

# The Post-Liver Transplant Quality of Life Instrument: Translation, Reliability, and Validity of the Persian Version

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## Research

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# Abstract

**Background:** The Post-Liver Transplant Quality of Life (PLTQ) instrument is a specific, disease-based questionnaire to evaluate health-related quality of life (HRQOL) of liver transplantation (LTx) recipients. The aim of this study is translation, cross-cultural adaptation, and evaluation of the psychometric properties of the Persian version of PLTQ (PV-PLTQ) questionnaire.

**Methods:** All of the stages of translation and cross-cultural adaptation of the original PLTQ instrument was carried out according to the published guideline. A total of 175 LTx recipients completed the PLTQ and short form-36 (SF-36) questionnaires. Sixty-eight randomly selected patients were asked to complete the PLTQ, 2 to 3 months later. Face validity, content validity, acceptability internal consistency, test-retest reliability, sensitivity to change, and convergent validity were evaluated.

**Results:** The results of face validity, content validity, and missing data proportion indicate that PV-PLTQ questionnaire is acceptable and easy to understand. Cronbach's alpha coefficient for the PV-PLTQ questionnaire was 0.97 (0.82 to 0.95) for domains. The results of test-retest reliability show moderate to good intraclass correlation coefficient from 0.6 to 0.86 ( $P < 0.05$ ). Also, the results of the Kruskal-Wallis test shows that this questionnaire is sensitive to HRQOL changes. The correlations between PV-PLTQ domains and physical and mental components of SF-36 present a good convergent validity ( $P < 0.05$ ).

**Conclusion:** In general, The PV-PLTQ questionnaire is a valid, reliable and sensitive to change instrument to evaluate HRQOL in LTx recipients and can be applied in further researches and clinical settings in the Persian speaking population.

## Introduction:

Liver transplantation (LTx) is an approved preferable life-saving intervention for patients with end-stage liver disease. Primarily, the survival rate of patients after transplantation was criteria for evaluation of clinical and research outcome of this procedure [1]. Statistical data shows that survival rate of LTx among recipients has grown significantly in the past two decades with regards to advancement in the treatments, drugs, and concentration on multidisciplinary approaches post-transplant care. The survival rate in the first and the fifth years after transplantation are reported 90% and 70% respectively [2].

The first LTx in Iran was performed in 1993 [3]. The number of LTx has been increased over time like other regions in the world. Until December 2016, 4485 LTx have been performed by 6 centers. The survival rates of LTx recipients in Iran in the first, fifth and tenth year post surgery were 85%, 77%, and 71%, Respectively [4]. These numbers in our center are 85%, 83%, and 80% for one, three, and five years.

Nowadays, the survival rate of liver transplantation recipients is not the only goal of liver transplantation procedure. Recovering the patients' social dysfunctions and improving quality of life (QOL) are the most essential outcomes of this intervention [5]. Health-related quality of life (HRQOL) has been defined by the World Health Organization, as a "state of complete physical, mental, and social well-being and not merely

the absence of disease and infirmity". Moreover, the reflex of the disease and interventions on the lifestyle, mental balance, and well-being of patients, according to their own judgments and perceptions [6].

Due to the growing number of liver transplantation recipients, and moreover the importance of post-treatment quality of life among patients, there is a necessity to assess their HRQOL via a standard and specific instrument [7]. The HRQOL assessment facilitates gathering practical data for health care professional and is an important parameter in assessing the effects of disease and evaluates the impact of therapeutic interventions on the performance of individuals' life [8].

An accurate assessment of HRQOL depends on the psychometric features of the developed instrument to measure this construct [9]. The usability of any instruments depends on the validity and reliability of each questionnaire in different populations which they will be employed and additional validation through a standardized process (translation into the local language and adaptation to the cultural context of the country) [10–12].

The aim of the present study was the translation, cross-cultural adaptation, and validation of the Post Liver Transplant Quality of Life (PLTQ) instrument in Persian speaking population to be used among LTx recipients.

## Materials And Methods:

### Instruments

1. **The PLTQ instrument:** The PLTQ instrument is a specific, disease-targeted questionnaire for measuring HRQOL in LTx recipients. This instrument was developed by Saab et al. [10]. It contains 32 items in eight domains including emotional function (4 items), worry (7 items), medications (4 items), physical function (6 items), healthcare (4 items), graft rejection concern (2 items), financial (2 items), and pain (3 items). Each item is scored by the Likert system from 1 (as persons' experience with the item all the time) to 7 (as persons' experiment with the item none of the time). Total score is expressed as the mean of all items with higher values presenting better HRQOL.

2. **The Short Form Health Survey (SF-36):** The SF-36 is a well-known, generic HRQOL questionnaire. This instrument has 36 questions with the different scoring systems in eight domains consists of physical function, role limitation due to physical problems, bodily pain, general health perception, vitality, social functioning, role limitation due to emotional problems, and perceived mental health. These domains form two distinct subscales; mental component summary score (MCSS) and physical component summary score (PCSS). Each domains, MCSS, and PCSS scores are calculated by mean of all domains score and can be reported from 0 (as poor QOL) to 100 (as good QOL). This survey has been translated and cross-culturally validated to a Persian version. [13].

**3. The Global Rating of Change (GRC):** The GRC is a subjective, quick, flexible and efficient instrument to track patients' conditional change [14]. In the current study, we designed a GRC questionnaire to determine any change in the participants' health condition between first and second PLTQ instrument administrations. This question was scored on a five-point Likert scale from - 2 (as totally deteriorated (to + 2 (as totally improved).

## **Translation and Cross-Cultural Adaptation:**

Initially, permission for translation and cross-cultural adaptation was taken from Sammy Saab. The processes of translation and cross-cultural adaptation was followed based on published guideline by Sousa and Rojjanasrirat [15]. Accordingly, two independent native Persian language speakers with good English language skills (one physiotherapist and one psychologist) translated the English version of the PLTQ questionnaire to Persian conceptually. All of the occurred discrepancies between two translated versions were discussed and resolved after comparing them with the original version by the translators and one of the authors (A.N.). A consensus version was finally created. Two professional English translators translated the forward translated version back to the English version independently. These translators were blinded to the original questionnaire. Finally, an expert panel committee including two physiotherapists, two psychologists, one psychiatrist, one post-transplant coordinator, one hepatologist and one liver transplant surgeon reviewed all versions of the questionnaires and cross-cultural adaptation processes carefully. After making a few changes to reach a better cross-cultural equivalence, the pre-final Persian version of PLTQ (PV-PLTQ) questionnaire was provided (Online resource 1).

## **Face Validity and Content Validity:**

In the presence of one of the authors (M.J.), the pre-final PV-PLTQ questionnaire was read and completed by 15 LTx recipients to evaluate the level of clarity of instruction, items and response format. Also, they were asked to discuss about difficulties in understanding items. The mean time to complete questionnaire was 11.6 (Standard deviation: 5.1) minutes. 87% of participants stated that all contents were totally clear and understandable. After reviewing the comments by an expert panel (with ten members) and making some corrections, the final PV-PLTQ instrument was developed. Furthermore, we asked expert panel members to score the content equivalency of instruction, items and scales by a four-point Likert scale.

## **Participants:**

A total of 180 volunteer LTx recipients were recruited consecutively from post-liver transplant hepatology clinic at Imam Khomeini Hospital Complex, Tehran, Iran over a period of 5 months. The participants were included in the study if they were LTx recipients and were older than 18 years. Patients with multiple organ transplants, re-transplant, inability to read and write in Persian, and major cognitive impairments were excluded from the study. Also, we excluded participants who omitted more than 50% of their responses. This study was approved by the Ethics Committee of Tehran University of Medical Sciences. Informed consent was obtained from each participant.

## Reliability:

The reliability of the PV-PLTQ questionnaire was tested by the test-retest statistical method. Also, Cronbach's alpha was provided for assessment of its internal consistency. To carry out test-retest reliability, 70 LTx recipients were randomly selected for longitudinal assessment and were asked to complete the PV-PLTQ questionnaire for the second time between 2 to 3 months later. Also, they were asked to answer the GRC questionnaire in the second test to measure the reproducibility and sensitivity to change of the PV-PLTQ instrument. Based on the GRC score, patients were divided into three categories: 1) patient with improvement, 2) patients with deterioration, and 3) patients with no change.

## Convergent Validity:

At the time of first assessment, participants completed the SF-36 along with the PV-PLTQ questionnaires. The PLTQ questionnaire has multiple domains which most of them are not defined in SF-36 survey but most of the questions of PLTQ assess the patients' physical and mental health status. Therefore, a satisfactory correlation between PV-PLTQ questionnaire domains and MCSS and PCSS was expected.

## Factor Analysis:

The factorial structure of the PV-PLTQ questionnaire was measured by factorial analysis with varimax rotation. Factors with eigenvalues  $\geq 1$  were considered proper as domains of PV-PLTQ questionnaire. Also, the highest item loading of each item determined which item is associated with each domain. A Confirmatory factor analysis (CFA) with the parceling method was used in order to evaluate the factor structure of the instrument [16]. In the parceling method, based on item-scale correlation coefficients, two or three items would be aggregated and made a parcel under its subscale. Then, CFA would be run on these created parcels. Also, the parceling method can approximately deal with sample size limitation. Root mean square error of approximation (RMSEA), Confirmatory factor index (CFI), Incremental fit index (IFI), Parsimony-adjusted normed fit index (PNFI), Parsimony-adjusted comparative fit index (PCFI), and Goodness-of-fit index (GFI) were calculated to show the suitability of PV-PLTQ instrument model.

## Statistical Analysis:

Sample size was calculated as 5 participants per item. After estimating about 10% possible attrition or incomplete questionnaire filling, 180 participants were determined as a suitable sample size. All data were analyzed using the Statistical Package for Social Science version 18.0 (SPSS, INC, Chicago, IL). P value  $< 0.05$  was considered as a statistically significant level. Shapiro-Wilk test was established to evaluate the normality distribution of data.

The content validity index at the items (I-CVI) and at the scale (S-CVI) methods were calculated to assess the level of content validity. I-CVI  $> 0.78$  and S-CVI  $> 0.9$  were considered as an acceptable level for expert panel agreement.

Acceptability and simplicity to complete the PV-PLTQ questionnaire was assessed by calculation of missing data proportion for each item and domain. Missing data proportion  $\leq 4\%$  was considered

satisfactory. Missing data were calculated using multiple imputation method [17]. In order to estimate internal consistency for total instrument and each subscale, Cronbach's alpha was analyzed. Cronbach's alpha  $\geq 0.7$  was considered satisfactory [18]. Intraclass correlation coefficient (ICC) was used to evaluate test-retest reliability in patients reported "no change" between two assessment phases. ICC  $< 0.5$ ,  $0.5-0.75$ ,  $0.75-0.9$ , and  $> 0.9$  were considered poor, moderate, good, and excellent reliability measures respectively [19]. To evaluate sensitivity to change of PV-PLTQ instrument, Kruskal-Wallis one-way analysis of variance was used. For this purpose, the amount of change of PV-PLTQ questionnaire score was compared between patients who reported "improvement", "no change", and "deterioration" during a longitudinal period [20]. The Spearman correlation coefficient between PV-PLTQ questionnaire domains and MCSS and PCSS was established to test convergent validity.

## **Results:**

### ***Patients Characteristics:***

Out of 180 included patients, 5 did not complete more than 50% of items and therefore were excluded. From 70 randomly selected participants for longitudinal survey, 2 of them did not want to continue the study due to personal reason and one was hospitalized. Table 1 summarize the demographic characteristics of participants in cross-sectional and longitudinal assessment phases.

### ***Content validity:***

The I-CVI for the PV-PLTQ instrument ranged from 0.8 to 0.92. Also, The S-CVI was 0.95.

### ***Factor Analysis:***

The factor analysis process extracted 5-factor with eigenvalues  $\geq 1$ . Subsequently, five domains were recognized for PV-PLTQ questionnaire: emotional (items 1,2,3,4,5,13,15,16,24, and 25), healthcare (items 6,7,8,27, and 31), medication (items 9,10,14,23,26,30, and 32), physical (items 11,12,19,20,21,22,28, and 29), and cost (item 17 and 18).

According to the results of principal component analysis of the parceling method, structure of the PV-PLTQ instrument could be explained by a 5-factor and 32 items solution. The path diagram of CFA with the parceling method was presented in Figure 2. Furthermore, the goodness of fit indices was shown in Table 2 for CFA with the parceling method. In the parceling model, RMSEA, CFI, IFI, PNFI, PCFI showed acceptable goodness of fit and GFI was nearly close to the acceptable value; i.e. 0.90. All of the regression weights between indicators and endogenous variables (healthcare, emotional, medication, physical, and cost), and endogenous variables and exogenous variable were statistically significant ( $p < 0.001$ ).

### ***Acceptability:***

All of the items had less than 4% missing data except items 20 (learning to walk after surgery) and 21 (patients' concern about the ability to drive) with 6% missing data (Table 3). The patients in the face validity phase recognized these items to be totally clear.

### ***Reliability:***

Values for Cronbach's alpha exceed the satisfactory level value more than .7 in the total instrument and each domain (Table 3). The ICC for total PV-PLTQ questionnaire and its 5 domains were .86, .73, .81, .79, .77, and .6 respectively ( $P < .001$ ). This result shows moderate to good test-retest reliability.

### ***Sensitivity to Change:***

The PV-PLTQ questionnaire score change had no normal distribution. Therefore Kruskal-Wallis statistical analysis was utilized. The results showed that changes in the score between patients who reported "improvement", "no change" and "deterioration" was statistically significant different ( $P < 0.001$ )

### ***Convergent Validity:***

The result of the Spearman test presents moderate to high correlation between total and all items of PV-PLTQ questionnaire and MCSS and PCSS ( $P < 0.05$ ). The highest Pearson correlation value was related to physical domain score of PV-PLTQ questionnaire score and PCSS of SF-36 ( $r = 0.53$ ,  $P < 0.01$ , Table 4).

## **Discussion:**

In the past few years, the number of LTx centers and utilization of this therapeutic intervention has been grown dramatically worldwide. Now, many countries with different cultures, religions, and languages are performing LTx for their patients. LTx is not only a cross-sectional treatment. It affects various aspects of patient's live which can be related to their HRQOL. LTx recipients have specific health conditions that need various types of medical and healthcare management than other patients. for example, they must always take immunosuppressive drugs that may expose them to some side-effects. These specific conditions are the key reasons for the need of a specific HRQOL instrument.

Internationally standard HRQOL instruments allow the comparison of the patients' condition and QOL among different cultures [21]. As use of generic or specific questionnaires is affected by different cultures, they must be translated, cross-culturally adapted, and validated based on standard guidelines [22].

PV-PLTQ questionnaire seems to be a relatively acceptable and simple to be completed based on result of pretesting face validity and missing data proportion. Items 20 and 21 had higher missing data proportions. These items are related to patients' concern about learning to walk and drive. Most patients in this center are mobilized or made to walk learn walking during hospitalization stage by a physiotherapist and they will be under follow-up of physiotherapy service after discharge. Subsequently,

they can walk, and drive soon after LTx; therefore, it may be concerning about walking and driving in the condition which they are now have these functions be confusing questions.

## **Factor analysis:**

Based on the factor analysis result, it could be postulated that the PV-PLTIQ indicated a promising and acceptable five-factor structure in Persian speaking population. The different number of domains between original PLTQ and PV-PLTQ may be due to different conditions of LTx recipients in Persian speaking population in comparison to U.S. As an example, worry and graft rejection concern domains did not detect. Most of the PLTQ questions ask the patients about their concerns and worry. Worry and concern are two words which their equivalent translation in Persian is a similar word. Although the expert panel tried to discriminate these questions from each other, but the factor analysis could not detect questions about worry and graft rejection concern as specific domains and most of their questions shifted to other domains. On the other hand, cost domain was totally detected in our analysis. Despite good insurance coverage for drugs and other healthcare procedures, patients have to pay some costs themselves. Furthermore, due to difficult financial condition for Iranian people, providing this cost is mostly troublesome for patients [23]. It can be the reason why the factor analysis detected cost domain with only two questions. A similar study was reported by Xiao et al which translated and cross-cultural adapted the PLTQ instrument to Chinese language. They detected 6 domains including worry, physical function, emotional function, financial, healthcare, and complication. Moreover, the limitation of sample size was a probable reason for failing PLTQ model with 8 domains.

## **Internal Consistency, Test-Retest Reliability, and Sensitivity to Change:**

The Cronbach's alpha of the PV\_PLTQ questionnaire was 0.97 which is greater coefficient value than previously reported by Saab et al. [10], Xiao et al. [11], and Molski et al. [12]. This result presented that the PV-PLTQ instrument has satisfactory internal consistency. We selected 2 to 3 months as the period between two assessment phases. Although the results of a published systematic review indicate that the HRQOL has been increased after LTx [24], but some components of HRQOL may be attributed in the short-time after LTx due to surgical or psychological complications or some immunosuppressive drug side-effects. It occurs specially in the first months after transplant and can influence on the test-retest reliability. In order to resolve this confounder factor, GRC was used to track participants' change during 2 to 3 months. ICC was calculated in only patients who reported no change. The results of test-retest reliability showed good to moderate ICC values ranging from 0.6 to 0.86. Although, Saab et al. have not reported ICC for test-retest reliability, but our results were similar to those of the other translation and validation of the PLTQ instrument [11, 12]. The changes in the PV-PLTQ questionnaire score was used to evaluate sensitivity to change power of this instrument. The results of Kruskal-Wallis showed that it seems PV-PLTQ instrument can be considered sensitive to change Persian HRQOL instrument.

## **Convergent Validity:**

The PV-PLTQ questionnaire and the MCSS and PCSS showed a relatively good significant convergent validity. Although, All the result of Pearson test investigated a statistically significant correlation between PV-PLTQ instrument domains and MCSS and PCSS, the correlation between healthcare and cost domains were less than others. These may be due to the nature of SF36 questionnaire content. In SF-36, we don't have questions about patients' financial condition. Moreover, there are some questions about patients' current health status but there are no question about individuals' concerns about healthcare.

Our main limitation in this study was the sample size. For performing some analysis like CFA there is a need for a larger sample size. The number of LTx procedures is relatively less than other surgical procedures and providing a large sample size is relatively difficult. The second limitation was single-center recruitment. Although our center has an average of 220 LTx annually from all over Iran and there are various indications for LTx in this center, but it is a fact that single-center is another main limitation.

## **Conclusion:**

We have developed the Persian version of the Post-liver Transplant Quality of Life instrument. This tool seems to be reliable, valid, and sensitive to change. Also, the participants indicated that this instrument is acceptable and easy to understand and response. Therefore, use of PV-PLTQ questionnaire can be recommended in the researches and clinical settings to evaluate Persian linguistics/speaking LTx recipients' HRQOL.

## **Declarations**

### **Author Contribution:**

MJ, NA, AN, MN, AJ, and BAM made substantial contributions to the conception and designed the study. MJ, NA, and MN contributed to acquisition of the data. MJ and MS analysed the data. BAM and AN was responsible for data safety monitoring during the study. MJ, and NA interpreted the data and drafted the manuscript. All authors had access to the data, revised the manuscript, and approved it.

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### **Conflict of Interest:**

The authors declare that they have no conflict of interest.

### **Acknowledgment:**

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## Tables

**Table 1. Demographic and clinical characteristics of participants in the cross-sectional and longitudinal survey.**

<b>Characteristic</b>	<b>Cross-Sectional Survey</b>	<b>Longitudinal Survey</b>
Total number	175	67
Age (years)*	46.2 ± 12.4	47.6 ± 12.8
Gender (n [%])		
Male	115 [39]	48 [30.5]
Female	60 [20.3]	19 [12.1]
Level of education (n [%])		
Under diploma	35 [20]	13 [19.4]
Diploma	103 [58.8]	38 [56.7]
Undergraduate	26 [14.9]	11 [16.4]
Postgraduate	11 [6.3]	5 [7.5]
Time since transplantation at initial survey (n [%])		
< 6 months	33 [18.8]	15 [22.4]
6 – 12 months	48 [27.4]	16 [23.9]
> 12 months	94 [53.8]	36 [53.7]
MELD score at transplant time*	19.7 ± 5.6	18.9 ± 5.9
Indication for transplantation (n [%])		
Cryptogenic cirrhosis	32 [18.3]	11 [16.4]
Autoimmune disease	23 [13.1]	10 [14.9]
PSC/PBS	21 [12]	8 [11.9]
Hepatitis B	19 [10.9]	7 [10.5]
Hepatitis C	16 [9.1]	8 [11.9]
NASH	16 [9.1]	6 [8.9]
Fulminant hepatic failure	9 [5.1]	5 [7.5]
Wilson disease	7 [4]	3 [4.5]
Budd-Chiari syndrome	6 [3.4]	1 [1.5]
ASH	5 [2.9]	1 [1.5]

HCC	5 [2.9]	2 [3]
More than one indication	16 [9.2]	5 [7.5]

MELD: Model for end-stage liver disease; PSC: Primary sclerosing cholangitis; PBS: Primary biliary sclerosis; NASH: Nonalcoholic steatohepatitis; ASH: Alcoholic steatohepatitis; HCC: Hepatocellular carcinoma.

\* Presented as mean ± standard deviation.

**Table 2. Goodness of fit indices of the confirmatory factor analysis with parceling method for the PV-PLTQ questionnaire.**

Model	Chi square	DF, p-value	GFI	RMSEA	CFI	IFI	PNFI	PCFI
<b>parceling</b>	292.9	114, <0.001	.83	.09	.94	.94	.76	.79

DF: Degrees of freedom, GFI: Goodness-of-fit index, RMSEA: Root mean square error of approximation, CFI: Confirmatory factor index (CFI), IFI: Incremental fit index, PNFI: Parsimony-adjusted normed fit index, PCFI: Parsimony-adjusted comparative fit index.

**Table 3. Internal consistency and test-retest reliability of PV-PLTQ questionnaire.**

PV-PLTQ Score/Domain	Mean ± SD	Cronbach's Alpha	ICC [95% CI] <sup>a</sup>	Proportion (%) of missing data
<b>Total Score</b>	5.17 ± 1.5	.97	.86 [.76, .92] <sup>a</sup>	-
<b>Healthcare</b>	5.7 ± 1.9	.95	.73 [.55, .84] <sup>a</sup>	2.8
<b>Emotional</b>	4.9 ± 1.54	.9	.81 [.67, .9] <sup>a</sup>	3.4
<b>Medication</b>	5.3 ± 1.7	.88	.79 [.64, .88] <sup>a</sup>	4
<b>Physical</b>	5.2 ± 1.6	.89	.77 [.6, .87] <sup>a</sup>	6.2
<b>Cost</b>	4.8 ± 2	.82	.6 [.36, .76] <sup>a</sup>	4

PV\_PLTQ: Persian version of post-liver transplantation quality of life instrument; ICC: Intraclass correlation coefficient

\* ICC was measured in the participants presented “no change” during two assessment phases based on Global Rating Scale (n=40)

<sup>a</sup> Statistically significant

**Table 4. Spearman correlation coefficient of the PV-PLTQ domain and SF-36.**

PV-PLTQ Score/Domain	SF-36	
	Mental Component Summary	Physical Component Summary
<b>Total Score</b>	.54	.5
<b>Healthcare</b>	.49	.3
<b>Emotional</b>	.59	.42
<b>Medication</b>	.49	.41
<b>Physical</b>	.41	.53
<b>Cost</b>	.45	.38

All correlations are statistically significant.

## Figures

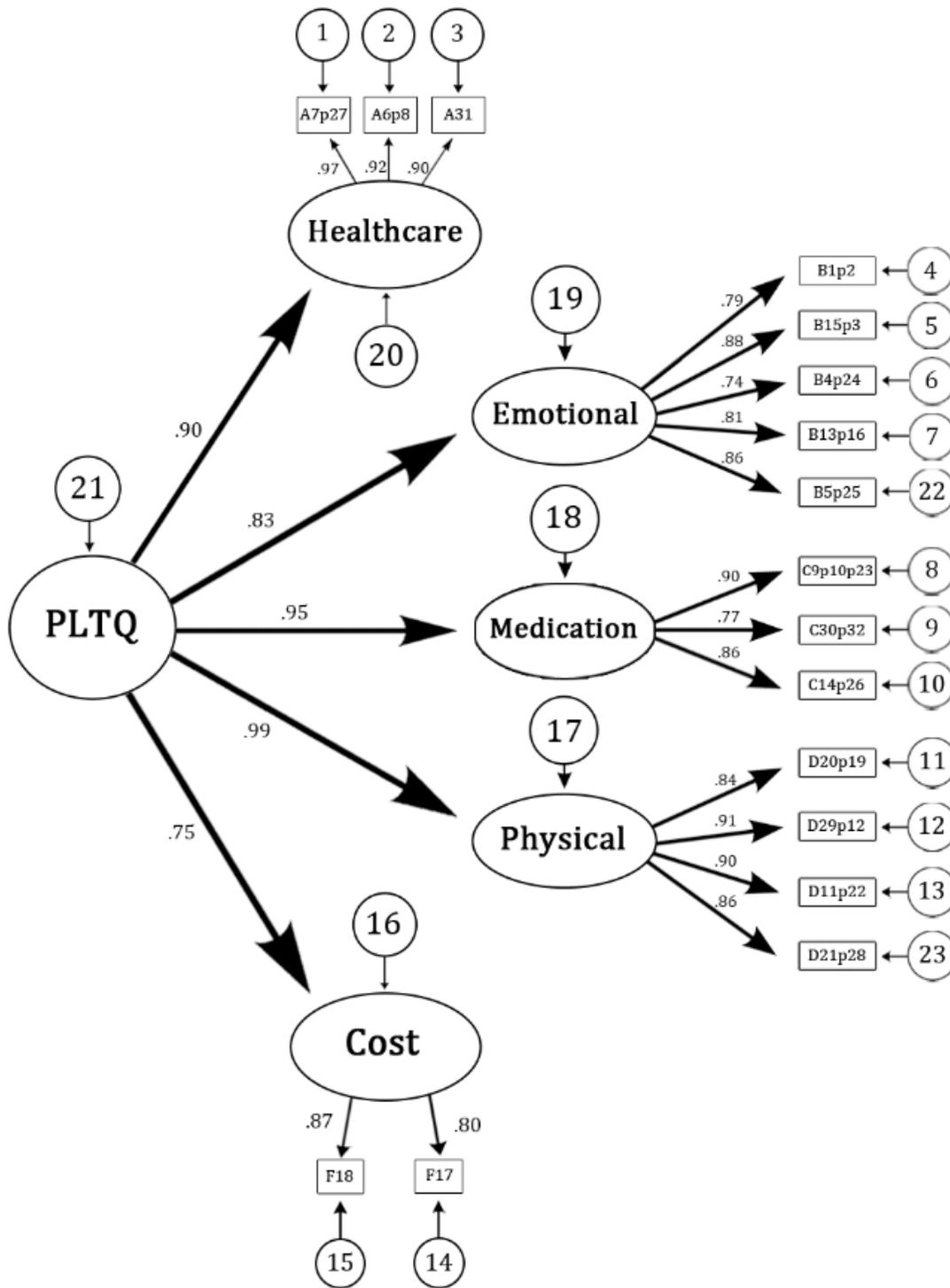


Figure 1

Path diagram of CFA with parceling method.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Appendix Persian version of PLT Questionnaire.docx](#)