DIF observed for both the SURE and CollaboRATE needs to be

further investigated. SDM was not influenced by the patient's ehealth literacy. These instruments can be used at a societal level to assess quality aspects of patient centredness, while at an organisational level they can be used as reflection tools to facilitate improvement works. In the latter case, the patient's and HCPs, responses to the instruments can, after a consultation, be discussed to learn and enhance SDM skills. Future studies of various designs are needed to further explore and evaluate SDM-related factors of importance to the patient's health, using the combined perspectives of patients and HCPs. Moreover, interventional studies with a randomised controlled design using large clinical multicentre samples from various settings should evaluate whether SDM can be enhanced if the SURE and CollaboRATE are used as reflection tools, and how this affects health and quality of life for patients with RLS.

AUTHOR CONTRIBUTIONS

Maria Björk: Writing – original draft; writing – review and editing; methodology; formal analysis. **Susanne Knutsson:** Writing – original draft; writing – review and editing. **Elzana Odzakovic:** Writing – original draft; writing – review and editing. **Amanda Hellström:** Writing – original draft; writing – review and editing. **Christina Sandlund:** Writing – original draft; writing – review and editing. **Martin Ulander:** Writing – original draft; writing – review and editing; supervision. **Jonas Lind:** Writing – original draft; writing – review and editing; supervision. **Amir H. Pakpour:** Writing – original draft; methodology; writing – review and editing; validation; visualization; formal analysis; data curation. **Anders Broström:** Writing – original draft; writing – review and editing; conceptualization; project administration; validation; methodology; funding acquisition; investigation; data curation; resources; supervision; formal analysis.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Björk, M., Knutsson, S., Odzakovic, E., Hellström, A., Sandlund, C., Ulander, M., Lind, J., Pakpour, A. H., Broström, A., & members of the Jönköping University (JU) Sleep Well Research Group (2023). Validation of two brief instruments (the SURE and CollaboRATE) to measure shared decision-making in patients with restless legs syndrome. *Journal of Sleep Research*, e14071. <https://doi.org/10.1111/jsr.14071>