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Development and psychometric evaluation of the Sexual Health Assessment Tool for Infertile Women (SEHAT-IW)

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Abstract

Purpose This study aimed to develop a valid and reliable tool for evaluation of sexual health assessment in infertile women.

Methods This was a mixed exploratory study consisting of two phases. At phase one, we reviewed the existing instruments and interviewed 20 infertile women to generate an item pool. Then, the research team examined items and invited a panel of experts ($n=15$) and a group of infertile women ($n=10$) to review the items to establish content and face validity. Accordingly, the provisional version of the questionnaire containing 62 items was provided. At phase two, a cross-sectional study was conducted to evaluate the questionnaire. The structural validity was examined by performing exploratory factor analysis. Internal consistency was estimated by the Cornbach's alpha coefficient and test–retest analysis was performed to assess stability.

Results The final questionnaire consisted of 45 items and a total of 372 infertile women completed the questionnaire. The mean age of women was 30.8 (SD 6.0) years and this was 5.6 (SD 4.2) for duration of infertility. The results obtained from exploratory factor analysis indicated a five-factor solution for the questionnaire that jointly explained 51.39% of variance observed. At this stage, 15 items were deleted due to low factor loading. The analysis of internal consistency and stability yielded satisfactory results (Cronbach alpha: 0.93, ICC 0.97, respectively). Further analysis indicated that lower sexual health in infertile women was associated with education (OR for primary education 2.61, 95% CI 1.44–4.76, $P=0.002$) and being housewife (OR 2.35, 95% CI 1.15–4.83, $P=0.01$).

Conclusion The findings showed that the Sexual Health Assessment Tool for Infertile Women (SEHAT-IW) is a reliable and valid instrument to assess infertile women's sexual health.

Keywords Infertile women · Psychometric · Instrument · Sexual health

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Introduction

Infertility has been recognized as international public and social health issue affecting around 13% of females and 10% of males [1]. Infertility is characterized as a disease that lacks any clinical pregnancy after 12 months of regular, unprotected sexual intercourse [2]. One of the most significant factors impacting marital satisfaction and sexual satisfaction is the state of fertility [3]. Infertility appears to pose a major challenge to the sexual life of couples. Management of infertility may influence many facets of infertile women's lives, resulting in many emotional and psychological disorders such as sexual dysfunction, anxiety, depression, marital distress [4], hopelessness, guilt, and worthlessness [5, 6].

One of the main factors of sexual health is the link between sexual health and infertility [5] and the fact that good sexual health is essential for individuals and society

[7]. The World Health Organization emphasizes sexual health as a continuum of physical, emotional, and social-cultural well-being associated with sexuality [8]. Despite widespread awareness of reproductive rights over the past 4 decades (since 1970), the focus has been put on population control and reduction of maternal and infant mortality, while infertility and sexual health remain largely hidden in the broader sense [9]. Psychological pressures for pregnancy, forced intercourse, and clinical measures can create a sense of anxiety that affects infertile women's sexual health [10]. Many fertility therapies that prevent spontaneous sexual contact may also be implicated in issues of sexual function such as erectile dysfunction (stimulation) and decreased libido and arousal [11].

Infertility affects physical and emotional health negatively. It also impacts the relationships between couples and has an economic burden on them. Stress impacts women more than men. All these factors can result in sexual dysfunction [12]. With ongoing infertility trends, the breakdown of the relationship between sexuality and fertility [9] may result in feelings of sexual inadequacy and depression. Considering the above-mentioned implications, the issue of sexual health screening in the early stages of infertility treatment is less addressed [13]. Therefore, it is important to assess and promote sexual health in this population. Unfortunately, there have been no dedicated instruments to assess sexual health in infertile women so far. Therefore, the need for a valid and reliable instrument that can measure infertile women's sexual health seems necessary. It is argued that using an instrument or questionnaire to measure health, including individuals' sexual health, is highly effective and efficient not only in health planning and policy making, but also in centers that are providing services to their infertile clients [14]. Considering these concerns and given the increasing number of infertile women [15], the present research aimed to develop a valid and reliable tool for evaluation of sexual health in infertile women.

Methods

This was a two-phase study using a sequential-exploratory mixed method in 2018–2019. In the following sections, these will be described.

Phase 1: Item denegation and providing provisional version

The concept of sexual health in infertile women has been established by performing a literature review and a qualitative study based on infertile women's experiences. As such sample of 20 infertile women were interviewed. The characteristics of women are shown in Table 1. Data saturation was achieved with 17 interviews, but three more interviews were also conducted for more certainty. Data gathering techniques employed included in-depth semi-structured

Table 1 Demographic characteristics of the qualitative phase samples

Number of participants	Age	Education level	Employment status	Infertility duration	Type of infertility
1	28	Higher	Housewife	6	Primary
2	32	Secondary	Housewife	5	Secondary
3	25	Secondary	Housewife	4	Primary
4	25	Secondary	Housewife	7	Primary
5	31	Higher	Employed	1	Primary
6	30	Higher	Housewife	2	Primary
7	38	Higher	Employed	10	Primary
8	31	Higher	Housewife	4	Primary
9	27	Higher	Housewife	4	Primary
10	33	Primary	Housewife	7	Primary
11	36	Secondary	Housewife	13	Primary
12	39	Higher	Employed	1	Primary
13	27	Secondary	Housewife	4	Primary
14	37	Secondary	Housewife	14	Primary
15	36	Secondary	Employed	10	Primary
16	33	Secondary	Employed	10	Primary
17	40	Secondary	Housewife	3	Secondary
18	34	Higher	Employed	4	Primary
19	32	Secondary	Housewife	10	Primary
20	42	Primary	Housewife	16	Primary

open face-to-face interviews and field notes. The conventional content analysis method is used for analysis of data. The data were processed using the systematic method of Lundman and Graneheim [16].

Then, the research team reviewed the information gathered during the sessions after defining the concept and determining the dimensions and items of the instrument. At this stage, an item pool of 100 questions was provided. Of these, 97 items were generated by the research team and 3 items were extracted from existing instruments [17–19]. Accordingly, to provide the provisional version of the questionnaire content and face validity were performed. We invited 15 experts (obstetricians and gynecologists, reproductive health specialists, psychologists, and methodologists) to evaluate items based on relevance, simplicity, and clarity. As a result, 36 items were removed. Face validity: it was conducted with a sample of ten infertile women. They were asked to evaluate if the items could be understanding easily, and are important and relevant to their conditions. At this stage, 2 additional items were. Then, the remaining 62 items made the provisional version and were subjected to further psychometric evaluation. Each item is scored from 1 (strongly agree) to 5 (strongly disagree). However, there were items that were recoded to imply a similar direction for the questionnaire.

Phase II: Psychometric evaluation

A cross-sectional study was conducted on a sample of infertile women attending to infertility clinics in a teaching hospital affiliated to Tehran University of Medical Sciences, Tehran, Iran. The inclusion criteria were: ability to speak Persian, sexually active, confirmed female infertility by physician, no history of mental disorder, physical disability, or dysfunction. Women were excluded if did not agree to participate in the study or did not complete the questionnaire correctly. The following procedures were applied to psychometrically evaluate the questionnaire:

Structural validity

The exploratory factor analysis was used to evaluate the structural validity. Since the recommended sample size for analysis is 5–10 individuals per item [20], we recruited six participants per item. To assess the suitability of the data for factor analysis, the Kaiser–Meyer–Alkin (KMO) sampling adequacy index and Bartlett's Spearman test were used. If a KMO value of 0.8 or 0.9 is obtained and the Bartlett Sphericity test is significant, it would be appropriate to conduct factor analysis [21].

Table 2 Demographic characteristics of the participants

	Mean (SD)	No. (%)
Age	30.8 ± 6.0	372 (100)
Infertility duration	5.6 ± 4.2	–
Employment status		
Housewife		316 (84.9)
Employed		56 (15.1)
Education level		
Primary		91 (24.5)
Secondary		150 (40.3)
Higher		131 (35.2)
Infertility reason		
Recurrent abortion		21 (5.6)
Uterine and cervical disorders		18 (4.9)
Unknown		127 (34.1)
Ovarian disorders		174 (46.7)
Fallopian obstruction		20 (5.4)
Hormonal issues		8 (2.2)
Immunological issues		4 (1.1)

Reliability

Internal consistency and stability have been evaluated at this stage. The Cronbach's alpha coefficient was estimated to determine the instrument's internal consistency and test–retest method was applied for stability. Thirty identical infertile women completed the questionnaires twice over a 2-week interval and interclass correlation coefficient (ICC) was calculated [22].

Further analysis

To assess the relationship between sexual health, demographic and reproductive variables, logistic regression analysis was performed. In doing so proportional to sexual health mean score, the sample was divided into two groups: those who scored higher and those who scored lower. Then, odds ratio and 95% confidence intervals for lower sexual health adjusted for age, education, employment, and duration of infertility were estimated.

Results

The study sample

All 400 infertile women completed the questionnaire. Of these, 28 infertile women were excluded due to incomplete response to the questionnaire. Thus, the data obtained from 372 participants were analyzed. The mean age of women was 30.8 (SD 6.0) years and the mean infertility duration

was 5.5 (SD 4.2) years. Most participants were housewives (84.9%). The characteristics of women are presented in Table 2.

Structural validity

The structural validity was assessed using the exploratory factor analysis (EFA). The adequacy of sample size was confirmed by KMO and Bartlett's test of sphericity. The KMO statistic was 0.93. Bartlett's test with a statistic of 10,155.92 was also significant at $P < 0.001$. Principal component analysis was used to extract the main factors. Due to factor loading of less than 0.3, 15 items were removed, and eventually, 47 items were loaded on five factors with eigenvalues more than one that jointly explained 51.39% of variance observed. Also, the scree plot suggested generating a five-factor model (Fig. 1). Factor 1 with 15 items and Factor 2 with 16 items were labeled as the 'negative psychological impact of infertility' and the 'influence of infertility and its therapies on sexual life', respectively. Factor 3 with 7 items was labeled as 'spouse role'. Factor 4 with 5 items and Factor 5 with 3 items were labeled as the 'effect of infertility on the nature of sexual relation' and 'the negative impact of friends/relatives and the absence of children on the quality of sexual life'. The results are shown in Table 3.

Reliability

Internal consistency and stability were estimated to determine the instrument's reliability. For the 47 items of the questionnaire, the Cronbach's alpha coefficient was 0.92, well above an acceptable threshold. The internal consistency for all factors was acceptable except for factor four where the initial alpha value was 0.2. However, by eliminating two items (43 and 44), it was increased to 0.7. The total alpha value also changed from 0.92 to 0.93. Therefore, the number of items in the final questionnaire was reduced from 47 to 45 items. Test–retest reliability of the instrument and its subscales as estimated by ICC was above the acceptable threshold (Table 4).

Determinants of sexual health

The association between sexual health and age, education, employment, and duration of infertility was assessed using logistic regression analysis. The result indicated that lower sexual health significantly were associated with lower level of education (OR for primary education 2.61, 95% CI 1.44–4.76, $P = 0.002$), and being housewife (OR 2.35, 95% CI 1.15–4.83, $P = 0.01$), whereas age and duration of infertility were not (Table 5).

Discussion

Considering that infertility severely affects women's lives, it is necessary to have specific instrument for evaluating such concerns. Women who suffer from infertility are more at risk for sexual and mental health problems. In these women, sexual-related quality of life is not optimal and even might influence couples' relationship [23]. This study was the first attempt to design and psychometrically evaluate a sexual health assessment questionnaire for infertile women**.**

The primary questionnaire was developed based on qualitative study; definition of sexual health as offered by the World Health Organization and reviewing the existing instruments. After performing the validity and reliability, the designed questionnaire contained 45 items tapping into five factors. The results showed that the questionnaire was

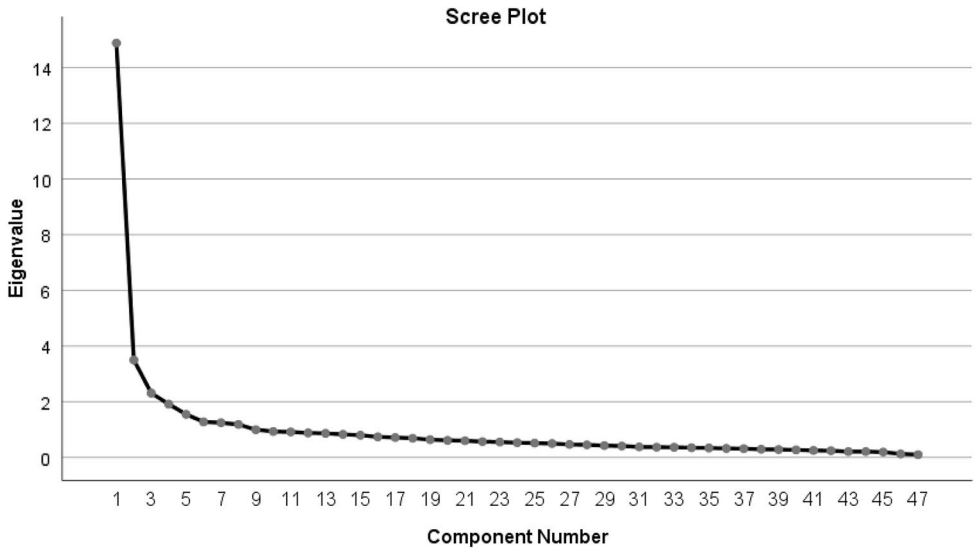

Fig. 1 Scree plot test for Sexual Health Assessment Tool for Infertile Women (SEHAT-IW)

Table 3 Factor loadings for exploratory factor analysis with varimax rotation of the Sexual Health Assessment Tool for Infertile Women (SEHAT-IW)

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
1. I'm afraid that I won't have a child in the future	0.51	0.07	−0.12	−0.00	0.36
2. Negative thoughts about infertility cause me not to focus on sexual relation with my wife	0.68	0.26	0.01	−0.1	0.16
3. I'm always afraid that my spouse's going to betray me	0.79	0.06	0.13	−0.01	−0.14
4. I get worried when my husband doesn't want to have sexual relation with me	0.76	0.1	0.03	0.01	−0.12
5. I'm always concerned about my spouse's feelings about my infertility	0.76	0.17	0.07	0.04	0.02
6. I'm disturbed by people around me behavior toward their children	0.53	0.12	0.06	0.04	0.15
7. Due to my infertility, I became very sensitive to the words of my spouse	0.7	0.14	0.21	−0.04	0.09
8. I'm tired of the long process of diagnostic-therapeutic treatment and frequent traffic	0.48	0.05	−0.01	−0.18	0.28
9. I prefer to be alone because of my infertility problem	0.58	0.25	−0.01	−0.16	0.21
10. I blame myself that I could not have children	0.64	0.13	0.06	−0.1	0.16
11. Having sexual relation according to the timing of treatment makes me nervous	0.43	0.42	−0.13	−0.19	0.14
12. I am so bored and laconic by infertility	0.44	0.31	0.02	−0.23	0.41
13. My interest in life and motivation has declined	0.55	0.3	0.14	−0.26	0.33
14. I became nervous about the constant use of drugs	0.5	0.19	0.1	−0.12	0.38
15. We don't have sexual relation anymore if we talk about having a child	0.49	0.33	0.36	−0.11	0.14
16. The rising cost of treatment impacts my sexual life adversely	0.3	0.55	0.08	−0.17	0.25
17. The cause of our cold marital relationships is the lack of children	0.33	0.54	0.22	−0.04	0.13
18. I do not enjoy consecutive sexual intercourse according to the treatment plan	0.19	0.53	−0.35	−0.24	0.06
19. Frequent sexual intercourse makes sexual relation less attractive for us	0.24	0.65	−0.2	−0.25	0.04
20. Infertility treatments and its complications have made me not enjoy my sexual relation	0.26	0.64	0.1	−0.25	0.2
21. I decline to have intercourse with my spouse again because I don't enjoy my sexual relation	0.23	0.65	0.2	−0.27	0.05
22. It has had a negative impact on my morals and actions because I do not enjoy sexual relations	0.29	0.71	0.24	−0.11	0.00
23. Because most of the sexual intercourse was purely for the purpose of having a baby and is unprepared it's pianistic for me	0.12	0.73	0.19	−0.07	0.1
24. Because I have pain in my sexual intercourse, it's hard for me to begin and have sexual relations	0.14	0.68	0.23	0.00	0.00
25. My wife and I are disturbed when a physician or treatment plan instructs us not to have sexual relation	0.15	0.39	0.05	0.38	0.08
26. My spouse flirts with sexual relation less than before	0.01	0.57	0.21	−0.05	0.24
27. My spouse is dissatisfied about having sexual activity with me	0.03	0.58	0.17	−0.02	0.16
28. I pretend to enjoy my spouse in the current state of sexual intercourse	0.1	0.72	0.18	−0.16	0.19
29. Because in the topic of infertility and its diagnostic-therapeutic measures my spouse does not support me; I neglect his sexual needs	0.19	0.53	0.45	−0.03	−0.08
30. I find myself sexually a failure	0.46	0.64	0.09	−0.15	−0.04
31. I lost confidence in myself as a sexual partner	0.46	0.63	0.06	−0.16	−0.05
32. I am always worried that I won't be able to keep my partner happy with sexual life in the future	0.46	0.63	0.06	−0.15	−0.11
33. Because of my infertility my spouse is morally ill	0.46	0.28	0.55	−0.11	0.04
34. My wife is telling me the ideas that people around me and my family have about my infertility	0.47	0.23	0.49	−0.02	0.12
35. My wife is blaming me for not having kids	0.34	0.35	0.52	0.05	0.13
36. My wife is helping me with the process of diagnosis and treatment	−0.01	−0.08	−0.62	0.3	0.11
37. My spouse pays more attention to me to preserve my morale if my pregnancy test results were negative	0.07	−0.15	−0.57	0.28	0.09
38. Because of my infertility my wife doesn't want to have sexual relation	0.25	0.45	0.46	−0.04	−0.03
39. My spouse's love and intimacy render me more relaxed with infertility	−0.1	−0.24	0.58	−0.41	0.07
40. My spouse and I talk to each other for the betterment of our sexual relationships	−0.26	−0.12	−0.19	0.36	0.35
41. My infertility has had no effect on the quality of our sexual relations	−0.08	−0.2	−0.37	0.59	−0.15

Table 3 (continued)

Items	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
42. To increase the likelihood of fertility, repeated sexual intercourse has improved my intimacy with my spouse	0.00	−0.07	−0.04	0.66	0.00
43. As time passes by, the quality of our sexual relations has not changed despite having a baby	−0.18	−0.19	−0.17	0.47	−0.09
44. As time passes by, our sexual relationships have become more enjoyable	−0.12	−0.18	−0.00	0.61	−0.56
45. My family and relatives ' curiosity and behavior about my infertility makes me sad	−0.26	−0.12	−0.18	0.36	0.38
46. A child's presence has a positive impact on a couple's quality of life	0.19	0.01	0.14	0.03	0.63
47. I feel like I will enjoy life more with being a mother	0.13	0.05	−0.19	0.00	0.55
Eigenvalues	14.9	3.5	2.3	1.91	1.53
% of variance observed	17.17	16.22	6.81	6.91	4.98

Factor1 negative psychological impact of infertility, *Factor2* influence of infertility and its therapies on sexual life, *Factor3* spouse role, *Factor4* effect of infertility on the nature of sexual relation, *Factor5* the negative impact of friends/relatives and the absence of children

Table 4 Cronbach's alpha coefficient and intra-class correlation coefficient for the Sexual Health Assessment Tool for Infertile Women (SEHAT-IW) and its subscales

Factors	Cronbach's alpha	ICC* (95% CI)	95% CI
Negative psychological impact of infertility	0.91	0.91 (0.85, 0.95)	< 0.001
Influence of infertility and its therapies on sexual life	0.7	0.96 (0.85, 0.95)	< 0.001
Spouse role	0.74	0.83 (0.71, 0.91)	< 0.001
Effect of infertility on the nature of sexual relationships	0.7	0.88 (0.8, 0.9)	< 0.001
Negative impact of friends/relatives and the absence of children on the quality of sexual life	0.95	0.96 (0.93, 0.98)	< 0.001
The tool (SEHAT-IW)	0.93	0.97 (0.95, 0.98)	< 0.001

*Intra-class correlation coefficient

Table 5 Odds ratio for lower sexual health obtained for logistic regression analysis

	Adjusted OR (95% CI)	*P*
Age (years)		
< 30	1.0 (ref.)	
30–40	1.01 (.0.63–1.62)	0.95
> 40	2.18 (0.87–5.05)	0.09
Education		
Higher	1.0 (ref.)	
Secondary	1.59 (0.94–2.69)	0.08
Primary	2.61 (1.44–4.76)	0.002
Employment		
Employed	1.0 (ref.)	
Housewife	2.35 (1.15–4.83)	0.01
Duration of infertility (years)		
< 10	1.0 (ref.)	
10–20	0.60 (0.03–11.18)	0.73
> 20	1.95 (0.92–4.14)	0.08

a valid and reliable instrument for evaluating sexual health in infertile women.

To the best of our knowledge, it seems that no instrument has been designed to assess sexual health in infertile women. Most existing instruments often evaluate sexual function or sexual dysfunction instead of sexual health. However, among existing instruments, the Sexual Health Instrument for Middle-Aged women [24] and the Ford Women's Sexual Health Questionnaire [25] and the Female Sexual Well-Being scale [26] to some extent seem similar to the instrument that was developed by the current study. For instance, the Sexual Health Instrument for Middle-Aged women (SHIMA) contains 36 items that intend to measure sexual health in middle-aged healthy women on the basis of an operational, and definition of the concept of sexual health [24]. The Ford Women's Sexual Health Questionnaire is a 40-item, non-specific tool that consists of eight dimensions. This questionnaire is designed for women of all ages and using a multidimensional concept of sexual health. The Female Sexual Well-Being scale is a general tool for women that have 19 items and 5 dimensions. One of the similarities between the FSWB and the SEHAT-IW is the fact that both instruments do not focus on assessing female sexual dysfunction

and both are considering the role of the spouses in women's sexual health.

The results obtained from factor analysis indicated that five factors contribute to sexual health in infertile women. The highest eigenvalue was for the negative psychological impact that infertility imposes on women's sexual health. This is an important area of concern and merits careful attention. Psychological factor plays a significant role in shaping sexual concerns, sexual difficulties, and sexual dysfunctions in the long term [27]. As such, there are some psychological disorders in infertile couples including marital dissatisfaction, lack of sexual satisfaction, loss of self-confidence in relation to sex and sexual intercourse, negative emotional effects, and anger that affects sexual life [28]. Additionally, psychologists believe that if the cause of infertility is female factor, women will face critical emotional conditions [29].

The findings showed that the concept of sexual health in infertile women is a multifaceted concept, and could be influenced by the nature of infertility and its treatments, mental health, emotional support from the spouse, and interpersonal–social relationships. For instance, it is argued that emotional support from the spouse could ease the suffering and, to some extent, could improve the couples' marital and sexual relationship [30, 31].

It is important to bear in mind that sexual health is not restricted to physical practice such as intercourse or similar, but, to a great extent, it relates to infertile women's sense of satisfaction and perfection from their physical, emotional, and social experiences in sexual relationships [32]. Therefore, for improving the quality of sexual life and well-being in infertile women, healthcare providers should focus on women's sexual health instead of focusing solely on their sexual performance.

Future applications

In infertility service centers and hospitals, usually, the focus is mainly on diagnostic-therapeutic procedures and the assessment of women's sexual status is a neglected issue. Therefore, the SEHAT-IW can be used in different situations by service providers to screen and evaluate sexual health in infertile women. Perhaps, this could help to identify barriers in promoting sexual health and to plan and implement necessary interventions. Also, it is recommended to use this questionnaire for outcome studies where there is intention to compare different interventions. However, one should note that using such an instrument in busy clinics and in a condition where women experience a sort of suffering and distress might lead to biased results. Thus, a general recommendation is to complete the questionnaire in a calm condition and if possible privately. Finally, it is important to know that care managers in infertility centers provide care to infertile individual/couples and manage care facilities. Thus, as suggested for other health conditions [33], they could have an important role in providing a supportive environment for women and perhaps if necessary help the infertile women to assess their sexual health accurately.

Conclusion

The findings suggest that the Sexual Health Assessment in Infertile Women is a valid instrument to measure sexual health. It is simple, easy-to-use, and comprehensive.

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Author contributions SHJ involved in the study design, analysis, and interpretation of data and critically revised the final manuscript. ZD collected the data and drafted the manuscript. AK and FA contributed to the statistics and critically revised the final manuscript. All authors read and approved the final manuscript.

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Data availability The data sets generated and analyzed during this study are not publicly presented because of a desire to protect the participants' anonymity; they are, however, available from the corresponding author on advisable request.

Compliance with ethical standards

Conflict of interest The authors declare that they have no competing interests.

Ethics approval and consent to participate Ethical approval for this study was obtained from the Ethics Committee of Tarbiat Modares University (IR.TMU.REC.1396.659). The present study only involved persons who gave their informed consent. For this, verbal informed consent was obtained from all participants before the start of the study, and all members of the participants completed informed written consent after being informed about the aims of the research. The designed questionnaire was distributed among the participants, while they remained anonymous; there was no private information that could enable the association of any answers with any of the persons in the present study. To protect the rights and interests of all participants, no records of consent by name were kept. Each completed instrument was given to the research fellow on the same day of data collection.

Informed consent Informed consent was obtained from all individual participants included in the study.

Consent for publication Not applicable.

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