

Jafarian, Fahimeh-Sadat, Yeowell, Gillian ORCID logoORCID: https://orcid.org/0000-0003-3872-9799 and Sadeghi-Demneh, Ebrahim (2022) Cross-cultural adaptation and validation of the Bad Sobernheim Stress questionnaire in Iranian adolescents with idiopathic scoliosis using thoracolumbar orthoses. Advanced Biomedical Research, 11 (39). pp. 1-7. ISSN 2277-9175

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Version: Accepted Version

Publisher: Medknow Publications

DOI: https://doi.org/10.4103/abr.abr_154_21

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Cross-Cultural Adaptation and Validation of the Bad Sobernheim Stress Questionnaire in Iranian Adolescents with Idiopathic Scoliosis Using Thoracolumbar Orthoses

Introduction

Scoliosis is a common spinal deformity that affects up to 5% of children[1] and often occurs during adolescence.[2] Children with scoliosis present a variable magnitude and pattern of the lateral curve that can progress depending on growth speed, and the initial magnitude of the curve.[3] Previous research reported that adolescents with scoliosis experienced a relatively more stressful life, more inferior psychological status, and decreased health-related quality of life (QoL) versus non-scoliotic peers.[4-6] Adolescent scoliosis aesthetically affects the trunk appearance and this condition can last over several years; hence, this deformity has the potential to influence body image and self-esteem adversely.[7] The risk of curve progression in adolescent scoliosis can be prevented by nonsurgical interventions such as orthotic management before reaching skeletal maturity.[8] Orthotic management can lead to alignment correction in adolescent scoliosis if a user is compliant.[9] The curve correction induced by orthoses requires the active participation of patients and their families during the treatment program, often lasting several months or years.[10] Wearing a trunk orthosis may itself cause social problems, in-brace pressure, and discomfort, which can further affect a person's psychological status and leave emotional scars.[11] Psychological stress is becoming a substantial concern in managing adolescent scoliosis due to its association with reduced treatment compliance.[10] Adolescents with scoliosis, therefore, can have various emotional challenges due to the orthotic management received. Thus, the assessment of psychological stress has become an integral part of the clinical indicators required to evaluate health-related factors in adolescents' use of orthoses for their scoliosis.

The recent literature on the effectiveness of therapeutic management for adolescent scoliosis has demonstrated a growing interest in using patient-oriented outcomes that reflect patients' perceptions about their health status and the management received.[10] Accordingly, Weiss et al. developed Bad Sobernheim Stress questionnaire-Brace (BSSQ-Brace) questionnaire to evaluate the psychological stress caused by orthotic management.[11] This questionnaire has been shown to be a valid and reliable tool to measure psychological stress in adolescent idiopathic scoliosis (AIS) who were under orthotic management.[12] BSSQ-Brace was initially developed in German and was culturally adapted into other languages, including Polish,[13] Spanish,[14] Chinese,[15] and Turkish.[16] The use of BSSQ- BrQs in different languages requires not only a good translation but also cross-cultural adaptation. To date, the BSSQ-Brace has not been culturally adapted for use by Iranian patients who are treated with the commonly used thoracolumbar orthosis (TLSO). Due to this and cultural differences between German and Persian language speakers, a cross-cultural adaptation of the BSSQ-Brace is required if it is to be adopted by Persian language speakers. The objective of this study was to evaluate the psychometric properties of the BSSQ- BrQs translated into the Persian language.

Material and Methods

This was a cross-sectional study performed from April 2016 to December 2018 in two phases. Phase I was to translate BSSQ-Brace into the Persian language, and Phase II was to test the psychometric properties of the translated questionnaire. Ethical approval was obtained from the Committee of Isfahan University of Medical Sciences. Participants gave informed consent before participation, in accordance with the standards of the Declaration of Helsinki.

Phase 1:

Translation The BSSQ-Brace was translated and culturally adapted into the Persian language according to standardized guidelines.[17] Firstly, the authors received a permission to translate the questionnaire into Persian from the developer of BSSQ-Brace. Based on the proposed guideline,[17] five stages were carried out: forward translation into Persian, synthesis, backward translation into German, evaluation of the translated drafts, and finally pretesting consensus draft.

Forward translation into the Persian language was carried out independently by three bilingual speakers who were fluent speakers of German and Persian. A committee consisting of three translators and two authors of this research reviewed the forward translation and rated the clarity of the translation. Any misunderstanding of terms was discussed in the group until a consensus was made, and the synthesized Persian version of BSSQ-Brace was developed. The synthesized version was translated back into the German language by the other two translators.

The back-translation was obtained and sent to the original developer of BSSQ-Brace for final approval. In the last stage, fifteen specialists in rehabilitation sciences and fifteen participants (for the pilot study) with scoliosis tested the prefinal Persian BSSQ-Brace. All participants were interviewed face-to-face by one of the authors (F-S.J). The findings of this stage indicated that all eight items were easy to understand. Thus, the prefinal version was accepted as the final version of the Persian BSSQ-Brace.

Phase 2: Testing psychometric properties

Fifty-five participants diagnosed with AIS volunteered for the second phase of the study. Participants were diagnosed with AIS by an orthopedic specialist in Alzahra hospital, Isfahan, Iran. All participants were under orthotic treatment for their AIS. Participants were included in the study if they met the following criteria: Aged between 12 and 16 years; a minimum duration for using a trunk orthosis was at least 4-month[18] and for more than 12 h a day (determined by patient or parent reporting); being able to read and write the Persian language. Patients who were unwilling to undertake the brace intervention or who had cognitive problems were excluded.

Measuring instruments

BSSQ-Brace consists of 8 items with a 4-point scale ranging from "not true at all," "hardly true," "nearly true," to "completely true," scored from 0 to 3, respectively. The 8-item scores are summed to provide an overall questionnaire score from 0 (maximum stress) to 24 (minimum stress). The stress level is classified as follows: 0–8 (high stress), 9–16 (moderate stress), and 17–24 (low stress).[12] Scoliosis Research Society-22r (SRS-22r) patient questionnaire is a valid and reliable scale that evaluates the health issues related to AIS.[19] This questionnaire was reported as an excellent tool to assess the QoL in an adolescent with idiopathic scoliosis[20] and has sufficient internal consistency and concurrent validity.[21,22] SRS-22r has five subscales for (1) functional activity, (2) pain, (3) mental health, (4) self-image, and (5) management satisfaction. Each item is scored with a 5-point scale ranging from 0 to 5, and a higher score indicates a better QoL.[23] The Persian version of the SRS-22r questionnaire[24] was used to assess the construct validity of the Persian version of BSSQ-Brace and SRS-22r questionnaires in the first session. One week later, the BSSQ-Brace was completed by all participants to measure test-retest reliability.

Statistical analysis

The sample size calculation in patient-reported outcomes (such as this study) is controversial, and there is no consensus in the guidelines.[25] The authors use the minimum subject to item ratio of 5:1, which is recommended for exploratory factor analysis.[26] The BSSQ-Brace has eight items; therefore, the sample size was initially set at least 40 participants. The recruitment of subjects was increased afterward to improve the power of the study. Pearson's correlation coefficient (r-value) was calculated to determine to construct validity. The r values between 0.9 and 1.0 indicate an excellent relationship.[27] Test-retest reliability was assessed by the interclass correlation coefficient (ICC) (95% confidence interval, [CI]) using a two-way random-effects model. Values equal to or more than 0.7 were considered high reliability.[28] Cronbach's alpha (with 95% CIs) was calculated to analyze the internal consistency. Values between 0.7 and 0.95 indicate good and acceptable internal consistency.[26]

Results

The Persian BSSQ-Brace was found to be a linguistically simple questionnaire. There was neither difficulty in translation nor a substantial difference between forwards and back translation of the questionnaire. A consensus was always found within the group discussion if any modification was required. The original developer approved the backward translation. The average time taken to complete the questionnaire was 3 min. One of the questionnaire items had a modification to improve the aimed situation due to cultural differences. The second item of the questionnaire (It is hard for me to be open with my brace) was replaced with "It is hard to reveal my brace by taking off my clothes" because it was easier to understand.

Fifty-five native Persian speakers with AIS, aged $14.76 \pm 1/53$ (mean + standard deviation), participated in Phase II of this research. Participants included 40 girls and 15 boys. All patients were treated using the Boston brace. The mean duration of brace wearing was 20.33 + 9.95 months. The demographic and clinical information of participants is reported in Table 1. The mean BSSQ-Brace score was 8 ± 0.5 , and the SRS-22r value was 63.4 ± 1.47 [more details on the questionnaires' score are presented in Table 2]. 32.7% of participants (18 people including 15 females and 3 males) reported high-stress levels (scored 0–8) and 63.7% (37 people including 25 females and 12 males) reported medium-stress levels (scored 9–16).[11]

The BSSQ-Brace showed a high correlation with SRS-22r (r = 0.74) [Table 3]. The SRS-22r subscales showed a correlation of 0.48–0.81 with the BSSQ-Brace [Table 3]. The test-retest reliability and internal consistency were good for BSSQ-Brace. Table 4 displays the results of reliability analysis with a Cronbach's alpha of 0.94. The ICC and scanning electron microscope were 0.94 and 0.38, respectively. Table 5 presents the results of the consistency analysis for BSSQ-Brace items. The highest value of the Intraclass Correlation Coefficient was for question six (0.93), and the lowest was for question seven (0.62).

Discussion

This study provided a cross-culturally adapted Persian version of the BSSQ-BrQ that demonstrated strong psychometric properties, including validity, reliability, and internal consistency to assess the stress level of people wearing a thoracolumbar brace for AIS (Appendix 1). Orthotic therapy can be an effective conservative management for AIS;

however, it may cause discomfort, which can negatively impact the users daily activities and as a consequence, reduce their QoL.[18] The emotional status of the brace users is associated directly with compliance to the bracing management.[18,29] The measurement of the psychological stress of the brace users' therefore, could be an integral part of the outcomes used to evaluate the effectiveness of bracing protocols in the research and clinical environments. There are several disease-specific questionnaires to measure QoL in people with scoliosis, which include SRS-22r, spine appearance, and BrQ.[30] These questionnaires take longer to complete than BSSQ-Brace and the stress level is assessed less directly.

The BSSQ-Brace focuses on the measurement of stress level induced by bracing the trunk for scoliosis. The psychometric studies showed satisfactory properties for Spanish,[31] Polish,[13] Turkish,[16] and Chinese[15] cross-cultural adaptations. This study showed that BSSQ-Brace is a valid and reliable questionnaire to evaluate the stress level of using the bracing protocol in adolescents with scoliosis in Iran. Around one-third (33%) of participants reported a high-stress level with the bracing protocol in this current study, compared to 27% in the original German version,[11] and approximately 23% in the Polish version.[13]

All participants in the current study used a TLSO made by a rigid thermoplastic. This orthosis has a symmetrical structure, which has been individually fitted to the patient's trunk. It can be worn under clothes and not be visible. There is another Persian translation of BSSQ-Brace in which participants used the cervicothoracolumbar (Milwaukee) orthosis.[32] The Milwaukee brace has a circumferential neck ring and high-profile structure and can significantly deteriorate emotional status and QoL compared with the low-profile TLSOs.[33] Nowadays, the Milwaukee brace has mostly been replaced by the TLSO to improve the QoL and compliance of the users.[11] Therefore, it is anticipated that this current cross-cultural adaptation study using the TLSO is likely to have greater applicability and generalizability due to its more common usage in current clinical practice compared to the less frequently used the Milwaukee brace.

SRS-22r is the most popular tool to test the construct validity of BSSQ-Brace within different cross-cultural adaptations, as used in the Chinese and Spanish studies.[14,15] The construct validity of this current study was 0.74, which is higher than reported values of 0.48 in Chinese,[15] 0.66 in Spanish,[14] and 0.63 in the former Persian[32] versions. Internal consistency (Cronbach's alpha 0.94) indicated an internally homogenous construct for the translated BSSQ-Brace in this current study. This is comparable with original German questionnaire (0.97)[12] and is superior to the internal consistency in the Polish (0.8),[13] Spanish (0.81),[14] Chinese (0.85),[15] Turkish (0.88),[16] and in the previous Persian (0.72)[30] versions. The test-retest reliability of the translated questionnaire in this current study was excellent (0.94), which is comparable to previously reported versions in Turkish (0.98),[16] Spanish (0.9),[14] German (0.88),[12] Chinese (0.85),[15] Polish (0.82),[13] and the former Persian (0.88)[32] version.

There are some limitations to this study. Participants were recruited through a convenience sampling method. This method was a nonrandomized sample and might not include the full range of severity for this condition. However, convenience sampling is commonly used in studies for cross-cultural adaptation. A 1-week interval for test-retest may be considered a long duration between the two sessions and could lead to some clinical change due to bracing effects. However, this duration was decided upon to mitigate against recall effects.[34] The data collection of this study was carried out in Isfahan city. This is one of the largest cities after the capital city (Tehran) and has a heterogeneous population representing the whole

country. Although there are some differences in Persian accents and vernaculars within Iran, there is no grammatical or semantic difference in the standard Persian language.

Conclusion

Our findings support the application of the Persian BSSQ-Brace for the evaluation of brace management in people with AIS.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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Characteristics	Values*
Age (years)	14.76 <u>+</u> 1.53 (12-17)
Sex Male n(%) Female n(%)	15 (27.2%) 40 (72.7%)
Orthotic wearing time (months)	20.33 <u>+</u> 9.95 (8-48)

Table 1. Demographic and clinical information (n=55)

*values are presented in M+SD and range unless indicated in another form.

	Mean	SD	Minimum	Maximum
Overall BSSQ-Brace score	8	0.5	1	15
1 st session	7	0.5	1	16
2 nd session	9	1	1	14
Overall SRS-22r score	63.4	1.47	48	73
1. Function	11.9	0.29	9	14
2. Pain	20.7	0.52	17	25
3. Mental health	13.75	0.55	9	17
4. Self-image	11.15	0.60	5	16
5. Treatment satisfaction	5.80	0.17	4	7

Table 2: Participants' scores for the Persian BSSQ-Brace and SRS-22r

BSSQ: Bad Sobernheim Stress questionnaire, SRS-22r: Scoliosis research society-22 patient questionnaire, SD: Standard deviation

	Persian BSSQ-Brace	
	r	P-value
SRS-22r	0.74	< 0.001*
Function	0.65	0.002*
Pain	0.50	0.024*
Mental health	0.81	0.001*
Self-image	0.80	0.001*
Treatment satisfaction	0.48	0.031*
*indicates significant correlat	ion; r: Pear	son's

Table 3. Correlation between the BSSQ-Brace and SRS-22r scores.

Table 4. Test-retest reliability and internal consistency of the Persian BSSQ-Brace

ICC	0.95% confidence interval	SEM	Cronbach's alpha
0.94	0.91-0.95	0.38	0.94

ICC: Intraclass Correlation Coefficient; SEM: standard error of measurement.

Table 5. The results of consistency analysis for different items of BSSQ-Brace.

Questionnaire items	Inter-item
	correlation
1. I feel uncomfortable by the appearance of my body in the brace	0.86
2. It is hard for me to be open with my brace	0.77

3. I feel uncomfortable in situations where other people can see my brace	0.78
4. I don't feel embarrassed when people see my brace	0.67
5 I avoid body contact so that no-one knows that I wear a brace	0.76
6. When deciding what kind of clothes to wear or how to wear my hair, I try to make	0.93
sure my brace is hidden	
7. I don't feel embarrassed to show my brace to people close to me (parents, friends,	0.62
and school friends)	
8. Because of my brace, I avoid activities/hobbies, which otherwise I love to do	0.82
Total	0.7