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ORIGINAL ARTICLE

Usefulness of the SF-36 Health Survey questionnaire in screening for health-related quality of life among parents of children with cancer: Latent profile analysis

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Key words

Cancer • Cut-off points • Parents • Quality of life • SF-36 Health survey

Summary

Background. Poor health-related quality of life (HRQOL) of parents of children with cancer as their main caregivers can adversely affect child's HRQOL. Short Form-36 Health Survey (SF-36) is a widely used instrument to measure HRQOL. However, there are no clearly defined cut-off points for screening for parents with poor HRQOL. This study aimed to find appropriate cut-off points for the SF-36 questionnaire in a sample of parents of children with cancer using latent profile analysis to add another possibility to use it.

Methods. In this cross-sectional study, a number of 108 couples (108 mothers and 108 fathers), who had children with cancer, were selected by simple random sampling method from the patients' files. The study was conducted at two settings, pediatric hematology/oncology wards of BESAT hospital (a hospital related to Hamadan University of Medical Sciences, Iran) in 2017. Latent

Background

Childhood cancer is an important cause of death in Asia, Central and South America, North Africa, and the Middle East [1]. According to the World Health Organization (WHO), each year about 300,000 new cases are diagnosed with cancer among children aged 0-19 years [2] and the estimated age-standardized incidence rates for all types of cancer ranges from 2.3 to 23.6 per 100,000 children worldwide (both sexes, ages 0-19) [3]. While, a higher incidence rate of cancer has been reported in developed countries (less than 40 per 100,000 children), the incidence of rate of cancer has been reported to be increased dramatically in developing countries including Iran [4]. In Iran, cancer related deaths rank first (14.2%, 23,300 cancer deaths) and only about 10,000 Iranian children were diagnosed with cancer during 2002-2012 [5]. In recent decades, because of remarkable progresses made in cancer treatment, the life expectancy and survival rates increase and cancer has become a chronic disease rather than an incurable disease [6]. It has been reported that the overall survival rate of children's cancer has increased from about 10% to approximately 90% over the last 40 years [7]. Extended

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Profile analysis (LPA) method was used to determine appropriate cut-off points for the SF-36 questionnaire. Data was analyzed by Mplus and R3.3.0 software.

Results. Based on the results, scores ≤ 44 , 45-63 and ≥ 64 for mental health, and scores ≤ 43 , 44-59 and ≥ 60 for physical health classes indicate weak, medium, and good, respectively. These cutoff points showed acceptable accuracy in classification of individuals. For the total quality of life, correct classification rates were 88%, 65% and 53% for each class respectively. For mental health (physical health), they were 79 (63), 50 (62) and 52 (63) for each class respectively.

Conclusions. The cut-off points for the classes identified here can be useful in screening parents of children with cancer in clinical setting to provide clinical interventions to protect vulnerable parents from negative outcomes.

remission periods have increased the number of children and families that need adjusting to daily living problems. Parents are the primary support system for children with cancer and they experience reduced health-related quality of life (HRQOL) remarkably compared with parents of healthy children, since diagnosis of cancer and during the treatment [8-10]. HRQOL is defined as the perceived health status and daily living with any changes in physical and mental health, and social functioning [11]. It has been reported by studies that HROQL of parents (of children with cancer) is associated with a variety of the factors including higher levels of education, age of child, time elapsed since cancer diagnosis, type of treatment, or treatment intensity, etc. [11-13]. However, there is not a consensus among the studies in associated factors. Higher HRQOL of parents (who have children with cancer) and parental adjustment can positively affect child's treatment, and even the outcome of treatment [12]. Therefore, it is crucial to investigate HROOL of parents among different areas, preferably using a valid and robust questionnaire in this area.

Short Form-36 Health Survey (SF-36) questionnaire is one of the most widely used questionnaire in studies not only for measuring HRQOL in parents of children

suffering from cancer [13-15], but also for assessing the health status of adults aged 18 and older [16-18] and comparing HRQOL in different cultural groups within a country [17], as well as assessing HRQOL of individual patients with various diseases in clinical settings [15, 19, 20]. The SF-36 questionnaire is a psychometrically sound, relatively brief, and a simple instrument that is frequently used in health studies [17] that is available in many languages and has been psychometrically validated [16, 21]. The Persian version of the SF-36 questionnaire (used in this study) has also been psychometrically validated in Iran as well. Scores are calibrated so that 50 is the mean score or norm [22]. In some studies, it is only stated that a lower score indicates poorer health [15, 23]. In some others, score 50 has been reported as a distinction point between the lower and upper score of health [23, 24].

Parents of children with cancer are considered as main caregivers especially when their children receive the treatment at home. The required time and effort needed to care for a child with cancer, along with the financial/ logistical issues created by treatment, expose parents to extensive stress which may have implications for parents' HRQOL. Healthcare systems should understand diminishing of HRQOL in parents having a child with cancer to manage its implications more effectively. By screening for parents, one can achieve early detection and reveal the risk factors affecting HRQOL to help health care professionals to provide intervention strategies to promote HRQOL of parents of children with cancer. This in turn can substantially improve quality of life of children with cancer. This highlights the need for separating parents with different levels of HRQOL and determining suitable cut-offs using appropriate statistical methods to identify parents with poor HRQOL. To our knowledge, despite the widely use of this questionnaire, the cut-off point of this scale is not clearly defined. Understanding and interpretation of results based on unique cut-off points might help identifying individuals at the potential risk for poor HRQOL in some conditions like comparison of HRQOL of caregivers or individual patients with various diseases or different cultural groups. Moreover, cut-off points can be used in clinical practice to screen HRQOL of parents of children with cancer.

The purpose of the present study was to find appropriate cut-off points for the SF-36 questionnaire in a sample of parents of children with cancer applying latent profile Analysis (LPA) in order to adding another possibility to use it. We also investigated the potential impact of demographic characteristics to see if they are related to HRQOL in our sample of parents of children with cancer.

Methods

DESIGN

The present cross-sectional study was conducted at two settings, pediatric hematology/oncology wards of a

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large and central university hospital (BESAT hospital) in 2017. This hospital is the only university hospital with pediatric and clinic departments in Hamadan, Iran. Pediatric hematology ward has 14 active beds, 14 staffs and 3 doctors. In this ward, services such as chemotherapy, blood and bone marrow sampling are provided.

POPULATION AND SAMPLE

The children diagnosed with cancer were selected by simple random sampling from the patients' medical records. Inclusion criteria were: (1) passing at least three months since the child's diagnosis of cancer; (2) not having a diagnosed physical or psychological illness in the parents that might effect on HRQOL (examples are depression, migraine, and physical chronic diseases); (3) being only one child with cancer in the family; and (4) both parents are alive. The sample size was estimated 112 couples (112 mothers and 112 fathers) with type I error of 0.05 and 90% power. Of the 112 couples invited, one did not respond to the invitation, one did not complete the questionnaire correctly, and two could not come back to the hospital within the study timeframe. Therefore, the sample size was reduced to 108 couples (the response rate was 96.43%).

DATA COLLECTION AND USED VARIABLES

Data was collected between May and October 2017. The data collection tools were demographic information including gender, age and education level of parents, the number of children in the family, gender, age and rank of birth of the child with cancer, and SF-36 questionnaires. The SF-36 questionnaire is a generic instrument for assessing the perceived HRQOL and daily functioning that are used internationally [25]. This questionnaire consists of 36 items and eight subscales, summarized in two summary domains: the physical (PCS) and mental component summary (MCS) measures or domains [26]. Its eight subscales include: physical functioning (PF, 10 items), role-physical functioning (RP, 4 items), bodily pain (BP, 2 items), general health perception (GH, 5 items), vitality (VT, 4 items), social functioning (SF, 2 items), role-emotional functioning (RE, 3 items), and mental health (MH, 5 items). One item asks about change in health status [22]. All items in each subscale are scored so that a high score defines a more desirable HRQOL. Then, the scores transfer linearly so that the lowest and highest scores in each subscale and total scores of PCS and MCS are set between 0 (worst HRQOL) and 100 (best HRQOL) [25, 27]. Scores are calibrated so that 50 is the average score or norm [25]. The PCS domain consists of physical functioning, bodily pain, general health perception and role-physical functioning subscales. The MCS domain consists of role-emotional functioning, vitality, social functioning and mental health subscales [28]. The score of each summary domain is the sum of these four subscales [26, 27]. In SF-36 questionnaire, usually the total score is not given and only the mean score of subscales and each summery domain are calculated

and compared with the 50 [24, 26]. The PCS and MCS domains were constructed to simplify the analysis of the outcomes by reducing the number of subscale scores, increasing the reliability and improving the validity of scores in distinguishing between physical and mental health outcomes [26, 29].

Montazeri et al. translated the SF-36 in Persian and assessed the psychometric property of the questionnaire in a sample of 4000 healthy adults. In Montazeri et al. study, Cronbach's alpha computed to assess internal consistency was between 0.77 and 0.90 for subscales [24]. In another study, internal reliability of the SF-36 was investigated and Cronbach's alpha values were determined as 0.90 for PCS and 0.87 for MCS [27]. In current study Cronbach's alpha values were between 0.70 and 0.83 for subscales, 0.70 for the PCS and 0.84 for the MCS domains indicating an appropriate internal consistency of the SF-36.

PROCEDURES

One of or both parents of a child were met in pediatric hematology/oncology wards of hospital when they brought their child for chemotherapy, visiting by the doctor, or follow up testing. After explaining the goals of the study, the questionnaires were given to a parent who was accompanied by her/his child and were asked to bring the completed questionnaire back at the next visiting time. Each questionnaire for mothers and fathers of the same child was put in separate envelopes. There was no name on the filled questionnaires and the questionnaire data was collected anonymously. The expected time to complete the questionnaire was about 45 minutes per person.

DATA ANALYSIS

Data was analyzed using Mplus 6.0 [30] and DiagTest3Grp package of R 3.3.0 [31]. Demographic characteristics of the participants were summarized using descriptive statistics and interpreted with ordinal logistic regression. Latent profile Model (LPM) [32] was used to find the cut-off points for the SF-36 questionnaire. P-value < 0.05 was considered to be statistically significant.

2-5-1 LPM. In the present study, several goodness of fit criteria were utilized, including:

- Akaike Information Criteria (AIC) [33];
- Bayesian Information Criteria (BIC) [34];
- Sample size adjusted Bayesian Information Criteria (SSABIC) [35].

The model with the lowest value of AIC, BIC, SSABIC is the most parsimonious model. The Lo-Mendel-Rubin Adjusted Likelihood Ratio Test (LMRT) and the Entropy criterion were also utilized to determine the number of latent classes as well as the accuracy of classification of individuals [36]. The LMRT is a statistical test to compare nested normal mixture distribution model with different number of classes (comparing a model with k classes and k-1 classes) [36, 37]. The entropy criterion

determines the accuracy of individual classification and its higher values indicate a better fit with the values greater than 0.80 indicating high discriminating ability of the latent classes [32, 36].

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Determination of cut-off points. Optimal cut-off points for obtained optimal number of classes were determined using the volume under the ROC surface (VUS) [38], as well as, the extended Youden index [39]. Then using these criteria, the posterior memberships of individuals to each class obtained from LPM were used as a gold standard. Let $D_1, D_2, ..., D_K$ be the K classes (in order) of the quality of life (QOL) and also let $c_1 = c_2, ..., c_{K-1}(c_1 < c_2 < ... < c_{K-1})$ be the K-1 cutoff points creating the K ordinal classes for the HRQOL for the parents participated in the study. Then the VUS can be calculated using F_i (I = 1, 2, ..., K) which is the cumulative distribution of HRQOL for each class. For a complete description of calculating VUS for three class or more see [31]. The values of VUS equal 1 mean perfect cut-off points. The Youden index takes its values between 0 (inadequate pointer) and 1 (perfect pointer). A complete description about calculating the extended Youden index for more than two diagnosed classes can be found in [34].

Results

DESCRIPTIVE STATISTICS OF DEMOGRAPHIC VARIABLES AND HEALTH RELATED QUALITY OF LIFE

More than half of the children was male (55.5%). The mean age of children was 10.5 ± 1.06 years. More than half of the children aged 5-8 years (59.3%), followed by 8-11 (27.7%), and 11-14 years (13%). More than half of the children were the first-born child (51.6%), followed by the second (28.7%), the third (13%) and the fourth child and more (6.5%) in the family. The most frequent cancer type was acute lymphocytic leukemia (69.4%), followed by lymphoma (10.1%), chronic lymphocytic leukemia (7.4%), sarcoma (4.6%), Wilms tumor (3.8%), and eye neoplasm (2.8%). The mean time since diagnosis of cancer in children was 12.4 ± 16.5 (95% CI: 72-3) months. The mean of age was 35.37 ± 11.7 for mothers and was 41.29 ± 7.4 for fathers. Most of the fathers were high school graduate (70.4%), 13.9% of fathers and 11.4% of mothers had a university degree, and 15.7% of fathers and 21.3% of mothers were primary school graduates or undergraduate.

The mean scores of the PCS and MCS domains were 54.91 ± 12.98 and 53.39 ± 11.67 for mothers, respectively and were 57.69 ± 10.45 and 52.82 ± 11.25 for fathers, respectively. Also, the mean score of total HRQOL were 55.26 ± 9.48 and 54.15 ± 11.04 for fathers and mothers, respectively.

CHOOSING THE OPTIMAL NUMBER OF LATENT CLASSES USING LPA

An LPA with one- to four-latent classes was performed on the eight subscales of the SF-36 questionnaire.

Number of latent class	AIC	BIC	Sample-size adjusted BIC $(n^* = (n + 2)/24)$	Entropy	LRT test	p-value
C = 1	15395.590	15449.595	15398.893			
C = 2	15232.682	15317.064	15237.843	0.898	177.245	< 0.001
C = 3	15090.496	15205.256	15097.515	0.942	156.941	< 0.001
C = 4	15072.051	15217.188	15080.928	0.906	35.707	0.154

Tab. I. Fit indices from the latent profile analysis.

C: Class; AIC: Akaike Information Criteria; BIC: Bayesian Information Criteria; LRT test: Lo-Mendel-Rubin adjusted test

Table I shows the results. According to the criteria listed in this table, the three-latent classes' solution was the best, so that the smallest AIC, BIC, and SSABIC were obtained when the number of three classes was used (considering four classes did not improve the results significantly). Based on the LMRT test, fitting a LPM with three classes is significantly better than a LPM with two classes (p < 0.001) for capturing the heterogeneity of observed responses on the eight subscales, while fitting a LPM with four classes did not improve the results significantly (P = 0.154). Moreover, the obtained entropy for the three latent classes' model (0.942) indicates a very well discrimination of the classes using the eight subscales (Tab. I).

Figure 2 illustrates the mean scores of the eight subscales of the SF-36 questionnaire for the three identified classes. One of the three classes included 11.1% of parents characterized by low scores on the six subscales including the physical functioning, pain, general health, energy, emotional well-being and social functioning subscales and high scores on the two subscales of role limitations due to physical health and emotional problems. The second class represents the moderate HRQOL (included 80% of parents) and the third class represents the good HRQOL (included

9% of parents) (Fig. 1). The mean scores of the total HRQOL and the two summary domains for the three identified classes as well as the total sample were provided in Figure 1.

OPTIMAL CUT-OFF POINTS FOR TOTAL QOL

The estimated cut-off points using generalized Youden index were 47.53 and 59.04 with Youden index 0.46 (95% CI: 0.36-0.57) and correct classification proportions of 87%, 47% and 58%, for weak, moderate and good QOL, respectively. The estimated cut-off points using ROC surface were 46.78 and 62.43 with VUS 0.58 (95% CI: 0.46-0.71) and correct classification proportions were 88%, 65% and 53%, respectively. Therefore, score \leq 47, 48-61 and \geq 62 indicating weak, medium, and good QOL, respectively.

OPTIMAL CUT-OFF POINTS FOR MENTAL HEALTH

The estimated cut-off points using generalized Youden index were 45.64 and 61.30 with Youden index 0.38 (95% CI: 0.27-0.49) and correct classification proportions of 81%, 58% and 37%, for weak, moderate and good mental health, respectively. The estimated cut-off points using ROC surface were 43.29 and 58.63 with

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VUS 0.46 (95% CI: 0.34-0.56) and correct classification proportions were 79%, 50% and 52%, respectively. Therefore, based on the results score \leq 44, 45-63 and \geq 64 indicating weak, medium, and good mental health, respectively.

OPTIMAL CUT-OFF POINTS FOR PHYSICAL HEALTH

The estimated cut-off points using generalized Youden index were 49.40 and 58.83 with Youden index 0.41 (95% CI: 0.31-0.52) and correct classification proportions of 76, 33 and 73%, for weak, moderate and good physical health, respectively. The estimated cut-off points using ROC surface were 43.29 and 58.63 with VUS 0.56 (95% CI: 0.45-0.64) and correct classification proportions were 63%, 62% and 63%, respectively. Therefore, based on the results score \leq 43, 44-59 and \geq 60 indicating weak, medium, and good physical health, respectively (Fig. 3). Figure 4 illustrates the correct classification proportions for the two subscales and total HRQOL.

Results of Fitting ordinal Logistic regression to investigate associated factors

The relative frequency of demographic characteristics of the study units for the three identified HRQOF latent classes was provided in Table II. For example, 62.5% of weak class was mothers. The potential effect of these demographic variables including age of parent, age and gender of child, gender of parent, parent's education level and birth rank was investigated on the three identified latent classes of HRQOL using ordinal logistic regression. Results were shown in Table III. According to Table III, none of the demographic variables had a significant association with the three identifies classes of HRQOL (P-value > 0.05).

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Discussion

SF-36 is one of the useful tools for screening HRQOL. The expanded utility of this questionnaire to classify HRQOL of parents of children with cancer including three classes of good, moderate, and weak, in both PCS and MCS domains, and total HRQOL can add one more feature to its ability to use. Current study was conducted to determine cut-off points for SF-36 using LPA aiming at screen subjects with poor HRQOL. To our knowledge, some other studies have used other methodologies to determine cut-off points, but all of them have identified only two classes [40-43] and no study has identified cutoff points of SF-36 in parents of children with cancer. LPA methodology is a suitable and powerful statistical technique that can search for the best number of classes of subjects and captures the heterogeneity between individuals to allocate them to the classes [32]. In the present study, the results of LPA suggested that the SF-36 can be used to screen parents of children with cancer with low HRQOL. The optimal cut-off points (thresholds) were ≤ 43 to ≥ 60 on the PCS domain, ≤ 44 to ≥ 64 on the MCS domain and ≤ 47 to ≥ 62 on the total scale and had fair to good correct classification proportions (88, 65 and 53% for the three classes respectively). The determined cut-points were especially successful in identifying parents of children with cancer with low HRQOL (over 80% correct classification) indicating the usefulness of SF-36 in screening for subjects with poor HRQOL (those who may need urgent appropriate interventions). We also determined a two-class cutoff point (threshold) to compare our used method with similar studies which determined a two-class threshold for the SF-36 [40-42]. With a threshold of 47, the sensitivity, specificity and the



area under the ROC curve were obtained 87, 90, and 91 % respectively in parents of children with cancer which achieved greater or comparable performance compared with similar studies with different methodologies. This research improved the utility of SF-36 as a widely used

questionnaire and provided remarkable scope for further validation and secondary analyses of existing datasets. Our findings related to association between demographic characteristics and HRQOL did not indicate any significant relationship between the three



identified classes of HRQOL of parents of a child with cancer and their demographic characteristics, such as gender, age and education level, as well as the number of children, gender and age of child and time since diagnosis of cancer in children. Our findings were in line with previous studies [13, 14, 44, 45], but contradicted with some other studies. In a study conducted in Korea, the gender of child with cancer was shown to have a potential influence on maternal adjustment and mental health. The authors concluded that this finding might be related to Korean culture that the first son is expected to take care of his parents during their aging period [12]. In other studies, the higher education level was associated with low HRQOL in parents of children with cancer [13, 46]. The authors stated that these parents wanted to be involved in the medical decision-making [46], or might like to look for information about their child's cancer and be familiar with risks that their children face. This preference might increase stress and have negative impact on their HRQOL [13].

Strengths and Limitations. There were some limitations in the present study. One primary limitation was the lack of a "gold-standard" questionnaire in general to measure HRQOL to validate the SF-36 domains in studies trying to determine cut-off points for the SF-36 questionnaire. So, we were unable to validate our results. Second limitation was the lack of enough

Tab. II. The relative frequency of demographic characteristics of study units in the three identified HRQOL latent classes.

Variable	Weak (n = 24)	Moderate (n = 173)	Good (n = 19)
Parent			
Father	37.5	50.9	57.9
Mother	62.5	49.1	42.1
Age of parent			
< 35	20.8	31.2	31.6
35-45	50	56.1	31.6
45-50	29.2	12.7	36.8
Education of parents			
Undergraduate	100	86.7	78.9
Graduate	0	13.3	21.1
Number of child			
< 3	50	72.8	63.2
≥ 3	50	27.2	36.8
Gender of child			
Female	33.3	45.7	47.4
Male	66.7	54.3	52.6
Age of child			
8-11	41.7	61.3	57.9
11-14	41.7	27.7	15.8
14-18	17.6	11	26.3
Rank of child			
< 3	62.5	84.4	68.4
≥ 3	37.5	15.6	31.6

* Ref stands for the reference category

Variable	Odds Ratio	95% CI	P-value
Gender			
Male	1.85	(0.84, 4.09)	0.129
Female (Ref*)	1	-	-
Age			
< 35	1.31	(0.33, 5.24)	0.705
35-45	0.72	(0.23, 2.24)	0.579
45-50 (Ref)	1	-	-
Education			
Undergraduate	0.39	(0.14, 1.11)	0.078
Graduate (Ref)	1	-	-
Number of child			
<3	1.42	(0.51, 3.96)	0.504
≥ 3 (Ref)	1	-	-
Sex of child			
Female	1.37	(0.68, 2.75)	0.379
Male (Ref)	1	-	-
Age of child			
8-11	0.56	(0.18, 1.79)	0.331
11-14	0.34	(0.10, 1.13)	0.077
14-18 (Ref)	1	-	-
Rank of child			
< 3	0.99	(0.28, 3.42)	0.982
≥ 3 (Ref)	1	-	-
Time since diagnosis	1.01	(0.98,1.03)	0.527

Tab III Comparison of the three classes, testing equality for latent class predictors with multiple ordinal logistic regressions.

Ref stands for the reference category.

samples to show the heterogeneity of subjects in terms of HRQOL. It is suggested to conduct large scale studies to determine cut-off points in different diseases. Third limitation was the use of self-report to assess HRQOL, which increased susceptibility to recall as well as social desirability bias and may result in an underestimation of HRQOL. Consequently, the HRQOL levels should be interpreted with caution. Fourth, in the present study, no information was gathered about the relapse or treatment protocol in children with cancer, because the participants were parents. Despite these limitations, this analytic study may have a number of strength and implications for healthcare policy. First, here LPA was used to determine cut-off points which have several advantages over other techniques like hierarchical/kmeans clustering. This is due to the fact that LPA is a model-based method, so maximum likelihood estimates are used to classify cases based on their posterior probability of class membership [47]. Second cut-off points were provided for both components of the questionnaire and the whole questionnaire (total quality of life) which add another possibility to use the SF-36 questionnaire.

Conclusions

The current study determined cut-off points for SF-36 using LPA method to classify HRQOL of parents of

children with cancer in the good, moderate, and weak classes, on both PCS and MCS subscales, and total HRQOL. The optimal cut-off points (two and three classes) obtained by LPA can be used in clinical settings to screen parents of children with cancer with low HRQOL. Nevertheless, further validations using larger datasets and gold standard are recommended for future studies. We also investigated the association between demographic characteristics and the HRQOL. None of demographic variables was significantly associated with the ordinal outcome of HRQOL.

Acknowledgements

We would like to thank the vice-chancellor of education and the vice-chancellor of research and technology at Hamadan University of Medical Sciences. We would also like to thank the participated parents of children with cancer who generously shared their experiences and time with us, and all nurses and personnel of the pediatric ward and clinic of Besat educational hospital for collaborating with this study. We appreciate the Research Editor institute that helps native English editing of the manuscript. This study Compliance with ethical standards and was approved by the Institutional Review Board of the Hamadan University of Medical Sciences [approval NO. 950 221 669] and ethical committee [Ethical NO. was IR.UMSHA. REC.1395.52].

Ethics approval and consent to participate

This study Compliance with ethical standards and was approved by the Institutional Review Board of the Hamadan University of Medical Sciences [approval NO. 950 221 669]. This study was compliance with ethical standards [Ethical NO. was IR.UMSHA.REC.1395.52]. Written informed consent was obtained from all participants and the purpose of the study was explained. It is also important to note that the results of the study were anonymously reported to comply with the ethical criteria.

Consent for publication

The article presented has been confirmed by all authors for publication.

Availability of data and materials

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

Acknowledgements

None.

Conflict of interest statement

The authors declare that they have no competing interests

Funding sources

This project was supported by the Hamadan University of Medical Sciences (grant number: 950 221 669-P/16/35/816, 2017).

Authors' contributions

LT conceived the idea. LT and NS performed content analysis, interpreted the results and participated and revised the draft of manuscript. AF designed study, and abstracted the data. AS participated in design study and in whole project. FC supervised the whole project, participated in initial study design, participated in study implementation and drafted the manuscript.

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Received on August 1, 2021. Accepted on February 8, 2022.

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How to cite this article: Tapak L, Cheraghi F, Sadeghi A, Shirmohammadi N, Feizybarnaji A. Usefulness of the SF-36 Health Survey questionnaire in screening for health-related quality of life among parents of children with cancer: Latent profile analysis. J Prev Med Hyg 2022;63:E142-E151. https://doi.org/10.15167/2421-4248/jpmh2022.63.1.2279

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