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Research Article

Development of an Appropriate Quality of Life Instrument for Cancer Patients in South Africa

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Abstract

Objectives: Quality of life assessment is a valuable tool in cancer care as it allows us to understand how cancer and healthcare interventions influence the lives of the patients. An appropriate QoL assessment instrument would enable healthcare practitioners to identify and manage problems, which have a negative influence on QoL of cancer patients, timeously. The objective of the study was to develop and validate a patient informed QoL assessment instrument for our patient population.

Methods: A quantitative design was used. A Quality of Life questionnaire was developed by using the themes and categories identified during interviews with cancer patients and subjected to psychometric analysis using the Rasch Measurement Model.

Results: After validation of the questionnaire, by means of the Rasch model, it was found that the questionnaire conformed to Rasch model expectations. The developed instrument comprised relevant domains of QoL for South African cancer patients who access public healthcare for treatment, as identified during interviews with patients. It is proposed that the instrument be further validated for other populations in South Africa.

Significance of the Results: An appropriate QoL assessment instrument can be used for the assessment of QoL of cancer patients in order to identify and address problems timeously. The instrument needs to be culturally sensitive and include the domains of QoL which are relevant to the patient population. The QoL assessment instrument developed in this study is appropriate for cancer patients in South Africa who access public health service for treatment.

Keywords: *Quality of Life (QoL); Domains of QoL; QoL Assessment; Rasch Measurement Model (RMM)*

Introduction

The significance of the study relates to the absence of a culturally sensitive, patient-informed quality of life (QoL) instrument for cancer patients living in South Africa using the public health care system. Quality of life assessment has become a valuable tool in cancer care, as it allows cancer care professionals to understand how healthcare interventions influence the lives of patients [1]. Despite the availability of a variety of QoL instruments, most were developed in the first world and, similar to what was found in a study investigating the suitability of QoL instruments for palliative patients [2] might not be suitable for this patient population. Our paper presents the second phase of a

dual phase study attempting to develop a culturally sensitive, patient informed QoL assessment instrument for the cancer patient population using the public health care system. The first phase of the study [3] explored what QoL means to these patients, whilst phase two used the findings of the first phase to develop and validate the instrument.

As in the rest of the world, cancer is a public health problem in South Africa and more than 100,000 people are newly diagnosed each year, most commonly with cancer of the breast, prostate, cervix, colon and rectum and of an unknown primary [4]. South Africa faces various cancer control challenges such as a lack of knowledge and awareness of the disease, lack of prevention and screening opportunities and poverty, leading to most patients presenting with late stage cancer when cure is no longer possible [5,6]. South Africa hosts two health care systems, private and public. The public health care service provides treatment and care to approximately 80% of the population free of cost as they do not have health insurance [7].

The public health sector follows a hierarchical referral system with nurse led primary health clinics being the point of entry. Patients who cannot be managed at this level are referred to regional hospitals from where those needing specialized care are referred to tertiary hospitals [8].

Authors agree that QoL is a complex phenomenon, without universal definition or standard measurement [9]. Some describe QoL as a broad, complex and highly individual concept, which involves all aspects of daily life and others stress the importance of personal goals and expectations, in the context of a person's culture and value systems [10-12].

In addition, QoL is multi-dimensional and subjective [13] and comprises different domains or dimensions, but authors differ about the domains of QoL [14-16]. Ferrans [14] describes four domains, including health and physical functioning, psychological/spiritual, social and economic, and family. Ding, Hu and Hallberg [13] include physical, functional, emotional and social wellbeing. However, Jansen van Rensburg [17], when investigating what QoL means to South African cancer patients, found six domains were applicable: physical, emotional, spiritual, social, financial and existential. Mitchell [15] supports the additional two domains by stating spirituality and religion have a major influence on the experience of cancer and QoL in countries such as South Africa, which is regarded as a religious country, where the majority of the population participate in religious activities.

QoL instruments are divided into three groups: generic, disease-specific and domain-specific [18]. The generic instruments are not population- or disease-specific and are suitable for people suffering from more than one condition. Disease-specific instruments apply to specific groups of patients, such as those with breast cancer or palliative patients, while domain-specific instruments measure specific symptoms such as pain and fatigue. Mitchel [15] purports that whatever the instruments, patients should be allowed to define QoL, as sick people and healthy people could differ in their definition.

Oncology nurses and other health care practitioners are constantly challenged to identify ways to measure how patients respond to treatment and supportive care interventions, due to demands for greater accountability for quality service delivery [19]. Outcome measurement is essential as it allows the assessment of the quality of care and the effectiveness of interventions to improve symptoms and QoL and increases our knowledge of patient experiences. Measurement of QoL can guide planning of clinical care, improve palliative care programs and enhance research [1,20].

The research problem for the study related to the absence of a culturally sensitive, patient-informed QoL assessment instrument suitable for cancer patients treated in the public healthcare sector in South Africa. Most patients using this healthcare sector live under the breadline [21] and are faced with health system challenges relating to the public sector. In addition, studies conducted in South Africa [2,17] found the domains of QoL of palliative patients are not necessarily included in the existing QoL instruments.

This article reports on the development and validation of a newly developed QoL assessment instrument for cancer patients in South Africa who access public health care.

Methods

The development of the QoL instrument formed part of a mixed method study [17]. We operationalised the themes and categories of the interviews [3] conducted in Phase 1 of the study to draft a developing instrument QoL A quantitative analytical study was done to test the internal construct validity of the instrument by means of the Rasch Measurement Model (RMM), which examines several properties of an assessment instrument [22]. By subjecting data of a developing instrument to the RMM, the researcher tests how well the responses from respondents conform to a set of Rasch model expectations.

When testing new instruments, the data should fit the item-trait interaction requirements of RMM. A Chi-square value greater than 0.05 indicates no statistically significant difference between observed (responses from the participants) and expected values (requirements of RMM), thus indicating that the data fit. For this reason, a Chi-square value > 0.05 is required. An item-trait interaction statistic is obtained by adding the total Chi-square values of all the items, which indicates the level of invariance of the items. A mean location score of ± zero with a standard deviation of 1 indicates that items and persons fit the model. Individual person fit residuals of between ± 2.5 are regarded as an adequate fit to the model. Item fit deviations are displayed by means of the item characteristic curve (ICC) function [22].

Inconsistent response patterns of individuals influence the item-fit and are indicated by person-fit statistics. The RMM shows misfit of a person as an extreme person, which implies the person's response can be removed to improve construct validity. An example of an extreme person is when the responses for an entire questionnaire are the same. Individual item and person fit residual values are computed in order to identify items and persons who cause misfit: values > 2.5 indicate misfit and < -2.5 indicate item redundancy [22].

The rating scale of the QoL instrument was tested by determining if thresholds (also called response categories) were ordered. Thresholds should be ordered and categories should be even, not too close to each other, or overlapping, or be too far apart. A large range of response categories indicates greater measurement coverage of the latent trait, which is displayed by the category probability curves and the threshold map [23]. However, a larger range often shows disordered thresholds and maybe an indication that there are too many response categories.

Inconsistent use of response options by respondents can lead to item misfit, which may influence threshold ordering. Rescoring may be necessary if the response categories are not used according to the level of the trait being measured. Disordered thresholds could also be the result of too many response options or incorrect labelling of the response options, which is confusing, for example: sometimes, often and frequently. If respondents cannot discriminate between categories, or do not use all the categories, the rating scale becomes dysfunctional. Item fit can be improved by collapsing categories, which display disordered thresholds [22].

Good targeting is essential for good measurement and implies the relative locations of persons and items. The number and difficulty levels of the items must be suitable for the ability levels of the respondents, as incorrect targeting will result in reversed thresholds and incorrect estimates of person and item parameters. During targeting, the mean location score of persons should be zero; the closer to zero, the better the targeting of person ability to item difficulty [24].

Differential item functioning (DIF), or item bias, occurs when one group of respondents, for example different genders, respond differently to an item. Invariance implies there is no item bias or DIF across the respondents, which favours validity of a measure [22].

During the validation process, construct validity is determined by testing response dependency. If the response to one item determines or cues the response to another item, there is a link between the two items, described as breach of local independence [24]. Local depen-

dency is tested by determining the residual correlation of items and a correlation > 0.3 between two items indicates possible dependency [25].

Testing for uni-dimensionality is important to ensure the instrument measures one underlying construct. When subjecting an instrument to the Rasch model, uni-dimensionality can be demonstrated when there are no meaningful patterns of subsets in the residuals, which indicate independency of the items, thus each item contributes towards the latent trait or construct [24].

When an instrument is sensitive enough to differentiate between high and low levels in persons, the person separation index (PSI) should be > 2 and the Cronbach's alpha should be > 0.8. The minimum Cronbach's alpha should be 0.7 for an instrument to be reliable [26,27].

When subjecting an instrument to the RMM for validation, weaknesses discovered can be resolved; for instance, if thresholds are disordered, categories can be collapsed on the response format. The scale can also be adjusted by adding or removing items, which do not fit one by one, until the problem is resolved. If possible, items should rather be resolved than removed, to maintain the reliability of the instrument. Local dependency can be resolved by means of creating subtests of items through clinical reasoning and theoretical support, where items with residual correlations above 0.3 are combined into subtests [28].

Procedure

Drafting the developing QoL questionnaires

During the first phase of the study [3] we asked two questions to the patients to explore what QoL means to them - what makes life hard for you? and what makes like good for you? We operationalized the themes and categories that emerged from the interviews into two questionnaires using the guidelines of Khadka., *et al* [23]. The questionnaires were as simple as possible due to the literacy level and the health status of the respondents and to prevent placing a high burden on the participants during completion. Questionnaire 1 focussed on what makes life hard and Questionnaire 2 on what makes life good. A section for demographic data was included to ensure that patients of different ages, genders, cultural groups, literacy levels and cancers were included. Questionnaire 1 consisted of 67 questions and Questionnaire 2 of 50 questions. The response options selected for the questionnaires were: yes = 1, no = 2, unsure = 3.

Two students studying in the field of oncology nursing were trained and enlisted to collect the data under the supervision of the first author. The study setting was the Department of Radiation Oncology at an academic hospital in Gauteng. Convenience sampling [29] was used to recruit the respondents during their scheduled appointments. The study was explained to those recruited, each respondent received an information sheet and informed consent was obtained in writing. Data were collected between February and March 2014. Ethical clearance (No M120919) and permission from the hospital was obtained for the greater study.

After administering the questionnaires, the raw data were captured onto Excel spreadsheets. Even though fifty respondents were approached for Questionnaire 1 and fifty for Questionnaire 2, nine of the questionnaires were not completed in full and thus discarded. The sample size for Questionnaires 1 and 2 was 47 (n = 47) and 44 (n = 44) respectively. The data were exported to the RUMM 2030 program for subjection to the RMM. When subjecting the questionnaires to the RMM, the researchers found the data did not fit the model (Chi-square was well below 0,05) and resolutions had to be made. It was decided to combine the two questionnaires (what makes life hard and what makes life good) into a third questionnaire. When drafting the third questionnaire, questions which proved confusing or duplication were removed, and others were rephrased. Questionnaire 3 contained 67 questions and a dichotomous scale was used to simplify the scale. We made this decision to fit the high acuity of cancer-related symptoms and low educational level of the patients. The response categories were a simple yes/no.

This article will focus on questionnaire 1, as questionnaire 2 and 3 did not conform to Rasch expectations. The whole process of validation of the three questionnaires can be read in the thesis [17].

Results

The majority of respondents who completed the first two questionnaires were Black African (57%; n = 27 and 55%; n = 24), between the ages 50 and 69 (51%; n = 24 and 55%; n = 24), with an educational level between Grade 8 and 12 (66%; n = 31 and 63%; n = 28). The highest percentage of respondents (28%; n = 13 and 27%; n = 12) suffered from haematological cancers, whilst 19% (n = 9) and 21% (n = 9) reported they suffered from breast cancer and 17% (n = 8) and 18% (n = 8) from gynaecological cancer. Table 1 summarizes demographic data of the respondents.

Variable	Questionnaire 1 (n = 47)	%
Age		
19 - 29	6	13
30 - 39	6	13
40 - 49	6	13
50 - 59	14	30
60 - 69	10	21
70 - 79	4	9
80 - 89	1	2
Gender		
Female	26	55
Male	21	45
Cultural group		
Black African	27	57
White	12	26
Coloured (mixed race)	5	11
Asian	3	6
Highest level of education		
No formal education	2	4
Grade 1 - 7	4	9
Grade 8 - 10	14	30
Grade 11 - 12	17	36
Tertiary education	10	21
Cancer group		
Haematological	13	28
Breast	9	19
Gynaecological	8	17
Head and neck	4	9
Lung	4	9
Colon	4	8
Oesophageal	2	4
Kidney	2	4
Prostate	1	2

Table 1: *Demographic data of respondents who completed questionnaire 1.*

Analysis of questionnaire 1: What makes life hard for you?

The fit statistics of the RMM for the first questionnaire are summarized in table 2, including the Chi-square statistic, mean location of items, standard deviation, item fit, person separation index (PSI) and the threshold ordering.

Run Number	Chi-square (> 0.05)	Person mean location (= 0)	Person standard deviation (= 1)	Item fit (± 2.5)	PSI (> 0.85)	Threshold ordering
1	0.098	-1.736	0.790	*Item 1 misfit (3.019)	0.907	*Item 24 disordered
2 Item 1 deleted	0.141	-1.741	0.814	Item 28 misfit (2.534)	0.911	Item 24 disordered
3 Clinical evaluation to reduce number of questions	0.502	-1.788	0.824	All items fit	0.886	Item 24 disordered
4 Item 24 deleted and Category 3 collapsed	0.021	-0.003	1.099	All items fit	0.891	Ordered
5 Six Subtests	0.156	-0.246	1.022	All subtests fit	0.85	N/a
6 Five Subtests	0.673	-0.226	0.947	All subtests fit	0.839	N/a

Table 2: *Fit statistics of questionnaire 1: What makes life hard for you?*

During the first round of analysis, Item 1 (Question 1; Q1) was highlighted as over-fitting (3.019). This indicated a possible redundancy of the item. Item 24 was disordered, but the other items were all ordered which showed the categories of Yes/No/Unsure were confusing to the participants. In round 2, item 1 was deleted, but item 24 was still disordered and item 28 was slightly over-fitting at 2.534.

The researchers wished to limit the number of questions, not to overburden the patients who were treated for cancer. Questions were evaluated according to their clinical significance and during the third round of analysis, 17 questions which were unclear or duplicated were removed, such as Q11 "Having to travel far to the hospital" and Q20 "Experiencing difficulties with travelling to the hospital". It was clear that Q1 "Not being able to do what you did before the cancer" appeared to be confusing to the respondents. Item 24 remained disordered, but all remaining items fit the model (between ± 2.5).

When evaluating the completed questionnaire, during round four of the analysis, the researchers realized the format of the questions was not consequent, for example when determining what made life hard, one question asked: Not being able to work: yes/no/unsure, and another question: Being too tired to carry out normal activities: yes/no/unsure. The inconsequent use of the third category (unsure) indicated doubt and the category was collapsed to create a dichotomous format of yes/no for all questions. In the next round of analysis, the mean location improved from 1.736 to 0.003, and the standard deviation improved from 0.79 to 1.099, with all items ordered, but the Chi-square was not fitting at 0.021.

During the next round of analysis, subtests were created to improve the Chi-square statistics. The subtests corresponded with the domains of QoL, which were identified in the first phase of the study: physical, financial, emotional, existential, social and spiritual. After round five, the data fitted the model. Subtest "Existential" consisted of only two questions and Spiritual one question, and the two subtests were combined into one, due to the concepts being associated theoretically. This step improved the fit of the questionnaire to the Rasch model ($\chi^2 = 0.673$) and a mean location of -0.226 and standard deviation of 0.947 was achieved. The person mean location and the person standard deviation and PSI remained within normal limits.

Targeting difficulty of items to ability levels of persons

Figure 1 shows the person-item threshold distribution of questionnaire 1, which indicates the items are well targeted for the sample.

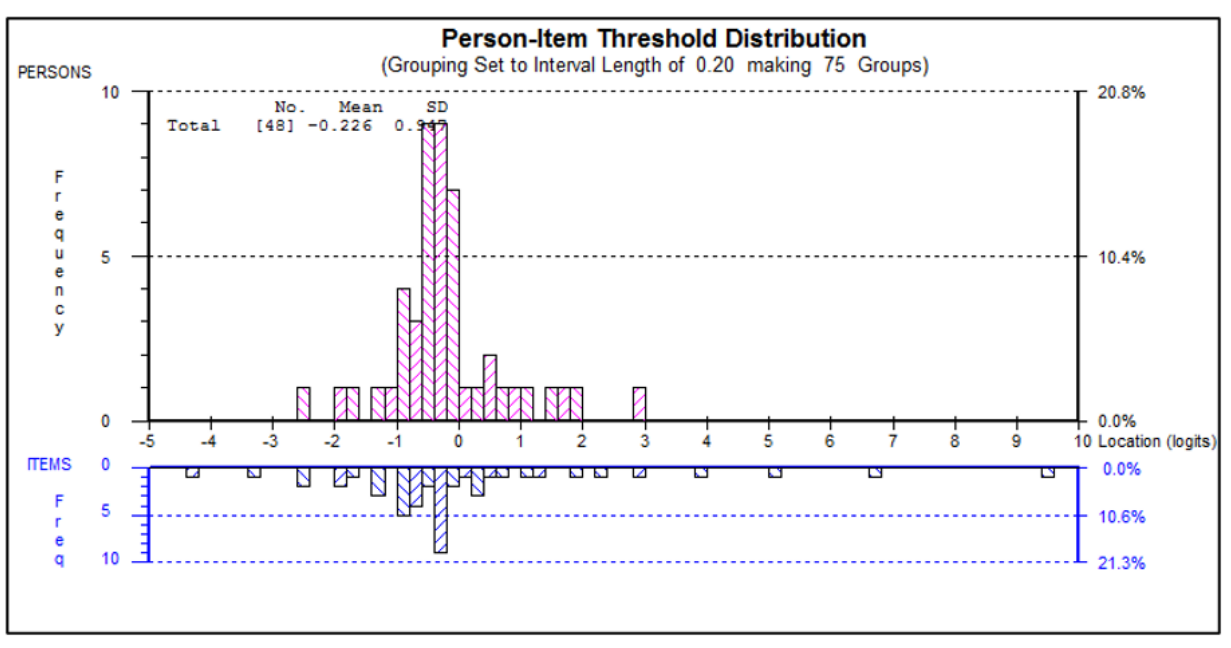

Figure 1: *Person-item threshold distribution of questionnaire 1.*

Differential item functioning

A summary of the differential item functioning of the five subtests is presented in table 3, which shows the results of the two-way analysis of variance (ANOVA). Due to an insufficient number of respondents in the categories educational level, age groups, culture and cancer groups, differential item functioning (DIF) was only done for gender.

	Class interval				Gender				Class interval by gender			
Subtest	**MS**	**F**	**DF**	**Prob**	**MS**	**F**	**DF**	**Prob**	**MS**	**F**	**DF**	**Prob**
Physical	0.096	0.12856	2	0.879	0.096	0.128	1	0.722	0.390	0.520	2	0.598
Financial	0.482	0.61067	2	0.548	0.390	0.494	1	0.486	1.122	1.421	2	0.253
Emotional	0.064	0.05948	2	0.942	1.052	0.967	1	0.331	0.558	0.512	2	0.602
Existential and Spiritual	1.476	2.24412	2	0.119	3.638	5.530	1	0.023	-0.056	-0.08	2	0.999
Social	1.290	1.67129	2	0.200	0.167	0.216	1	0.643	2.019	2.615	2	0.085

Table 3: *DIF summary for five subtests with criterion at P < 0.00333.*

According to the ANOVA results, there was no apparent DIF for gender, but the graphical presentations of the DIF for the subtests (Figure 2 to 6) displayed different curves for males and females. The discrepancy between the graphs and ANOVA can be explained by the small sample size for this questionnaire and the fact that the largest group of respondents had breast- and gynaecological cancers and constituted only females.

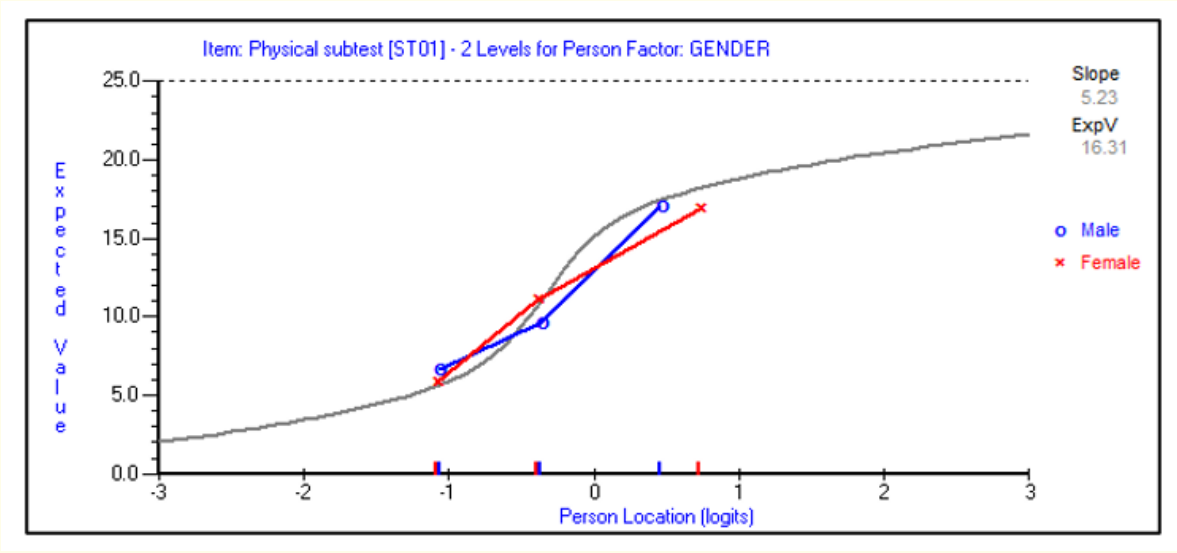

Figure 2: *Physical factors DIF for gender.*

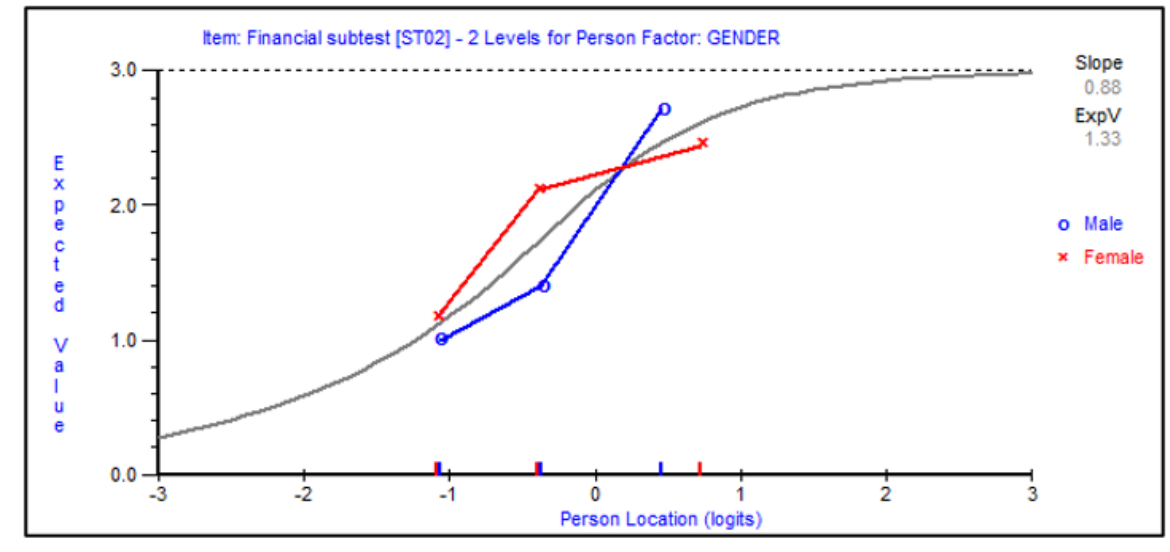

Figure 3: *Financial factors DIF for gender.*

Local dependency

Local independence was achieved between the five subtests, which implied the subtests did not overlap and the residual correlations

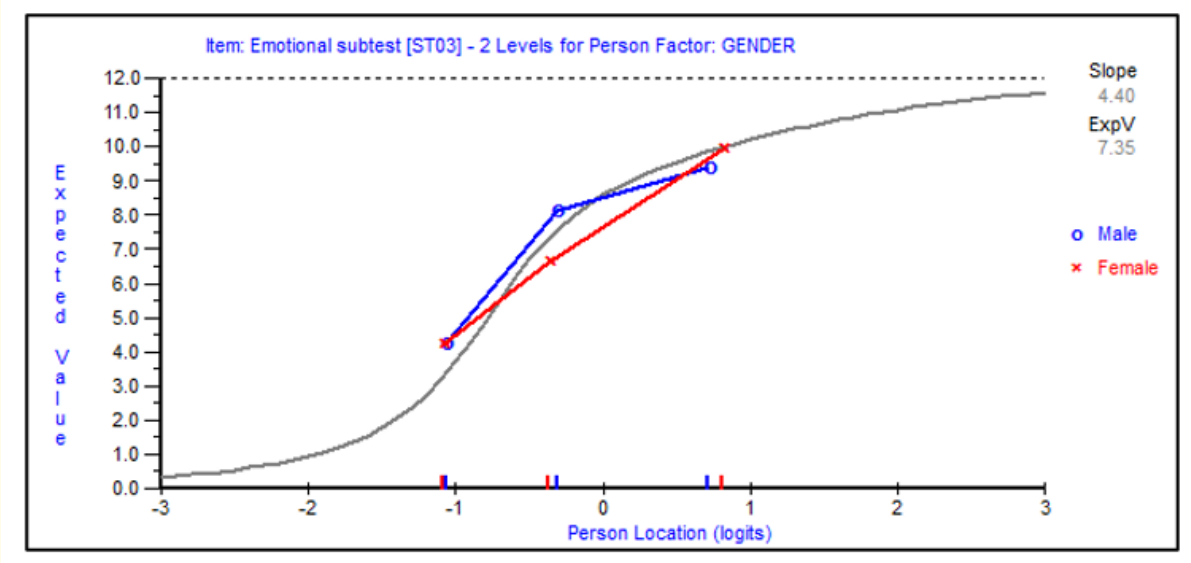

Figure 4: *Emotional factors DIF for gender.*

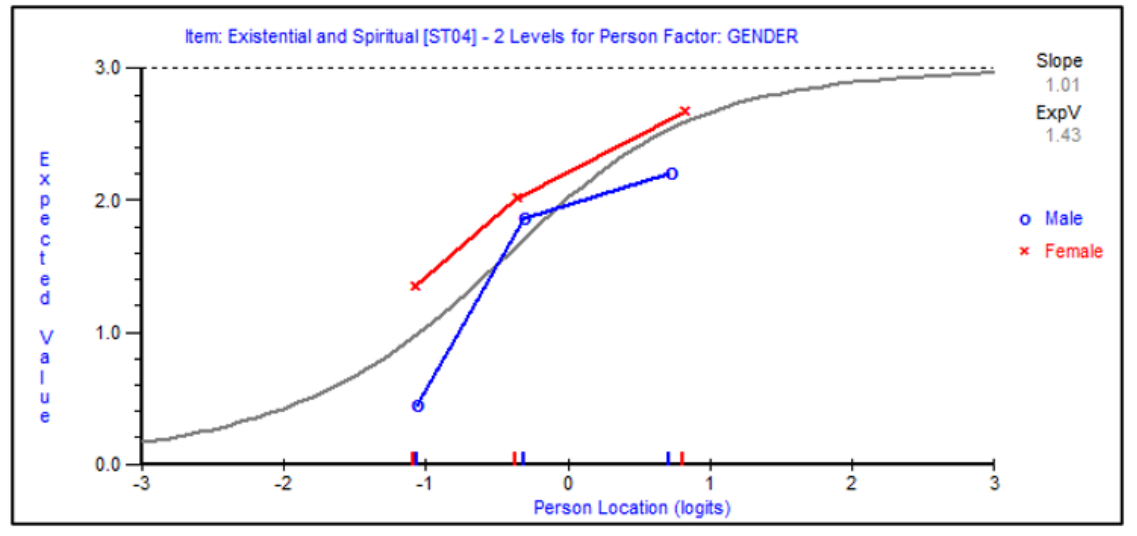

Figure 5: *Existential and spiritual factors DIF for gender.*

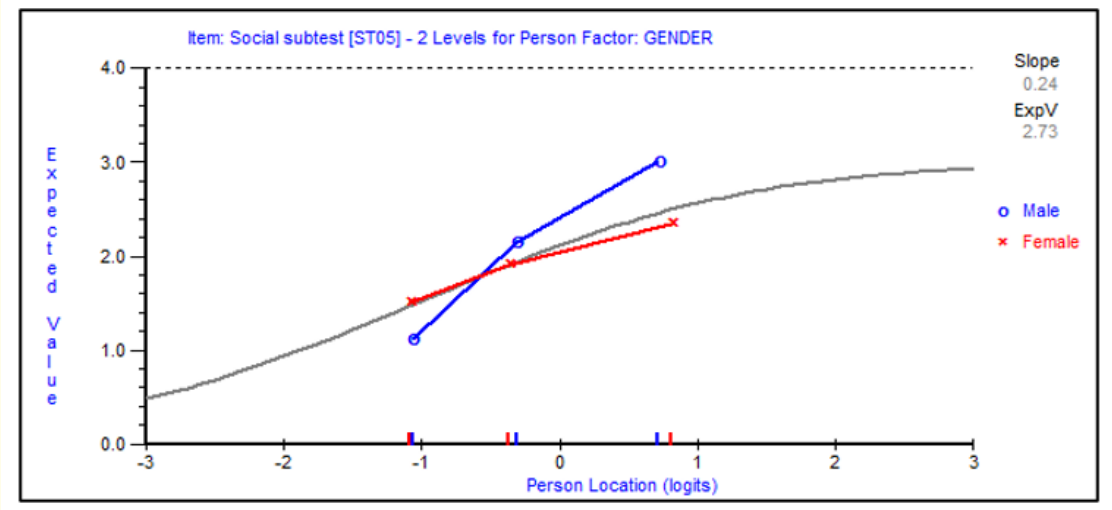

Figure 6: *Social factors DIF for gender.*

between subtests were all below the criteria of 0.3 correlation. The interpretation for this study was that each of the subtests contributed towards QoL of cancer patients.

Uni-dimensionality

Uni-dimensionality was illustrated by the t-test, indicating insignificant difference between groups and that only 4.65% fell outside the recommended criteria of 5%, which meant that the individual scores of the subtests contributed to one underlying construct and could be summed to get a total which would indicate the degree of QoL a cancer patient experienced.

Discussion

The article reports on a study which aimed to develop a culturally sensitive, patient informed QoL assessment instrument for the cancer patient population in South Africa using the public health care system.

The RMM was used for the validation of the questionnaire in order to detect measurement issues [25] and item fit statistics were examined to determine if the data fitted the model [22], which indicated some of the questions were problematic.

After validating the questionnaire by means of the RMM, it was found that it fitted the model. The researchers attempted to get a picture of which factors maintained QoL and which had a negative impact on QoL.

Although questionnaire 1 met the expectations of the Rasch model, the structure of some of the questions was problematic, especially for patients with low educational levels. The researchers realized that it is important to structure the questions the same way to avoid confusion, e.g. “Not being able to plan for the future” and “not being able to work” could be answered as “no” when it was true. The interpretation of the questions could have been incorrect, especially as 28% of respondents who completed Questionnaire 1 were functionally illiterate [30]. It is proposed that the questions all be asked the same way, for example: “Life is hard because I cannot sleep” yes/no and “Life is hard because I have severe pain” yes/no.

Creating subtests during the validation of the questionnaires improved the fit of the data to the RMM. The questions were grouped according to domains of QoL; physical, financial, psychosocial, spiritual and emotional, to create subtests.

During the validation it was clear that for this population with a low literacy level, it was better to use only two response categories such as yes/no, as the third category unsure was confusing to the respondents.

Recommendations

Implementing questionnaire 1 with larger samples is proposed for further validation and for other populations in South Africa. The instrument could also be tested in sub-Saharan Africa and for patients accessing private healthcare for cancer treatment.

Conclusion

The authors agree that QoL is a highly individual concept and that an assessment instrument developed in a first world country may not be appropriate for use in a developing country. This study aimed to develop a patient informed instrument for cancer patients in South Africa, which includes the relevant domains of QoL.

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Conflict of Interest

The authors hereby declare that there was no conflict of interest in the study and the preparation of this manuscript.

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