



Translation, Cultural Adaptation, and Psychometric Features of the Persian Version of the Copenhagen Multi-Centre Psychological Infertility-Fertility Problem Stress Scales (COMPI-FPSS)

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Authors' contributions

This work was carried out in collaboration among all authors. All five authors, designed the study, and wrote the protocol. Authors LAA, and FJK, and EKL performed the statistical analysis. Authors LAA, and FJK, managed the literature searches and wrote the first draft of the manuscript. All authors read and approved the final manuscript.

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ABSTRACT

Aims: This study was conducted for translation, cultural adaptation, and validation of the Persian version of the Copenhagen multi-centre psychological infertility-fertility problem stress scales (COMPI-FPSS).

Study Design: This study was a methodological study.

Place and Duration of Study: This research was done in an infertility clinic of an educational hospital in Rasht (north of Iran), from November 2019 to January 2020.

Methodology: This study was performed in two phases including tool translation and psychometric testing. Totally, 200 infertile people selected through convenience sampling among subjects met inclusion criteria were included in the study. After obtaining permission from the original tool designer, the COMPI-FPSS (14 items) was translated into Persian using the forward-backward method. Face, content, and construct validity, as well as internal consistency (Cronbach's alpha coefficient and McDonald's coefficient omega) were evaluated, and test-retest was conducted. The data were analyzed using exploratory factor analysis (EFA) by SPSS software Ver. 16.

Results: EFA led to retaining of 11 items with 3 factors of "personal domain", "marital domain", and "social domain", which explained 54.42% of the total variance. Cronbach's alpha coefficient for the whole questionnaire was calculated as 0.89; also the overall McDonald's coefficient omega of the questionnaire was equal to 0.82. The correlation between the two test administrations with a 14-day interval was estimated as 0.93.

Conclusion: The Persian version of the COMPI-FPSS with 11 items and 3 factors had the desired cultural adaptation, validity, and reliability and it is recommended to use it in the future studies and infertility treatment centers.

Keywords: Infertility; psychometrics; questionnaire; stress; translation.

1. INTRODUCTION

Infertility and its treatments are among stressful situations in life having many physiological and psychological effects on the people's lives [1]. Infertility refers to the inability to achieve pregnancy following one year of intercourse without using contraceptive methods [2], falling into two categories, primary and secondary, with various female, male, and unknown causes [3].

According to worldwide reports, approximately 15% of the married couples are unable to bear any children [4]. Prevalence of infertility is estimated by 9% in the United States, 8.5% in Canada, 10-15% in the Middle East, and by 21.6% in Iran [5].

Infertility is an important issue for men and women in all societies of the world [6]. Yilmaz et al., showed that infertile women experience more stress than men and use more stress coping methods than men [7]. In women, the most important factor in increasing stress and anxiety level is losing fertility and motherhood, more negative self-concept, and loss of generational continuity [8]. Patel et al. [10] reported that prevalence of fertility-specific stress in women was equal to 80% in general [9]. But on the other hand, men are just like women, and they may be physically and psychologically damaged by various fertility treatments. Mirzaei et al. [5] found that the perceived stress in men was higher than the women.

Infertile couples can experience stress both physically and psychologically [9]. People face with a two-side ambiguity when their desire to have children fails. On the one hand, people are mentally and psychologically willing to have children, and on the other hand, such a desire is not physically possible thus, this ambiguity imposes a lot of stress on the people [11]. Despite the increased psychosocial consequences of infertility, there is still a limited understanding about it, and phenomenon of infertility has been neglected so that, this crisis has almost become exclusively medical [12]. Scientific advancement and invention of new methods of assisted reproductive technology (ART), such as in-vitro fertilization (IVF) in the recent years have opened a window of hope to infertile couples. However, there is ample evidence that infertility-induced psychological problems can contribute to exacerbation of infertility and failure of treatments [11]. Therefore, infertile couples not only need medical treatment, but also psychological and emotional support [13].

Determining level of infertility-specific stress will be a great help to the people who are educating and counseling infertile couples in infertility clinics [14]. Emotional, psychological, and social aspects of treatment should not be overlooked in a comprehensive infertility treatment, because they are important factors in enhancing quality of care [15]. However, evaluating effectiveness of care or making related decision depends on correct measurement. Measurement, which is

considered as one of critical and vital steps in research requires the use of appropriate tools. For this purpose, either a new tool must be designed or original tools should be used after making sure of their psychometric properties (validity and reliability). Before using a tool, it is necessary to evaluate its psychometric properties and pay enough attention to them [16]. On the other hand, the lack of standard tools for measuring stress of infertile couples leads to the lack of awareness and makes the situation harder to deal with [17].

One of the tools developed by Schmidt to measure infertility-specific stress is the Copenhagen multi-centre psychological infertility-fertility problem stress scales (COMPI-FPSS) [18]. Having relatively few questions, ease of understanding and implementation, multidimensionality, and its specificity to measure stress related to couple fertility problems are among prominent features of the COMPI-FPSS. There are some other stress assessment questionnaires [19-21], however, they lack sufficient ease, feasibility, and comprehensiveness for various reasons, such as large number of questions or non-specific nature of the tool. Therefore, it can be very useful, practical, and helpful to have a questionnaire that is comprehensive, does not have a large number of questions, and is specific to infertile people.

Since, the COMPI-FPSS is available in English language and on the other hand, as a scale designed in one country cannot be used only by translating it in another country and there is a need for cultural adaptation proportionate to cultural and social context of the society, therefore, this study was done for translation, cultural adaptation, and determining psychometric features of the COMPI-FPSS.

2. MATERIALS AND METHODS

This methodological study was performed in two phases including tool translation and psychometric testing. This study was conducted on 200 infertile people referring to the infertility clinic of an educational hospital in Rasht (north of Iran) from November 2019 to January 2020, selected through convenience sampling among subjects met inclusion criteria: willingness to participate in the study, confirmed and recorded infertility in their medical record, having no children, no previous or current history of chronic and disabling physical diseases, or neurological and psychological disorders (based on self-report

and information recorded in their medical record), the ability to understand Persian, and having reading and writing literacy.

For investigating adequacy of sample size in methodological studies, various guidelines have been mentioned in various sources. Generally, 10 - 20 subjects are required for each variable (item) of the questionnaire, but the minimum total sample size of 200 people is defensible [22]. In the present study, sample size was equal to 200 people (n=200) as well. The Persian version of the COMPI-FPSS was used to collect data. The main questionnaire was developed by Schmidt [18] and included 14 items, 6 items were related to personal subscale, 4 items related to marital subscale, and 4 items were related to social subscale. This scale can be applied to both infertile men and women. Scoring method for each item in the questionnaire was as follows: Answering options for questions 1 and 2 in the personal domain and questions 1 and 2 in the marital domain of the questionnaire were based on the 5-point Likert scale (1. Completely disagree 2. Somewhat disagree 3. No idea 4. Somewhat agree, and 5. Completely agree) and the rest of the questions were set in the range of 4 rating scores (1. Nothing 2. Slightly 3. To Some Extent, and 4. Very Much). In general, a higher score from the scale questions indicates more stress [23].

2.1 Translation

In the present study, before conducting psychometric testing, according to the approach proposed by Wild et al., [24] the following steps were taken to translate the COMPI-FPSS: 1) Obtaining permission from the original designer of the tool and making the necessary arrangements (an email was sent to the original designer of the questionnaire, Dr. Schmidt and permission was obtained to use the questionnaire and performing its translation and psychometric testing and then, receiving the code of ethics from the Vice Chancellor for Research of Guilan University of Medical Sciences, Rasht, Iran), 2) Translation of the questionnaire from source language into target language by two translators familiar with English and Persian languages with specialty in the fields of reproductive health and psychiatry independently of each other, 3) Combining the two initial translation versions into a single translation by the research team, 4) Translating back the final version translated from target language to source language by a bilingual

(English-Persian) translator specialized in the linguistics, 5) Reviewing the translated version from target language to source language by the research team and its approval by designer of the main questionnaire, 6) Conducting a pilot study on 10 infertile couples and asking them about wording, simplicity, and ease of understanding sentences of the Persian version of the questionnaire, as well as correcting and summarizing comments, and 7) Presenting the final version of the questionnaire translated into Persian.

2.2 Face and Content Validity

For determining face validity of the questionnaire, 20 people were investigated in 2 steps among infertile couples (10 people for conducting qualitative investigation of face validity and 10 people for conducting quantitative investigation of face validity, and calculating item impact scores).

In investigating content validity, 13 people specialized (expert panels) in the fields of midwifery, reproductive health, gynecology and infertility, psychiatry, and instrumentation were asked to check the questionnaire. The above experts were asked to report on the scale items, such as grammar, use of appropriate words, placement of items in their proper place and appropriate scoring, or any doubts or suggestions. After obtaining qualitative feedback from evaluators and correcting items, the quantitative method was used to determine content validity as a complementary method. There are two indicators including content validity ratio (CVR) and content validity index (CVI) for quantitative investigation of content validity. In the CVR, the necessity regarding having an item is evaluated, and in the CVI, the experts consider relevance of the items to the research purpose.

2.3 Construct Validity

For evaluating construct validity of the questionnaire, its factor structure was investigated by exploratory factor analysis (EFA) method and using principal axis factoring (PAF) and Varimax rotation. PAF is conducted based on common variance analysis among observations (items) and is commonly used to clarify theoretical structure [16].

2.4 Convergent Validity

In the following, for investigating convergent validity, 25 participants—apart from those participated in the stage of assessing construct validity—were asked to simultaneously complete the fertility problem inventory (FPI) in addition to COMPI-FPSS in order to calculate the Pearson's correlation coefficient between the two mentioned scales using SPSS software. The FPI was designed and evaluated by Newton et al., in 1999 and included 5 domains (social concerns, sexual concerns, communication concerns, childless lifestyle, and the need for parenthood) [19], which was first psychometricised by Samani et al., in Iran and has been found to have a favorable validity and reliability [17].

2.5 Reliability (Internal Consistency and Stability)

For assessing reliability of the COMPI FPSS, stability and internal consistency of the scale were tested. Internal consistency of the questionnaire was investigated through Cronbach's alpha coefficient and McDonald's coefficient omega and stability was evaluated through intra-cluster correlation coefficient (ICC), in which correlation of the scores obtained from the two administrations of the questionnaire with a 2week time interval was determined in a group of 30 infertile people (including 27 women and 3 men, aged 30-34 years old, who had diploma, and lived in city). One-third of them had received scattered treatments, the most cause of infertility was a female-related infertility, and majority of them (40%) had undergone infertility treatment for 1- 23 months.

3. RESULTS AND DISCUSSION

3.1 Clinical and Socio- Demographic Characteristics of the Patients

Majority of the surveyed women [n=53 (31.4%)], aged 30 – 34 years old, had a mean age of 32.5 ± 6.53 years old, had a university degree, lived in a city ,and were housewives. Majority of men [n=13 (42%)] aged between 30 - 34 years old with an average age of 35.39 ± 7.26 years old. The most received treatments [n=65 (32.5%)] were scattered treatments (pharmacotherapy and diagnostic therapies, such as laparoscopy), and majority of women [n=63(37.3%)] reported a one-time and majority of men [n=14(45.2%)] reported more than 2-time failure in infertility treatment. The most cause of infertility was reported to be female-related infertility

[n=93(46.5%)] and the longest duration of marriage for both of men and women was between 5 - 9 years. Majority of women [n=87(51.7%)] had undergone infertility treatment for 1 - 23 months.

3.2 Face and Content Validity

The results of quantitative investigation of face validity of the questionnaire indicated that the impact score of the items was in the range of 1.5 - 4.9. Regarding investigating content validity, considering that in CVR using Lawshe's table, the minimum acceptable numerical value in the evaluation by 13 experts was equal to 0.54 [25], 14 items of the questionnaire could obtain an acceptable threshold. Therefore, none of the items was removed at this stage. Also, since a CVI above 0.79 was considered to be appropriate, then in 14 items of the questionnaire, numerical value of CVI was estimated above 0.79. Regarding CVI of the second round of the questionnaire, assessed by 3 experts, CVI score of the items in the questionnaire was equal to 1, indicating the maximum value of CVI. The average CVI of the whole

questionnaire (SCVI / Ave) was estimated as 0.98.

3.3. Construct Validity

For investigating construct validity, first, the outliers and missing data were evaluated along with normality of the data. Based on the findings, there were no missing data, and the outliers, assessed based on the mean scores on each item indicated that the mean score given by the subjects to the item 14 (relationships with workmates) was lower compared to the other items. Also, since presupposition of data normality can be checked based on the Skewness index (± 3) and the Kurtosis (± 7), item 14 lacked a normal distribution, therefore, this question was removed and EFA was performed with the remaining 13 items.

Adequacy of the number of subjects for EFA was obtained according to the results of Kaiser-Meyer-Olkin (KMO) test and the Bartlett's test of sphericity (Table 1). KMO of 0.89 and significance of the Bartlett's test of sphericity showed that the data were appropriate for factor analysis. For extracting the factors in this research, principal

Table 1. KMO value and bartlett's test of sphericity

KMO	0.888
Chi-Square approximation	1209.764
Significance level	0.0001
Degree of freedom (df)	78

Table 2. Initial eigenvalues, total variance explained, and cumulative percentage of the three factors extracted from the COMPI-FPSS

Factor	Total variance explained					
	Initial eigenvalues			Extraction sums of the squared loadings		
	Total	% of variance	cumulative %	Total	% of variance	cumulative %
1	5.59	45.07	45.07	5.42	41.70	41.70
2	1.37	10.53	55.60	0.97	7.46	49.20
3	1.10	8.41	64.00	0.68	5.26	54.42
4	0.89	6.83	70.83			
5	0.65	5.03	75.86			
6	0.58	4.50	80.36			
7	0.53	4.06	84.41			
8	0.47	3.60	88.01			
9	0.41	3.14	91.20			
10	0.36	2.75	93.90			
11	0.30	2.27	96.20			
12	0.27	2.04	98.22			
13	0.23	1.78	100.00			

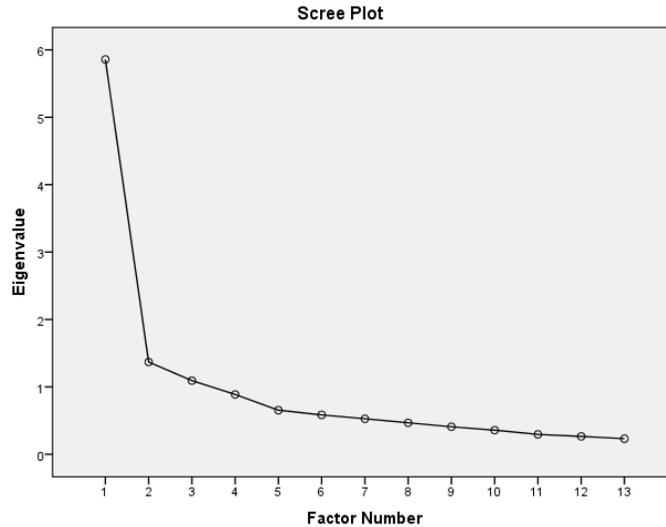


Fig. 1. Scree plot in relation to the extracted factors based on eigenvalue index

axis factoring (PAF) method was used and for determining the number of factors, eigenvalues more than one (Table 2), and scree plot were used (Fig. 1).

According to the results of the scree plot and eigenvalues table, the 3-factor structure with eigenvalues more than one (5.59, 1.37, and 1.10) in total accounted for 54.42 % of the variance and seemed to be the best solution for the Persian version of the COMPI-FPSS due to its conceptual clarity and simplicity of interpretability.

Based on the rotated matrix of COMPI-FPSS items, the items related to each factor were identified using Varimax rotation. Labeling of the three extracted factors that had common items with the extracted factors in the original questionnaire was done completely based on the original questionnaire. The fourth factor had less than 3 items (Items 3 and 4), which was viewed as an undesirable factor, therefore, after consultation with the research team, this factor was deleted. At this stage, the variables highly correlated with each other were included in one factor, and these factors were named as the first factor of marital domain (including items 7,8,9, and 10), the second factor of personal domain (Items 1,2,5, and 6), and the third factor of social domain (items 11,12, and13) (Table 3).

3.4 Convergent Validity

For determining convergent validity, 25 infertile participants were asked to complete an 11-item

COMPI-FPSS as well as FPI. After entering the data of 25 participants in SPSS software and calculating the Pearson’s correlation coefficient between the two scales, the results indicated a relatively strong and significant correlation ($r = 0.60$ and $P < 0.001$) between the two mentioned questionnaires.

3.5 Reliability (Internal Consistency and Stability)

Internal consistency of the whole scale (Cronbach’s alpha) was calculated as 0.89, also for each sub-scale including the marital domain, personal domain, and social domain, it was obtained as 0.81, 0.83, and 0.72, respectively. The overall McDonald’s coefficient omega was measured as 0.82, and for marital domain, personal domain, and social domain, it was equal to 0.70, 0.70, and 0.67, respectively.

Also, the results of ICC between the two administrations of the scale (a 14-day interval) were as follows: For the whole scale, it was obtained as 0.93 (Table 4), for the first factor, it was equal to 0.86 with a confidence interval of 0.77-0.93, for the second factor, it was obtained by 0.85 with a confidence interval of 0.74 - 0.92, and for the third factor, it was equal to 0.82 with a confidence interval of 0.69-0.96, considering that the lower bound of all the confidence intervals mentioned above was more than 0.6.

Table 3. Rotated matrix of COMPI-FPSS items based on varimax rotation

Items	Factors		
	1 Marital	2 Personal	3 Social
What are the consequences of your childlessness for your marriage?	0.70		
7. Childlessness has caused a crisis in our relationship. How much stress has been imposed by your fertility problem on the following aspect: 9-Your marriage?	0.68		0.35
What are the consequences of childlessness for your marriage/ relationship?	0.63		
8. Childlessness has made us to think about divorce. How much stress has been imposed by your fertility problem on the following aspect: 10-Your sex life?	0.55		
1- My life has been disrupted because of this fertility problem.		0.69	
2-It is very stressful for me to deal with this fertility problem.		0.64	
How much stress has been imposed by your fertility problem on the following aspects: 6- Your mental health		0.60	0.34
5-Your physical health		0.59	
How much stress has been imposed by your fertility problem on the following aspects: 11- Your relationships with your family?			0.66
13- Your relationships with friends?			0.57
12- Your relationships with your family in law?			0.52
How much stress has been imposed by your fertility problem on the following aspects: 3- Your relationships with people having children?			0.84
4- Your relationships with pregnant women?			0.73

Table 4. Reliability (test-retest) of the whole COMPI-FPSS on a sample of 30 infertile people

	P-Value	DoF 1	DoF 2	Confidence interval	Intra-cluster correlation coefficient (ICC)
Total score	<0.001	29	725	0.89– 0.96	0.93

The results of above table indicated that ICC of the scale was equal to 0.93 with confidence interval of 0.89– 0.96.

4. DISCUSSION

The COMPI-FPSS was translated and underwent psychometric testing in response to the need for a fast, easy, valid, and reliable scale to measure stress level of infertile couples in different clinical situations. This study was the first study on translation, cultural adaptation, and validation of the COMPI-FPSS in Iran. Our findings indicated that

process of English-to-Persian translation (forward translation), back translation, and cultural adaptation was correct and desirable and the resulting questionnaire was acceptable and understandable.

Face and content validity of the Persian version of the COMPI-FPSS were good and desirable, which is consistent with the studies by Yilmaz et al. [14] and Schmidt [18].

The results of investigating factor structure of the Persian version of the questionnaire using EFA indicated that the 3 factors were extractable with

11 items. Yilmaz et al. [14] evaluated construct validity of the Turkish version of the COMPI-FPSS by confirmatory factor analysis (CFA) and indicated the three-factor identity of the 14-item questionnaire and confirmed the original structure of the questionnaire. In their study, as in the original questionnaire, items (1, 2, 11, 12, 13, and 14) in the personal domain, items (3, 4, 5, and 6) in the marital domain, and items (7, 8, 9, and 10) were in the social domain and no item was excluded. Another cross-sectional study was conducted by Sobral et al. [23] entitled as "COMPI-FPSS Is a Brief, Valid, and Reliable Tool for Assessing Stress in the Patients Seeking Treatment" in Portugal aimed at validating the COMPI-FPSS. CFA was used for validation of factor structure of the 14-item COMPI-FPSS using AMOS statistical software and maximum likelihood estimation. In this study, the 3-factor structure (personal, marital, and social domains) was confirmed for all the subjects and the final model included 3 items in each subscale. Accordingly, the COMPI-FPSS items were reduced from 14 items to a shorter version of 9 items. Items 1, 3, 4, 8, and 14 were removed from the questionnaire, and the other items remained in their places. The results of the present study are consistent with the study by Sobral et al., in terms of elimination of items 3, 4, and 14, but in terms of order of items in each factor, our results are somewhat inconsistent with the findings of the above two studies. It is believed that discrepancy in the findings can be due to differences in sample size, individual-social, and reproductive characteristics of the subjects, sampling method, different socio-cultural contexts governing each of the research environments, and the used statistical methods.

In the present study, optimal convergent validity of the Persian version of the COMPI-FPSS was confirmed by calculating the Pearson's correlation coefficient between the total score of COMPI-FPSS and FPI and the existence of moderately high and significant correlation between the overall scores of the two questionnaires. Similar to the findings of the present study, Sobral et al. [23] also confirmed convergent validity of the COMPI-FPSS.

Regarding reliability of the Persian version of the COMPI-FPSS, according to the findings, internal consistency of the whole scale and each of its factors was confirmed by calculating the Cronbach's alpha coefficient and McDonald's coefficient omega. Consistent with the results of the present study, in study by Schmidt,

Cronbach's alpha coefficient of the personal domain was obtained as 0.81 for women, and 0.78 for men. It was measured by 0.73 and 0.72 for women and men respectively in marital domain, and 0.79 for women and 0.84 for men in social domain [18]. Also, Yilmaz et al. [14] reported values of 0.83, 0.72, and 0.81 for Cronbach's alpha coefficients of each of the three personal, marital, and social factors, respectively.

Regarding determining stability of the Persian version of the COMPI-FPSS, findings indicated stability of the results over time, in other words, proper and good reliability of the Persian version of the COMPI-FPSS was confirmed, which is consistent with the results of the studies by Sobral et al. [23] and Yilmaz et al. [14].

The present study had some limitations. Firstly, it is not clear to what extent the scores of this scale are related to the actual stress levels in daily lives of infertile couples. The second limitation of the study was related to its spatial and temporal area. This study was conducted on infertile couples referring to infertility clinic of an educational hospital and also infertile patients seeking treatment in 2019 and therefore, its findings cannot be generalized to other infertile clients who are not looking for infertility treatment and caution should be considered while generalizing the findings. Also, no comparison was made between level of stress experienced separately by men and women participating in the present study. Based on these limitations, it is suggested to evaluate the scale in different regions of the country using larger sample size in order to eliminate possible limitations of the Persian version of the scale. It is also suggested to perform divergent or discriminant validity and CFA in order to further strengthen psychometric testing of the tool. Meanwhile, it is recommended to compare and report the stress experienced by infertile men and women in the future studies. In addition to its optimal validity and reliability, other strengths of this scale are ease of implementation, small number of its items, and short time needed to answer its items.

5. CONCLUSION

Generally, the Persian version of the COMPI-FPSS with 11 items and 3 factors is a valid and reliable tool for assessment of stress due to infertility and fertility problems of infertile couples and it can be used in the future studies as well as clinical settings especially in infertility treatment centers.

CONSENT

All the authors declare that an informed written consent was obtained from all the patients participated in the present study.

ETHICAL APPROVAL

All the authors hereby declare that the present study was approved by the department of research and technology and the ethics committee of Guilan university of medical sciences, Rasht, Iran, with the ethics code of IR.GUMS.REC.1398.101. Therefore, this study was performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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