Health Problems Questionnaire in Multiple Sclerosis Patients: Development and Validation

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Research Article

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Abstract

Background

Multiple sclerosis patients are faced with numerous problems during their illness. Development of a self-report measure of health problems in multiple sclerosis patients is required based on cultural factors, which can advance our understanding of the level of health problems for care planning and improvement of coping and quality of life. The current study aimed to develop and validate the scale of health problems of Multiple Sclerosis.

Methods

This present study is an exploratory sequential mixed method study that was conducted in three phases. In the first phase, the concept of health problems in MS patients was defined using the content analysis approach. In the second phase, the item pool was generated from findings of the first phase. In the third phase, psychometric properties of the scale were evaluated including face, content and construct validity as well as reliability.

Results

After examining the psychometric properties of validity and reliability, 33 items were designed in the final questionnaire. Factor analyses revealed five factors: physical problems, psychological problems, emotional problems, family problems, and socio-economic problems. Internal consistency and stability of the developed questionnaire confirmed with 0.93 and 0.95 respectively that indicated excellent reliability.

Conclusion

The 33-item developed questionnaire is valid and reliable for measurement of levels of health problems in Iranian people with MS.

Background

Multiple sclerosis (MS) is a chronic inflammatory demyelinating illness leading to progressive neurological disorder and an array of debilitating symptoms. (1). This disease affected people 20–40 years. Prevalence MS is 1.1 million people in the world (2). According to the latest statistics from the MS Society of Iran, the number of people with MS is 78,890 (3). MS is one of the most important life-changing diseases because it damages the best periods of the people’s life and leads to inability (4).

MS symptoms and problems are variable and unpredictable such as fatigue which occurs in about 80% of people, pain, spasms, weakness, visual impairment, imbalance, Tremor, impotence, depression and
cognitive problems (5). In addition, MS patients experience several physical and psychological problems that strongly influence their daily performance, family and social life, independence, and individual planning for the future; it destroys the feeling of being good in a person (6, 7).

In addition to the above stated problems experienced by MS patients worldwide, Iranian MS patients also are faced with some additional problems including the lack of access to the needed medications, lack of necessary support for rehabilitation and medical costs, etc., which increase the attention and care of these patients in the Iran country for disease better management and improve quality of life (8). There have been several studies for investigating the problems of these patients that majority of these studies addressing only one aspect of these problems, including some of the patients' physical problems, using separate questionnaires for the same problem (9–11).

The main issue is that the problems of these patients in all aspects should be examined by a detailed, standardized and native questionnaire and then, problems related to each dimension of patients were identified through standard designed questionnaire so that with using results can be effective steps to solve the problems of these patients.

Forbes et al. (2006) has developed a questionnaire that measures health problems and health-related quality of life in people with MS. In this study, only some of the individual problems of patients including fatigue, pain, urinary-intestinal incontinence, depression, pressure ulcers, sexual problems and employment were assessed by a researcher-made questionnaire (12). However, there are no separate questions regarding other problems in patients with MS such as family problems and etc. also, these questionnaires are used in different communities and cultures without considering cross-cultural appropriateness (13). Indeed, specifics questionnaire for measurement of health problems in MS patients has not designed. Another reason for choosing this study is to identify the health problems of MS patients through standard and native questionnaire based on socio-cultural condition in all dimensions and comprehensively in a single questionnaire is one of the main research priorities of the Iranian MS Society (14). Since the details are not available about levels of health problems in all dimensions these patients. Research on health problems of MS patients indicated that the data were preliminary and inconclusive and more research is required in this area.

The purpose of the present study was to develop a valid and reliable questionnaire that assesses level of health problems of MS patients, MS Health Problems Questionnaire (MSHPQ). Hence, since the assessing health problems in patients with MS, can appropriate information for problems identification and future decisions such as education, care interventions, reformation and improvement provide. On the other hand, the used questionnaire must adapt with socio-cultural context in Iran. Therefore, the present study with this purpose was conducted.

Materials And Methods

Study design and participants
This study was an exploratory sequential mixed method study that was conducted in three phases and two sections of qualitative and quantitative. An exploratory sequential mixed method study essentially includes the following steps (15):

1) Defining the concepts
2) Formulating the items of the questionnaire
3) Developing the questionnaire
4) Testing validity and reliability of the questionnaire

Data in this study were collected from February 2019 to December 2020 at the MS Society in Jahrom, Iran. The current study was conducted in three phases as follows (Fig. 1):

**The first phase**

In this phase, the concept of health problems in MS patients was conceptualized and defined using the conventional content analysis qualitative method. In this method, the codes and their classification were directly extracted from the interviews. In content analysis, the researcher interpreted the finding using presenting data in words and themes which involved understanding, interpreting and conceptualizing of the underlying meanings of the qualitative data (16). In this phase, 15 patients with MS participated in the study. The collection data were conducted using semi-structured and individual interviews. Inclusion criteria of patients were (1) definite diagnosis of MS illness, (2) willingness to participate in the study, (3) ability to express experiences, (4) at least two years passed form MS illness. Exclusion criteria of participants were patients at the stage of experiencing acute and critical attacks of the disease. Each interview lasted on average 45-60 min. A total interviews were conducted in MS Society in Jahrom based on the participant's prior agreement and at the time they were comfortable. Interview with patients continued to data saturation. Interviews were tape-recorded, transcribed verbatim in MAXQDA software, Ver10 to manage the coding process. Then, analysis data were conducted using qualitative conventional content analysis and Graneheim and Lundman model (17). In this stage, the initial codes were extracted and the subcategories and categories were formed. In the end of this phase, the dimensions of health problems were extracted and provided a final definition of the concept of health problems in MS patients.

**The second phase**

In this phase, the items pool of was formed to design a health problems questionnaire in MS patients based on the following steps:

1. Dimensions extracted from the first phase of the study for health problems
2. Reviewing relevant texts in the field of health problems
3. Reviewing relevant health problems questionnaires
The third phase

In this phase, psychometric properties were conducted. This properties included face, content, and construct validity, and reliability of the items pool for designing questionnaire. These properties include the following:

A) **Face validity**: The face validity was conducted in the two qualitative and quantitative sections. The qualitative section was performed using individual interviews with 12 MS patients. The patients regarding difficulty, relevancy and ambiguous of the items were asked and then their recommendations on the items were applied. In the quantitative section, the item impact was calculated for the importance each of item and remove inappropriate items. Then, the developed questionnaire was completed by 12 MS patients. The impact score of 1.5 and lower was considered inappropriate and was deleted (18).

B) **Content validity**: The content validity was conducted in the two qualitative and quantitative sections. In qualitative part, 12 expert were asked to assess the questionnaire about grammar, using appropriate words, placement of items in the appropriate place and right scoring (19). In quantitative part, content validity ratio (CVR) and content validity index (CVI) were calculated for each item of questionnaire. The CVR of each item calculated using scoring the items in a three-point scale including essential, useful but not essential and not essential by 10 experts, based on Lawshe (1975) (20) and modified table by Ayre and John Scally (2014) (21). Given the number of 12 experts, items with the CVR value of 0.80 and higher were maintained. In the CVI, the relevance of each item was analyzed by 10 experts on a four-point Likert scale (not relevant: 1; a little relevant: 2; somewhat relevant: 3; and extremely relevant: 4) (22). In this part, items with the CVI value of 0.79 and higher were preserved (23).

C) **Initial reliability**: In this part, correlation coefficient between items and as well as between items and whole questionnaire were calculated through Cronbach's alpha and inter-item correlation coefficient (ICC) by 28 MS patients.

D) **Construct validity**: in this part, exploratory factor analysis (EFA) and the known - groups comparison were used to determine the construct validity of the MSHPQ. The EFA was used to determine the interrelationship between items and to summarize related items in a dimension (24). In the EFA from the Principal Component Analysis (PCA) for factors extraction, Kaiser- Meyer- Olkin index (KMO) for determine sampling adequacy, Bartlett's Test for evaluation the correlation between the items of the questionnaire in order to integrate them and varimax rotation for simplify and interpret the factor structure through taking the eigenvalues higher than one was used. The number of participants required for carrying out factor analysis per each item between 3 - 10 people (25). Hence, in this study, the questionnaire was completed by 200 MS patients through convenience sampling (Table 1). The factor loading for each item in order to item maintenance at least 0.5 was considered.

E) **Final reliability**: Reliability of the MSHPQ scale was determined through two internal consistency and stability methods. For determinate the internal consistency, the MSHPQ was completed by 20 MS patients and then Cronbach's alpha coefficient was calculated. Alpha coefficient above 0.7 was
considered as appropriate for the reliability (26). In order to evaluate the stability of the MSHPQ, a test-retest method was conducted. The MSHPQ were completed by 20 MS patients at two time stages with on 2-week intervals (27). Then, the correlation of scores between the two tests was determined with ICC. The ICC above 0.8 represents the optimal stability of the questionnaire (28).

**Statistical analysis**

Statistical analyses was conducted through the SPSS version 20.0. Normality data through Kolmogorov-Smirnov test was confirmed. Descriptive analysis test, factor analysis, EFA, KMO, Bartlett's Test, Cronbach's alpha, ICC and Pearson test were used for data analysis in the present research.

**Declaration**

The present study was approved by the ethics committee of Jahrom University of Medical Sciences in Iran (Code of Ethics IR. Jums. Rec.1397.041). We followed the guidelines outlined in the Declaration of Helsinki and patients received information, both written and verbal, stating that completing the questionnaire was voluntary, anonymous, and that study results would be published. Before the data collection, all participants signed an oral and written informed consent form. They were also ensured regarding anonymity and confidentiality of the data, and voluntary participation in the research.

**Results**

The results of the study are presented in three phases as follows.

**The first phase**

In this phase, the concept of health problems in MS patients was defined based on the literature review and patients experiences using the conventional content analysis. Health problems in MS patients is a dynamic, complex and multidimensional concept which has different dimensions. The dimensions of health problems in MS patients included physical problems, psychological problems, emotional problems, family problems, and socio-economic problems.

**The second phase**

In this phase, the findings of the literature review and qualitative content analysis were applied to generate an item pool for the MSHPQ scale. The item pool consists of 83 items in three aspects of individual problems, family problems, and social problems. Then, the research team reviewed the items of the MSHPQ scale in order to assess overlapping items that 10 items were removed from the questionnaire and remained 73 items.

**The third phase**

A) **Face validity**: In the qualitative part of the face validity, three items were modified based on patients’ recommendations. In the qualitative part of the face validity, six items were deleted due to an impact item
score lower than 1.5. Therefore, 67 items remained for the MSHPQ scale.

**B) Content validity:** In qualitative part, two items were modified according to specialist's panel comments. In CVR analysis, the 19 items were deleted because of the CVR value of lower than 0.80. In CVI analysis, three items were removed because of the CVI value of lower than 0.79. Therefore, 45 items remained for the MSHPQ scale.

**C) The initial reliability:** the internal consistency MSHPQ using Cronbach's alpha was 0.94. The correlation between items No. 13 “MS disease causes me to become very tired” with the whole MSHPQ was 0.03, and item No. 5 “I suffer from spasms and muscle cramps caused by the disease” was −0.025. Therefore, this two items removed because of a correlation of lower than 0.3. Eventually, 43 items preserved for the MSHPQ scale.

**D) Construct validity:** in this part, the number of 200 MS patients from MS Society of Jahrom were completed the 43-items MSHPQ scale. Based on Table 2, the KMO value equals 0.921, which shows the appropriateness of the selected sample size in the supervision scale for the EFA (200 patients). Furthermore, the value of the Bartlett test of sphericity was significant (P = 0.001). Therefore, the data are appropriate for the factor analysis. The EFA with PCA and varimax rotation led to the extraction of three factors with eigenvalues above 1. Table 3 shows the eigenvalues, percentage of variance for three factor and as well as factor loadings for the items that met retention criteria. Therefore, 10 items were deleted from the MSHPQ scale because of factor loading lower than 0.5. Finally, 33 items and five factors remained for the MSHPQ scale. Three factors of the MSHPQ scale included the following: factor one “physical problems” with 12 items, factor two “psychological problems” with 5 items, factor three “emotional problems” with 4 items, factor four “family problems” with 4 items, and factor five “socio-economic problems” with 8 items,. The three rotated factors explained for 63.84% of the total variance.

The items of the MSHPQ were rated on a five-point Likert-type scale, 1 = never, 1 = rarely, 2 = sometimes, 3 = often and 5 = always.

**E) Final reliability:** Cronbach's alpha for the 33-item MSHPQ scale was 0.93 that showed optimal internal consistency. The ICC between test and retest measurements was 0.95 that indicated an acceptable stability of the MSHPQ scale during the time. As well as Cronbach's alpha and ICC for three factors was determined that are shown in Table 4.

**Discussion**

The present research dealt with the development and validation of a scale for health problems in MS patients. Furthermore, as objective measures of health problems do not appear to capture fully the patient's experience, that self-reports are employed. The result showed that the MSHPQ scale was a reliable and valid instrument for the evaluation of health problems. Our approach to creating a new instrument was multifaceted and iterative, with both qualitative and quantitative methods used in its development. Since no instrument had been designed in Iran to evaluate the health problems and the
feedback to health personnel in a semi-structured model of problems identification and care planning, it was crucial to develop and validate an instrument that could evaluate the important dimensions of health problems and could provide an opportunity for giving feedback to health personnel.

In the different studies were used separate questionnaires to assess the problems of patients with MS, for example measurement of fatigue through FSS scale (29), stress, anxiety and depression through DSAA 21 scale (30), physical problems using several questionnaires (12, 31 - 32). The MSHPQ scale evaluate all of the health problems including physical, psychological, emotional, family and socio-economic problems in MS patients in a single questionnaire. In fact, the weaknesses of the other instruments were attempted to be eliminated in this instrument. The advantage of an overall MSHPQ scale is that it gives a holistic picture and information of the impact of MS disease on patients. As an example, the Forbes et al. (2006) (12) instrument regarding health problems, which is repeatedly used in various studies, does not evaluate some areas of the health problems like emotional, family and socio-economic problems and cannot be used for the MS patients with multidimensional problems. Many people with MS in addition to physical problems experience many other problems such as disorder in family and social relationships, dysfunction, social role, occupational problems and etc. that require to attention and consideration (33). Patients with MS experience difficulties in emotion regulation, psychological condition, providing medical expenses which predict poorer quality of life. These findings indicate that emotional and psychological outcomes control skills should be investigated in further detail when considering interventions to enhance well-being in MS patients (34). Also, patients with MS experiencing more difficulties in emotion and psychological condition regulation than health people. Mediation analyses indicated that depression mediated the emotion regulation difficulties in MS. So that Difficulties in emotion regulation predicted poorer psychological and social quality of life in MS patients (35).

One of the strengths of this study is that the MSHPQ was developed the both inductive and deductive method and also have been used excellent validation consist of face, content, and construct validity, and reliability (internal consistency and stability). As well as the MSHPQ is a 33 items short questionnaire that can be responded by MS patients in short time (10–15 min). The greatest strength of this study was the design and development of a context-based health condition to assess Iranian MS patient's health problems.

The lengthy and ongoing processes in development, validation and evolution of a new questionnaire and as well as suffering scale of self-report are from current study limitations. Another limitation was this that not possible to gather objective data on patients’ disability levels, which may be a mediating factor in health problems of patients.

**Conclusion**

In this study, the five-dimension MSHPQ was developed as a short self-report scale for measurement of health problems in Iranian people with MS. The MSHPQ is a valid, reliable and context-based scale which
can be used in several situations including education, research, care management, needs assessment and identification, and support services.

**Abbreviations**

MS multiple sclerosis; MSHPQ Multiple Sclerosis Health Problems Questionnaire; one way ANOVA one-way analysis of variance; ICC intraclass correlation coefficient; PCA principal component analysis; KMO kaiser- meyer- olkin; CVR content validity ratio; CVI content validity index; EFA Exploratory factor analyses.

**Declarations**

**Availability of data and materials**

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

**Consent for publication**

Not applicable.

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**Competing interests**

The authors declare that they have no competing interests.

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**Authors' contributions**

Conception, design, Analysis and interpretation of the data: Ali Dehghani.

Data collection: Ali Dehghani.

Writing the article: Ali Dehghani.

Critical revision of the article: Ali Dehghani.

Final approval of the article: Ali Dehghani.
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Tables

Table 1
Demographic characteristics of the samples in EFA section (N = 200)

| variables                          | N (%)       |
|------------------------------------|-------------|
| Age (years)                        | Mean ± SD   |
| Duration of MS (years)             | Mean ± SD   |
| Gender                             | male        |
|                                    | female      |
| Educational status                 | Under diploma |
|                                    | diploma     |
|                                    | Upper diploma |
| Number of recurring during the past year | No recurring |
|                                    | once        |
|                                    | More than two times |

| Kaiser-Meyer-Okkin (KMO) measure of sampling adequacy | 0.921 |
|-------------------------------------------------------|------|
| Chi-Square value                                      | 9754.518 |
| Df                                                    | 681  |
| P                                                     | 0.001 |
Table 3
results of a PCA of the 33 - items MSHPQ scale (N = 200)

| subscales          | Item                                                                 | Factors |
|--------------------|----------------------------------------------------------------------|---------|
| Physical problems  | I have trouble doing daily ordinary activities (bathing, wearing own clothes, etc.) | 0.701   |
|                    | I have trouble doing light activities (walking more than a kilometer, etc.) | 0.687   |
|                    | I suffer from physical pains                                        | 0.632   |
|                    | I suffer from general weakness and lethargy                          | 0.680   |
|                    | I suffer from visual impairment like double vision, etc.             | 0.556   |
|                    | I suffer from an imbalance like loss of control of body movements   | 0.765   |
|                    | I suffer from urinary and bowel incontinence                         | 0.567   |
|                    | I suffer from insomnia                                              | 0.621   |
|                    | I suffer from memory disorder and forgetfulness                      | 0.641   |
|                    | I suffer from stinging and hand and leg numbness                     | 0.556   |
|                    | I suffer from the side effects of drugs related to the disease       | 0.666   |
|                    | I simply get tired                                                   | 0.532   |
| Psychological problems | The disease has caused negative feelings such as sadness, depression, and anxiety | 0.876   |
|                    | I feel distressed and confused                                        | 0.895   |
|                    | I feel feared without justified reason                                | 0.789   |
|                    | I feel consuming a lot of mental energy                              | 0.680   |
|                    | I feel dissatisfied toward my body style                             | 0.654   |
| subscales               | Item                                                                 | Factors |
|------------------------|----------------------------------------------------------------------|---------|
|                        |                                                                      | 1  | 2  | 3  | 4  | 5  |
| **Emotional problems** | The disease has caused to be sensitive and irritable                  | 0.765  |
|                        | The disease has made more introverted and indifferent toward surrounding issues | 0.687  |
|                        | The disease has led to a decline in my emotional relationships with my spouse and family members | 0.634  |
|                        | I can't handle my negative emotions                                   | 0.589  |
| **Family problems**    | The disease has reduced my relationship with family members           | 0.710  |
|                        | The disease has reduced my role and function in the family             | 0.749  |
|                        | The disease has caused problems in my matrimony and sexuality          | 0.678  |
|                        | The disease led to reduce to family supports from me                   | 0.690  |
| **Socio-economic problems** | The disease has caused problems in my job                              | 0.743  |
|                        | The disease has reduced my social relationships with others            | 0.780  |
|                        | The disease has reduced my ability and function in the community       | 0.634  |
|                        | I have trouble doing social activities (attending in ceremonies, etc.) | 0.648  |
|                        | I suffer from perspective of community toward MS disease               | 0.670  |
|                        | I have problems from accessing to prescription drugs for disease       | 0.543  |
|                        | I have trouble in provide my medication and medical treatment         | 0.512  |
The lack of socio-economic supports (financial, educational, supportive, services, etc.) led to problems for me.

| subscales                       | Item                                                                 |
|--------------------------------|----------------------------------------------------------------------|
| 1 Physical problems            | 12                                                                 |
| 2 Psychological problems       | 5                                                                  |
| 3 Emotional problems           | 4                                                                  |
| 4 Family problems              | 4                                                                  |
| 5 Socio-economic problems      | 8                                                                  |
| MSHPQ                          | 33                                                                 |

| Factors | Subscales          | Number of items | Internal consistency | Stability |
|---------|--------------------|-----------------|----------------------|-----------|
| 1       | Physical problems  | 12              | α = 0.94             | ICC = 0.97|
| 2       | Psychological      | 5               | α = 0.86             | ICC = 0.91|
| 3       | Emotional problems | 4               | α = 0.84             | ICC = 0.89|
| 4       | Family problems    | 4               | α = 0.79             | ICC = 0.95|
| 5       | Socio-economic     | 8               | α = 0.89             | ICC = 0.90|
|         | MSHPQ              | 33              | α = 0.93             | ICC = 0.95|

Table 4
The Cronbach’s alpha and ICC values for MSHPQ scale and its factors

Figures
Figure 1

Flow diagram of the development and validation of the health problems Questionnaire in MS patients (MSHPQ)

Supplementary Files
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