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Published on: 01 Feb 2020 - Psycho-oncology (Psychooncology)

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TITLE:

Development of the Melanoma Concerns Questionnaire© (MCQ-28©); refinement of the EORTC QLQ-MEL38 Module

RUNNING HEAD:

MCQ-28© development study

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This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the Version of Record. Please cite this article as doi: 10.1002/pon.5251

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ABSTRACT:

Objective: Few patient-reported outcome measures (PROMs) have been developed that adequately measure the patient-experience following diagnosis and treatment of melanoma. Building on previous research, which developed the European Organisation for Research and Treatment of Cancer [EORTC] Quality of Life Module [QLQ-MEL38], the aim of this study was to further test the hypothesised domain structure and psychometric properties of the Phase 3 module, in a new larger sample of melanoma patients.

Methods: Melanoma patients (n=270) were recruited from four countries [Australia, England, Serbia and Spain]. Patients completed the EORTC core questionnaire [QLQ-C30], the QLQ-MEL38 and a socio-demographic survey. Using this new larger dataset, comparisons were made with the hypothesized domain structure of the EORTC Phase 3 module using Principal Components Analysis. Items which formed subscales in a revised domain structure were then tested for goodness of fit (GoF) to the Rasch Model.

Results: The original hypothesised and final domain structures were similar, but not identical. Twenty-four items (83%) loaded onto the same distinct subscales previously generated by Phase 3 and item-by-item comparison of the two pattern matrices indicated an extremely close match. Ten items were removed from the QLQ-MEL38 Phase 3 module and re-scoring of some

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items was required. Four subscales, together with five individual items, comprised the final instrument.

Conclusion: The newly developed measure [named the *Melanoma Concerns Questionnaire*©; MCQ-28©] was found to tap into several important psycho-social domains of concern to melanoma patients, particularly those being managed in 'usual' clinic settings.

KEYWORDS: Melanoma, Quality of Life, Cancer, Surveys and Questionnaires, Psychometrics, Reproducibility of Results

BACKGROUND:

Melanoma is considered one of the most serious forms of skin cancer and the worldwide incidence has risen rapidly over the last 50 years [1]. Epidemiological differences are frequently reported [2] and incidence can vary 100-fold between countries. Previous publications in the present research series [3,4,5] have reflected how melanoma affects all age groups and skin types, and that treatment pathways vary considerably according to the stage of the disease. About 80% of patients survive melanoma, although all remain at risk of disease progression and/or recurrence for many years and carry a higher risk of second primary melanomas [6]. For such patients, melanoma can be considered a chronic, life-threatening disease.

Patient lifestyles may be affected accordingly [7], including their health-related quality of life (HRQoL), which the World Health Organization Quality of Life Group defined as '…a broad ranging concept affected in a complex way by the person's physical health, psychological state,

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level of independence, social relationships, personal beliefs and their relationship to salient features of their environment' [8].

Recently developed immunotherapies and targeted therapies have resulted in significantly longer overall survival in patients with advanced melanoma [9,10] and may be used in an adjuvant context after surgery and radiotherapy. These novel agents, however, are also associated with unique sets of adverse events. To date, the melanoma patient's experience of symptom management and subsequent impact on quality of life has not been well described [11,12,13].

The choice of the best patient reported outcomes measure (PROM) requires careful consideration of research goals, patient population and expected effects of the interventions (14). Until recently, only two HRQoL questionnaires had been specifically designed and validated for use with melanoma patients; the Malignant Melanoma Module [15] and the FACT-Melanoma (FACT-M) [16]. Improvements in the structure and response format of the FACT-M have been recommended, although they have yet to be adopted [3]. The EORTC Melanoma Module (QLQ-MEL38) completed Phase 3 development in 2016 and comprised 33 scoring items in 6 subscales, two single items and three items associated with clinical trials. The timeframe for responses related to patient experience were *'during the past 4 weeks'* and *'during the past week'*. The removal and/or re-phrasing of some items was recommended, together with an alteration of the patient's response timeframe.

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The aim of this study was to further test the hypothesised domain structure and psychometric properties of the Phase 3 module, in a new larger sample of melanoma patients, guided by combination of Classical Test Theory [CTT] and Item Response Theory methods; Principal Components Analysis and Rasch Analysis, respectively.

METHODS:

Participants

Patients (n=270) were recruited in four countries; Australia, England, Serbia and Spain. For Serbian and Spanish patients, the QLQ-MEL38 items were translated from English according to EORTC-QLG guidelines [17]. Recruitment included patients with local and metastatic disease in five different treatment strata, balanced for sex and age distribution.

Data collection and screening

This study largely followed the guidelines for module development recommended by the EORTC which have been previously reported [5]. In summary, following informed consent, patients completed the EORTC core questionnaire EORTC QLQ-C30 [18], the QLQ-MEL38, a socio-demographic survey and a debriefing questionnaire, to identify any confusing or irrelevant items. Stage of disease (local, or metastatic) was assessed at the time of interview and a summary of clinical data was recorded. Similar to the Phase 3 study, the range of responses to the 33 items from the QLQ-MEL38 were checked for floor or ceiling effects, using

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tabulation of means and standard deviations, and prevalence rates [5]. Additionally, a subset of patients was invited to complete a second questionnaire, to assess test-retest reliability. Reliability coefficients were calculated for scores two weeks apart, for patients whose disease and Eastern Cooperative Oncology Group (ECOG) performance status [19] were stable. Statistical analysis was conducted using IBM/SPSS-25 [20].

Principal Components Analysis

Principal Components Analysis (PCA), with Oblimin rotation [21], was conducted to examine how closely the hypothesized structure of the Phase 3 QLQ-MEL38 matched with the domain structure produced by the new patient sample. Items with loading coefficients above 0.4 were retained in the model. Pattern matrices were compared and differences in item loadings were noted. Subscale reliability, prior to Rasch Analysis, was assessed using Cronbach's alpha coefficients [22].

Rasch Analysis

Item Response Theory (IRT) methods were then utilized to test the goodness of fit (GoF) to the Rasch model [23] using RUMM 2030 software [24]. The default procedure for RUMM uses the Partial Credit model, which allows items to have varying numbers of response categories and does not assume the distance between response thresholds is uniform.

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The sample size recruited (n=270) was adequate to analyse (a) the GoF to the Rasch model of the subscales identified in the PCA, and (b) assess the validity of the 4-point response format for each item by inspection of the item threshold maps. Each successive solution was checked for convergence and model fit, assessed by a range of statistics according to published guidelines [25]. A well-fitting solution was indicated by a probability from the Item-Trait Interaction Chi-square greater than 0.05, after being divided by the number of items in the subscale (Bonferroni adjustment). Fit residual values, for both person and item, were inspected; a mean close to zero and a standard deviation (SD) less than 1.5 was considered desirable. Individual item fit residual values greater than +2.5 were taken to indicate misfit and less than -2.5 to indicate item redundancy. Internal consistency was assessed using the Person Separation Index (PSI) with values above 0.7 considered acceptable for group level analysis. Threshold maps were inspected for noteworthy disordering, which would indicate inconsistent use of the response options. Rescoring, by merging some categories on the 4-point response format, was considered if a significant improvement in model fit could be produced.

Residual correlations were examined to check for local dependence and dimensionality assessed using equating t-tests to compare person estimates derived from the two most disparate subsets of items [26]. A threshold level of less than 5% was considered acceptable. Differential Item Functioning (DIF) was checked for possible item bias, caused by the responses of different groups in the sample. DIF was assessed for the two major disease groups (local vs

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metastatic). Person item threshold maps were plotted to assess whether the new subscales appropriately targeted the respondent group.

Rephrasing and response time interval

Lastly, the final draft of the new questionnaire was critically reviewed by all members of the research team and, together with anecdotal feedback from some patients, was assessed for (1) any potential improvement in wording of items and (2) whether the response format of *'within a week'*, or *'within the last 4 weeks'*, remained appropriate for all items for this set of patients. Consensus was reached between research group members, via email.

A brief name was assigned to the subscales and scoring syntax developed to calculate raw scores and standardized scores from 0-100. Test re-test reliability was assessed using a Wilcoxon matched pairs signed ranks test and two-way mixed model intra-class correlation coefficient for absolute agreement [27]. Analysis of between group differences for the QLQ-C30 and the newly-formed subscales for disease group and strata group were conducted using Mann–Whitney *U* tests.

Ethics approval

In Australia, research ethics approval for the study was granted by the Sydney Local Health District Ethics Review Committee, Royal Prince Alfred Hospital (HREC/11/RPAH/37) and by

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Metro South Health District, Princess Alexandra Hospital, Queensland (HREC/11/QPAH/443). Ethical approval was also granted, as required, in all other participating countries.

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RESULTS:

Initial data screening of items and within patient missing values

From the initial sample of 270 patients [Australia, n= 84; England, n=34; Spain, n=103 and Serbia n=49], 20 patients had >4 responses missing on the QLQ-MEL38 (i.e. >10% of responses) and these patients' data were omitted from the PCAs. **Data from the remaining 250 patients (93% of the total sample) were included in the psychometric analysis (Table 1).** To replicate the results of the PCAs conducted in the EORTC Phase 3 study, the same set of 33 items were included in the PCA analyses using the new patient dataset. Item response frequencies and range of responses are shown in Appendix 1.

Demographic characteristics of the sample (n=250)

The final patient cohort (n=250) was 53% female, with an overall mean age of 60 years (SD=15.0) (Table 1); 60% (n=150) with local disease and 40% (n=100) metastatic disease. Data on ECOG status and employment were not recorded for the Spanish cohort (n=90). For the remaining 160 patients, almost half (47.5%) were still employed (working full, or part-time) and 72% were fully active, as defined by their ECOG status.

Table 1 – about here

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Principal Components Analysis (PCA)

Inspection of the scree plot, using the new patient dataset, indicated that 5 components provided the optimum solution. Two items (MEL41 '*How important is it for you to see the same members of your healthcare team at each clinic visit?*' and MEL54 *'Have you used spiritual or religious beliefs to help you cope?'*) did not load above 0.4. In the stepwise analysis, two further items (MEL63 *'Have you received realistic and reliable information about the extent (spread) of your disease*?' and MEL65 *'Have you had problems in understanding information given about your likely survival?'*), were also removed. The five components explained 53% of the variance.

Comparison with QLQ-MEL38 domain structure

Using the new data suggested a structure of 29 items across 5 subscales, rather than 33 scoring items across 6 subscales in the Phase 3 study [5]. Nevertheless, twenty-four items (83%) loaded onto the same distinct subscales previously generated by Phase 3 and item-by-item comparison of the two pattern matrices indicated an extremely close match (Appendix 2, page 1). Two items (50 and 51), which had previously comprised the 6th domain in Phase 3, moved into subscale 2, associated with disease risk. Item 35 also moved into this subscale, after the beginning of the item had been re-worded from '*Have you* worried about length of time needed for melanoma surgery to heal' to '*How much have you* worried….'. One further item (40), related to 'waiting for results of medical tests', also moved into this subscale. (Appendix 2, page 2).

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Rasch analysis

Overall fit, item and person fit statistics for successive solutions, are shown in Table 2.

Table 2 – about here

***Subscale 1 – Disease Prognosis/Acceptance*:**

Category probability curves for the newly-formed 8-item subscale showed slight disordering for 2 items, but not sufficient to require re-scoring (Appendix 3: Figures 1-2) and could be explained by small frequencies in the response category *'A little'*. Summary fit statistics for the subscale were within accepted limits, with a good PSI of 0.776 (Table 2). Equating t-tests indicated that scores for only 3.6% of patients would be significantly different, supporting uni-dimensionality. Differential Item Functioning (DIF) for item MEL52 *'Have you felt able to plan for the future?*' was found for patient group (local vs metastatic). The wording of this item was similar to MEL42 '*Have you felt hopeful for the future?*' and therefore, was removed from the subscale, without compromise to content validity. The next analysis showed that MEL45 *'Have you felt able to accept that melanoma is a serious condition'* showed slight DIF for patient group (local vs metastatic) (Appendix 3: Figure 3) and was removed. At the lower end of the subscale, metastatic patients were more likely to endorse this item. The final subscale was named 'Disease Prognosis/Acceptance', comprised of 6 items on a 4-point response format.

***Subscale 2 – Treatment concerns/Future Disease Risk*:**

The threshold map for the new 9-item subscale showed disordering for 2 items (Appendix 3: Figure 4). These were not sufficient to require re-scoring and explained by small frequencies in

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the response category 'Quite a bit'; for example, MEL40 *'Have you worried whilst waiting for results of medical tests'* (Appendix 3: Figure 5). Summary fit statistics were all within acceptable limits, with a good PSI of 0.746 (Table 2). Equating t-tests indicated that scores for only 2.8% of patients would be significantly different, supporting uni-dimensionality. DIF for item MEL36 *'Have you worried about side effects of your treatment'* was found between patient groups (local vs metastatic disease). When this item was removed, no further DIF was present and GoF to the Rasch model improved (χ^2=38.31, df=24, p=0.322), Table 2. This subscale was named 'Treatment concerns/Future disease risk' and comprised 8 items on a 4-point response format.

***Subscale 3 – Care delivery/Communication*:**

The threshold map showed disordering for all three items in this subscale with *'A little'* rarely used. Rescoring the three items to a 3-point subscale, merging 'Not at all' with 'A little', corrected the category probability curves (Appendix 3: Figures 6-11) and threshold map (Appendix 3: Figure 12). Goodness of fit to the Rasch model improved and no DIF was observed. Summary fit statistics for the re-scored subscale were all within accepted limits, with a good PSI of 0.773 (Table 2). Despite only three items in the subscale, the item map showed it was well targeted for this patient group (Appendix 3: Figure 13). This subscale was named 'Care delivery/Communication', comprising 3 items with a 3-point response format.

***Subscale 4 – Surgery site items*:**

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Three items associated with swelling, numbness or pain at the site of the melanoma, formed a subscale in the initial PCA. The category frequencies for all three items, MEL31 '*Have you had swelling near your melanoma site?*', MEL32 '*Have you had numbness at the site of your melanoma?*' and MEL33 '*Have you had problems with pain at or near your melanoma site*' showed a highly skewed distribution (with a low incidence of these issues in this patient group, see Appendix 1). Analysis could not proceed in RUMM, which reported extreme scores for 135 patients; more than half the dataset. Rescoring did not improve either the threshold map or the GoF to the Rasch model. In particular, the PSI could not be reliably calculated. This indicated that, for this group of patients, the responses to these items were not additive, but could be used as single-items only.

***Subscale 5 – Supportive Care*:**

The threshold map showed disordering for 5 of the six items in the initial subscale and inspection of the category probability curves showed that the responses 'Not at all' and 'A little bit' were consistently under-used. Rescoring the two responses corrected for any disordering (Appendix 3: Figures 14-25). Summary fit statistics for the re-scored subscale were all within accepted limits, with a borderline PSI value of 0.582. This corrected the threshold map (Appendix 3: Figure 26) and item map showed good targeting for this patient group (Appendix 3: Figure 27). Equating t-tests indicated that scores from only 1.64% of patients would be significant, supporting uni-dimensionality. This subscale was named 'Supportive Care' which comprised 6 items, with a 3-point response format.

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Test-retest reliability and sensitivity:

Test re-test reliability was examined for 23 patients whose disease status was classed as 'stable' and who completed a second questionnaire after two weeks. No significant differences were found for the four main subscales on the new questionnaire, between the two time points. Wilcoxon matched pairs signed ranks tests returned p values >0.345 and Intra Class Correlation Coefficients were moderate to good, except for one subscale (Table 2). For sensitivity analysis, between group differences in patients' scores for the four main subscales were conducted; two disease groups and five strata groups. Table 3 shows, lower scores for physical functioning, role functioning and social functioning, as measured by the EORTC QLQ-C30, were found for patients with metastatic disease, together with higher levels of fatigue and appetite loss, as would be expected. The new questionnaire showed that the same group of patients were less concerned about treatment/future disease risk and achieved higher QoL scores for both care delivery/communication and supportive care. One plausible explanation is that patients being treated for metastatic disease would likely experience a higher level of communication with the care team and increased supportive care. So, added benefit seemed to accrue, in terms of a wider measurement of QoL, when administering the new questionnaire in addition to the QLQ-C30.

Table 3 – about here

Across the strata groups, variations in subscale scores of the new questionnaire were evident. For example, patients recruited to this study, early after diagnosis, showed the highest scores

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for treatment concerns/future disease risk. Patients who were in 'follow-up only' (n=114) scored lowest for care delivery/communication and supportive care (Figure 1). These subscales show promise as proxy indicators for varying levels of concern experienced by this complex patient group.

Figure 1 – about here

DISCUSSION:

Historically, *quality of life* for cancer patients has been an ambiguous and elusive concept [28]. The promotion of psychosocial well-being is not yet a routine standard of care for all patients at most cancer centres in the world [29] and much work remains to be done [30]. In particular, melanoma patients still reportedly feel insufficiently informed about psychosocial support and desired more treatment information [31]. The field of psycho-oncology has seen the recent emergence of clinical practice guidelines [32,33]. These brought psychosocial issues to the attention of clinicians/researchers, by making *distress* the so-called 6th Vital Sign; viz, it should be measured in addition to temperature, blood pressure, pulse, respiratory rate and pain. Full recognition that the 'people part' of cancer care has been characterised as *vital* to a well-managed and compassionate cancer system makes ethical, emotional and economic sense [34]; a sentiment shared by other leading commentators [35]. Continuing high levels of anxiety associated with attendance at follow-up appointments have also been reported, commonly related to the ongoing fear of cancer recurrence and the associated need for emotional support and, increasingly, psychosocial intervention [36,37].

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Against this background, one of the contemporary research imperatives has become not only to continue the qualitative description of HRQoL issues [38], but also the development of clinically-relevant quantitative instruments. Accordingly, the new instrument identified a set of items which have the capacity to measure several key areas of concern for melanoma patients being managed in the 'usual' clinic setting. Guided by conventional CCT and IRT methods, and mindful of a rare critique [39], this study interrogated a new data set and compared findings with those found in the earlier QLQ-MEL38 study and its precursor. Three questions about clinical trial participation (MEL66, MEL67, MEL68) were not used for scoring purposes [but could be used separately as single items, by investigators, if relevant to local research circumstances]. Stepwise PCAs indicated also the removal of MEL41, MEL54, MEL63 and MEL65, based on loading coefficients lower than the expected threshold. Three further items were removed (MEL36, MEL45, MEL52) because of significant DIF between patient disease groups. Items in two of the 5 subscales required re-scoring. In all, therefore, ten items were removed from the QLQ-MEL38, based on a combination of PCA, Rasch, clinical judgement and face validity. The time frames for response to items were amended after consultation [with contributing authors] (Figure 2). The final version comprises a total of 28 items; four subscales (comprising 23 items), plus 5 individual items (MEL55, MEL56, MEL31, MEL32, MEL33). It has been named the Melanoma Concerns Questionnaire©; MCQ-28©.

Study limitations:

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Test re-test validity was found to be adequate; however, this was assessed in a very small sample of patients (n=23). From anecdotal patient feedback, respondents found it difficult to score some items according to the presented timeframe ('within 1 week' or 'past 4 weeks'), particularly for patients in long term follow up. To make timeframes more acceptable, the new instrument has adopted 'since the diagnosis and treatment of your melanoma' for some items as the time window for patients' response. The findings from the present study have indicated that further field testing should be conducted, in relation to the response timelines.

Clinical implications:

The subscales measured by this PROM span several psycho-oncological domains, deemed important to melanoma patients. They provide a fresh opportunity for patients to record the psychosocial impact of living with melanoma; for example, via routine real-time evaluation of their experience during regular attendance at a medical oncology clinic. The EORTC QLG has recently commenced the development of an Advanced Melanoma Module, for use in clinical trials of targeted therapies, which will specifically focus on the measurement of side effects of these new treatments. For some patients, therefore, clinicians may consider the administration of both the MCQ-28 and any future EORTC advanced melanoma module, for those with recent experience of treatment for advanced disease.

The subscale scores have the potential to inform future decision-making by treating care teams and to serve as an early warning of patients' unmet information and support needs. New

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clinical interventions may then need to be developed to address these issues and the questionnaire would serve as a measurement tool to reveal the efficacy of these, following their implementation.

CONCLUSIONS:

Using CTT and IRT methods [PCA and Rasch], a new instrument with demonstrably robust psychometric properties [now named the *Melanoma Concerns Questionnaire*©; MCQ-28©] has been developed. Findings, thus far, have confirmed the reliability and suitability of the MCQ-28© to measure important aspects of their QoL and areas of concern for melanoma patients, at all stages of disease.

ACKNOWLEDGMENTS:

Grateful thanks are due to patients who participated in the development of the new questionnaire and to collaborating healthcare professionals, at all four centres. The support provided by clinical and research staff at the two coordinating centres, the Patricia Ritchie Centre for Cancer Care and the Melanoma Institute Australia, is readily acknowledged. Thanks are also due to the Friends of the Mater Foundation, Sydney, for funding the University of Sydney to conduct this study under its auspices.

CONFLICT OF INTEREST:

There are no conflicts of interest

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DATA AVAILABILITY STATEMENT:

The data that support the findings of this study, together with copies of the MCQ-28 questionnaire and scoring instructions, are available from the corresponding author upon reasonable request.

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Table 1 Socio-demographic and clinical characteristics of patient sample (n=250)

		Patient sample	
		Frequency	**% valid**
Participating Country	Australia	82	32.8
	England	33	12.8
	Spain	87	34.8
	Serbia	48	19.2
Sex	Female	133	53.2
	Male	117	46.8
Age	<50	64	25.6
	51-65	87	34.8
	66 +	99	39.6
Education	Some high school	53	21.8
	Completed high school	63	25.9
	Further vocational training	30	12.4
7 missing	Academic degree or higher degree	97	39.9
Employment Missing=90	Full time	59	36.9
	Part time	17	10.6
	Retired (Age)	59	36.9
	Other (Disabled, Carer, Unemployed/at Home)	25	15.6
Disease status*	Local disease	150	60.0
	Metastatic disease	100	40.0
Performance Status (ECOG) Missing=90	Fully active (0)	115	71.9
	Partially active, reduced light duties (1)	38	23.8
	In bed < 50% of the day (2)	7	4.4
	In bed > 50% of the day (3,4)	0	0
Strata group	Early after diagnosis	17	6.8
	Surgery +- adj RT/Rx	60	24.0
	Systemic Treatment	24	9.6
	Routine follow up	114	45.6
	Immunotherapy/Pall Immunotherapy	35	14.0
Primary Site 14 Missing	Back	54	22.9
	Leg	46	19.5
	Arm	20	8.5
	Chest	20	8.5
	Head and Neck	15	6.4
	Foot	16	6.8
	Abdomen	12	5.1
	Scalp	10	4.2
	Occult	11	4.7
	Other	32	13.6

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** Note: For some patients, although accurate pathological staging was not available, the clinicians were able to allocate to local or metastatic disease based on their clinical condition at interview*

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Table 2: Overall Fit, Item and Person fit statistics [rounded to 3 decimal points]

		Overall fit			Item Fit		Person Fit						DIF analysis by disease group	
Factors/subscales	**Analysis [No. of items]**	**X^2**	**df**	**p**	**Mean**	**SD**	**Mean**	**SD**	**PSI***	**Cronbach α**	**ICC on test-retest data only**	**% sig. t-tests <5%**	Threshold p value	*Lowest p value
Factor 1 Disease prognosis and acceptance	Original Scale [8]	42.5	24	0.011	1.668	1.67	-0.563	1.775	0.776					
	Item 52 removed DIF [7]	42.9	21	0.003	0.236	1.65	-0.563	1.677	0.751					
	Item 45 removed DIF [6]	**29.3**	**18**	**0.045**	**0.059**	**1.60**	**-0.650**	**1.79**	**0.734**	**0.863**	**0.742**	**3.6%**	**0.002**	**0.004**
Factor 2 Treatment concerns and future risk	Original Scale [9]	47.45	27	0.009	0.074	1.241	-0.227	0.978	0.746					
	Item 36 removed DIF [8]	**38.31**	**24**	**0.322**	**0.089**	**1.047**	**-0.232**	**0.978**	**0.737**	**0.781**	**0. 539**	**2.8%**	**0.002**	**0.005**
Factor 3 Treatment options/ Communication	Original Scale [3]	*57.39*	18	<0.0001	0.044	1.212	-0.301	0.979	0.565					
	Rescored to 3 point scale [3]	**44.52**	**12**	**<0.001**	**0.073**	**1.251**	**-0.247**	**1.046**	**0.583**	**0.693**	**0.698**	**N/A**	**0.006**	**0.005**
Factor 4 Surgery items	Original Scale [3]	Restriction in range for all three items – not suitable for Rasch analysis												
Factor 5 Supportive Care	Original Scale [6]	57.39	18	<0.0001	0.044	1.212	-0.301	0.979	0.565					
	Rescored to 3 point scale	**56.30**	**18**	**<0.0001**	**0.073**	**1.251**	**-0.247**	**1.046**	**0.582**	**0.620**	**0.457**	**1.64%**	**0.003**	**0.001**

**Lowest probability value for Uniform or Non Uniform DIF found in each analysis in shown*
(Threshold value calculated using Bonferroni (BF) correction (0.05 divided by (number of items x number of test groups)
Bolded data indicates best fitting scale; adopted

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Table 3 QLQ-C30 and MCQ data for sample, split by disease status

	Patient Group						
	Local disease only			Metastatic disease			
	Mean	Standard Deviation	Valid N	Mean	Standard Deviation	Valid N	**Z M-W U test**
Physical	90.19	15.77	149	81.76	20.07	100	**-3.77**
Role	89.19	20.28	148	75.50	30.29	100	**-4.05**
Emotional	81.04	22.43	150	80.22	20.36	99	-.73
Cognitive	87.25	20.45	149	84.83	19.83	100	-1.63
Social	87.58	19.96	149	75.83	28.27	100	**-3.49**
Fatigue	18.15	20.04	150	28.72	23.93	100	**-3.76**
Nausea Vomiting	3.02	11.79	149	6.67	18.80	100	-2.34
Pain	14.67	21.15	150	19.17	27.26	100	-1.00
Dyspnoea	10.44	21.89	150	12.79	21.67	99	-1.25
Insomnia	19.59	25.77	148	26.26	31.68	99	-1.40
Appetite loss	6.44	20.69	150	14.00	24.70	100	**-3.57**
Diarrhoea	8.50	19.82	149	11.00	24.18	100	-.46
Financial	4.22	15.10	150	8.33	19.75	100	-2.20
Global Health Status	8.05	19.24	149	16.84	27.09	99	-3.09
Melanoma Concerns Questionnaire							
Disease prognosis and acceptance	73.20	22.31	150	79.30	19.04	100	-2.08
Treatment concerns / Future disease risk	**42.70**	22.62	150	33.36	18.13	100	**-3.31**
Care delivery /Communication	46.31	29.56	149	**78.74**	25.53	98	**-7.99**
Supportive Care	59.79	26.80	150	**76.62**	23.83	100	**-4.93**

Legend: **Red Bold font** denotes a statistically significant difference between groups (p=<0.001)

FAC1 Disease prognosis and acceptance – high score = high acceptance
FAC2 Treatment concerns / Future disease risk high score = high concerns
FAC3 Care delivery /Communication high score = good communication
FAC5 Supportive Care high score = high level of supportive care

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Figure Legends

Figure 1: Median scores for the subscales of the MCQ-28©, split by strata group

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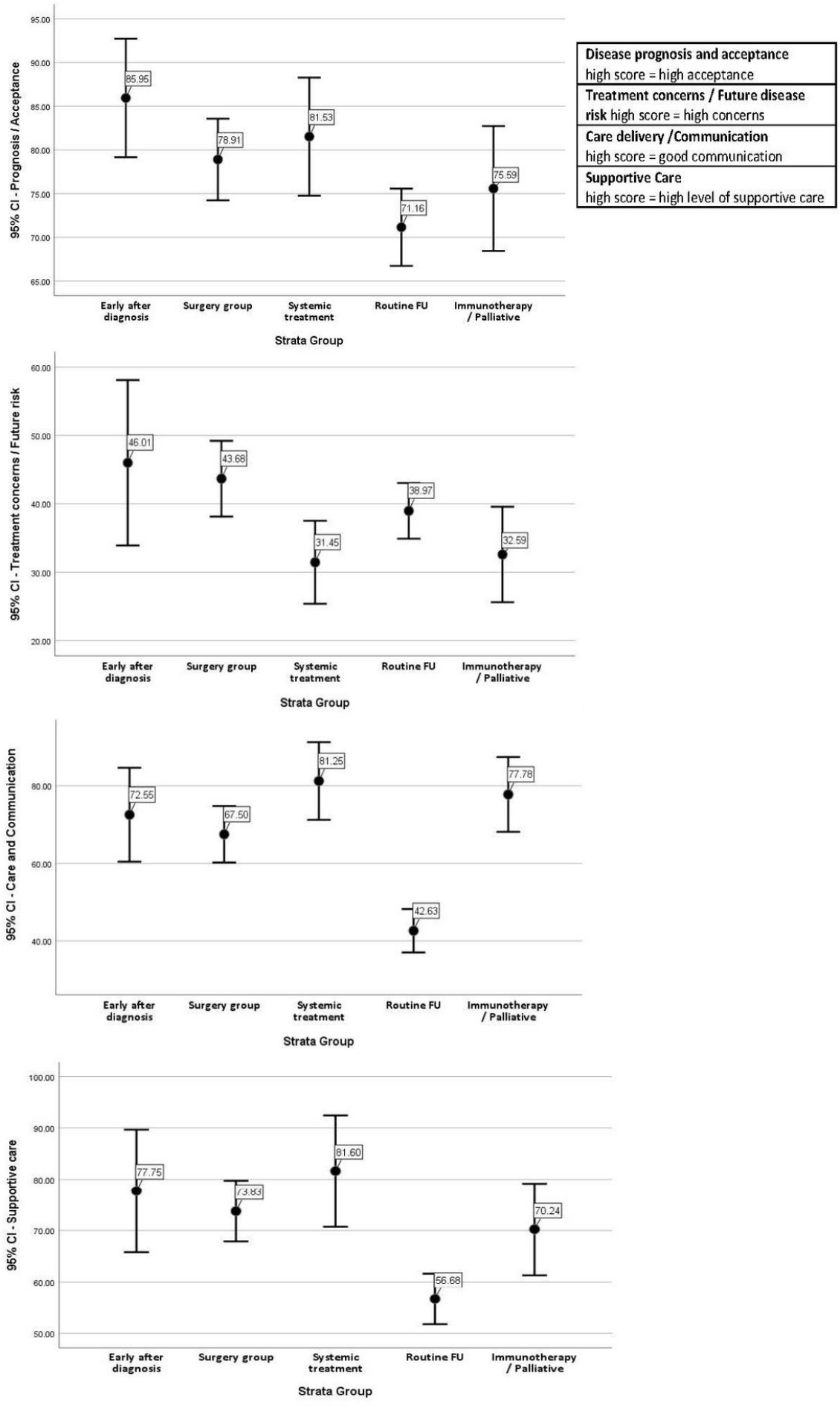
Figure 1: Median standardized scores for the subscales of the MCQ-28©, split by strata group



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