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Quality of life in multiple sclerosis: development and validation of the 'RAYS' Scale and comparison with the SF-36

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Abstract

Objective. To develop a self-administered rating scale for quantifying quality of life (QoL) in multiple sclerosis (MS) patients.

Methods. The RAYS scale items were derived from a source of 600 questions composed by our Centre's experts from commonly used instruments that assess physical, psychological, and social–familial dimensions. Prior to finalization of the RAYS QoL, candidate items were administered to 15 health rehabilitation professionals. Clarity, importance, relevance and specificity were graded for each item by every professional independently. Items chosen for the final version were graded as good or excellent on all these aspects. The Medical Outcome Study Short Form-36 (SF-36) was used to compare health appraisal with the RAYS scale.

Results. Each of the three subscales of the RAYS covers a different dimension (physical, psychological, and social–familial) and each includes 15 self-report items scored from 1 (best) to 4 (worse), focusing on the preceding week. Validation was achieved through administration of the scale to 50 randomly selected MS patients and to 50 age-, sex-, education- and family status-matched healthy controls. All RAYS dimensions among MS patients reached a Cronbach's coefficient $\alpha > 0.8$. Mean values for all dimensions were greater in patients than in controls ($P < 0.002$). Patients scored below norms for the general population in the majority of the SF-36 subscales (on average 32% lower). Significant correlation was found between the two scales especially in the physical and social functioning subscales.

Conclusion. The RAYS scale demonstrated high internal consistency and significant discriminative value, and is thus a suitable disease-specific tool for measuring QoL in MS.

Keywords: multiple sclerosis, quality of life, rating scale

Disability, handicap and mortality are traditional measures of medical outcome. These measures are not sufficient to capture the full impact of chronic diseases for which a cure is not yet available and death is only a distant eventuality. The limitations of traditional measures of outcome led to a search for new measures so that not only disabilities and handicaps, but also the subjective satisfaction with life, as judged by the patient, should be used to reflect the impact of morbidity on the life of patients.

The WHO definition of quality of life (QoL) is 'the individual's perceptions of their position in life in the context of the culture and value system in which they live and in relationship to their goals, expectations, standards, and concerns' [1]. There are two approaches to its assessment: the objective and the subjective. The objective refers to dimensions of life that all people value or require such as food, shelter, mobility, and good health. More important is the subjective evaluation of inner experiences, which have both positive and negative dimensions. An important concept is that of health-related quality of life (HRQoL), which is defined as 'the value assigned to the duration of life as modified by the social opportunities, perceptions, functional states and impairments that are influenced by disease, injuries, treatments or policy' [2].

In the management of multiple sclerosis (MS), a chronic progressive disease affecting young adults and often resulting in severe neurological disability over the course of years, one of the main goals of medical care is to optimize the patient's QoL. Moreover, health care costs and quality of care are at the forefront of the current debates concerning attitudes towards the rapidly expanding novel therapeutic drugs in MS. These issues relate to process and outcome of care, motivating an interest in QoL as an outcome measure of treatment. It is necessary to demonstrate conclusively that a treatment

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delivers quality at a justifiable cost with respect to alternative treatments and resource utilization.

Despite its overall personal and social importance, assessment of QoL in MS has only recently become a prominent area of study [3–5]. The Medical Outcome Study Short Form-36 (SF-36), a generic questionnaire regarding HRQoL, is frequently used to assess patients with MS [6,7]. However, the SF-36 instrument was reported to be insensitive to some of the QoL changes in MS [8] and a disease-specific instrument may provide additional information regarding QoL that will aid physicians and caregivers to gain better insight into the lives of their patients and can thereby lead to improved patient care and treatment. The aim of the present study was to construct and validate a disease-specific tool to assess QoL in MS patients.

Methods and subjects

The study project was divided into three stages: (i) question generation; (ii) RAYS QoL scale construction and (iii) instrument validation.

Stage 1: question-generation

The goal of the question generation stage was to produce a 'bank' of questions that would cover all aspects of QoL related to MS. The questionnaire was designed to be a self-reporting scale covering the period of the preceding week. This was achieved by collecting questions generated by physicians and allied health professionals working with MS patients (neurologist, neuro-urologist, neuro-ophthalmologist, psychiatrist, rehabilitation, physiotherapist, occupational therapist, social worker, psychologist, speech therapist), literature review [9–19], and interviews with experts in QoL. A total of 600 questions were identified, and these were then subgrouped into three QoL domains as follows:

Physical functioning: related to impairment or dysfunction in motor disability, sphincteric problems, somatic pain, sensory disturbances, co-ordination, and visual difficulties.

Psychological functioning: related to cognition, anxiety, depression, sleep disturbances, fatigue, sexuality, self-esteem, perceived lack of incentive to live.

Social functioning: related to social and family support, contacts with other people, interpersonal deprivations, communication, role fulfillment, leisure activities, employment, personal dignity, unmet needs.

Stage 2: RAYS QoL scale construction

Questions generated at stage 1 were rated by seven experts for clarity, importance, relevance, and specificity. Experts were all medical and para-medical personnel working closely with MS patients for a period of at least 5 years. Each question was scored for each of these four criteria in the following manner: 1, poor; 2, fair; 3, good; 4, excellent. Only items which were rated as a 3 or 4, were included in the final questionnaire. Ratings were performed according to a glossary of terms and defined anchors that are descriptive short statements that helped the rating process (i.e. question is well defined and not ambiguous versus question is clearly defined but open to interpretation).

The final version of the RAYs QoL (see Appendix) includes 50 self-rated questions, 15 questions in each domain and five 'additional concerns' questions. Each question was rated on a 5-point Likert scale [20]. Each item was structured with a response pattern indicating five different levels of impairment (0, none; 1, mild; 2, moderate; 3, severe; 4, extreme). Negatively worded items were distributed to balance all subscales and were turned to give all item scores the same direction. As a result, scores may range from 0 to 200, with higher scores reflecting more severe impairment in QoL. Most measures that assess chronic conditions use a 4-week time frame, while assessing acute conditions relies on shorter periods. As MS is a chronic condition characterized by acute exacerbations, the items in the RAYS scale encompass the last 7 days in order to be able to precisely capture the great symptom variability that is typical of MS.

Stage 3: instrument validation

Fifty patients with a definite diagnosis of MS according to Poser criteria [21], followed at our Center, were selected randomly from our computerized patients' registry to participate in the study. The majority of patients (40/50) had a relapsing–remitting disease course at the time of evaluation. Ten patients suffered from a progressive disease course. Fifty healthy subjects matched as a group for age, sex, education, and marital status were recruited through our hospital personnel department and completed the RAYS QoL scale as the comparison group. The study was approved by the Hospital Internal Review Board and the Israeli Ministry of Health Ethical Committee. All participants signed an informed consent agreement following extensive explanation of the study's aim.

Questionnaires were completed at the Neuroimmunology Unit during a scheduled follow-up visit. RAYS and SF-36 were endorsed by the patients. One of the researchers was on hand to answer or clarify patient queries. Each patient was examined neurologically and their disability was rated using the Expanded Disability Status Scale (EDSS), [22]. The EDSS is an eight-functional system scale that includes: motor, sensory, cerebellar, brainstem, visual, mental, sphincteric and others. Each is graded from 0, no disability, to 5 or 6, maximal disability. According to the score in each functional system, an integrated score between 0, normal examination to 10, death from MS, is derived. An EDSS score of 6.0 represents moderate disablity with need of assistance to walk a distance of 100 m.

Stage 4: comparison with a generic QoL scale (SF-36)

QoL scores for all eight scales of the SF-36 were calculated for all 50 MS patients that took part in Stage 3 of the study.

Statistical methods

The following statistical tests were used in analysis of data:

Construct validity

Construct validity was tested by measuring the difference in

the RAYS scale scores to distinguish between groups expected to be inherently different, i.e. MS patients versus healthy controls. Defining groups that are clinically distinct and then determining the degree by which the RAYS scores confirm the expected distinction demonstrates the instrument's validity. An unpaired *t*-test was used to compare the scores of patients and controls because matching was accomplished by group variables and not on a one-to-one basis.

Discriminatory power

The distribution of scores, i.e. the response variability as examined by assessing an item's cumulative endorsement, which refers to the percentage of patients that endorsed a certain item as relevant to them, regardless of the severity accorded to said item (any score other than zero) and dimension median.

Internal consistency

Internal consistency of subscales was examined by calculating Cronbach's alpha coefficient and by assessing item–total correlation to own subscale correlation as estimated by Spearman's correlation coefficient. Alpha values > 0.75 were considered significant.

The two-sample *t*-test and non-parametric test were applied for testing differences between patients and controls for quantitative parameters. Pearson correlation coefficients were used to compare the results of the RAYS and the SF-36 scales.

All tests were two-tailed and *P* values of 0.05 or less were considered statistically signifcant. The data were analysed using SAS software.

Table 1 Demographic characteristics of MS patients and controls

	MS Patients ($n=50$)	Controls ($n=50$)
Female:male	27 : 23	27 : 23
Mean age (years)	44.1 ± 8.3	45.2 ± 6.9
Range	17–65	23–65
Disease duration	8.2 ± 3.6	–
Range	2–16	
EDSS	3.2 ± 2.1	–
Range	0–8.5	
Education		
Elementary	5	6
High school	17	18
University	28	26
Marital status		
Single	11	12
Married	30	31
Other	9	7

Table 2 RAYS QoL scale construct validity analysis (mean ± SD)

Dimensions	MS patients ($n=50$)	Controls ($n=50$)	*P* (unpaired *t*-test)
Physical	15.1 ± 11.5	2.4 ± 3.1	0.0001
Psychological	12.1 ± 9.0	5.9 ± 5.9	0.0008
Social–familial	26.5 ± 10.7	20.1 ± 8.2	0.0012
Additional concerns	7.0 ± 3.2	2.8 ± 3.2	0.0000

Results

Characteristics of sample

The demographic variables used to match MS patients and controls are shown in Table 1. Both groups were similar in age, female:male ratio, education and marital status. The mean disease duration was 8.2 ± 3.6 years (range 2–16 years). Forty patients had a relapsing–remitting disease course and 10 patients had a primary progressive course. Disability ranged from mild (no significant neurological disability and freely ambulating, EDSS 0–3.0, 26 patients), moderate (EDSS 3.5–6.0, 14 patients) to severe (significant help needed in ambulation/wheel-chair bound with multiple neurological deficits, EDSS 6.5–8.5, 10 patients). The mean EDSS score was 3.2 ± 2.1, range 0–8.5.

Construct validity

The mean values for each domain of the RAYS are presented in Table 2. The results of the MS patients are significantly different from those of the healthy controls on all of the subscales, suggesting that the scale has a high construct validity. Further, as predicted, control subjects reported better QoL than MS patients on the RAYS. The fact that healthy controls had some dissatisfaction manifested by non-zero scores in the RAYS, implies that the RAYS does not suffer from a 'floor effect', i.e. the RAYS scale does not have a baseline threshold which has to be surmounted in order to achieve a score.

Discriminatory power

Items of the RAYS scale had a relatively homogenous distribution. The item cumulative endorsement differed significantly between patients and controls (Figure 1). Statistical significance for the difference between groups in each subscale was as follows: physical, $P=0.0001$; psychological, $P=0.0003$; social–familial, $P=0.0012$. The median scores of the subscales and quartiles range in MS patients and the control group are presented in Table 3. The results of the non-parametric analysis for comparing the median values showed statistically significant differences in all three dimensions with a *P* value < 0.01. This confirms an acceptable degree of variability in the response range reflecting discriminate validity of subscales.

Internal consistency

The internal consistency of the subscales of the RAYS is demonstrated in Table 4. Cronbach's alpha coefficients were

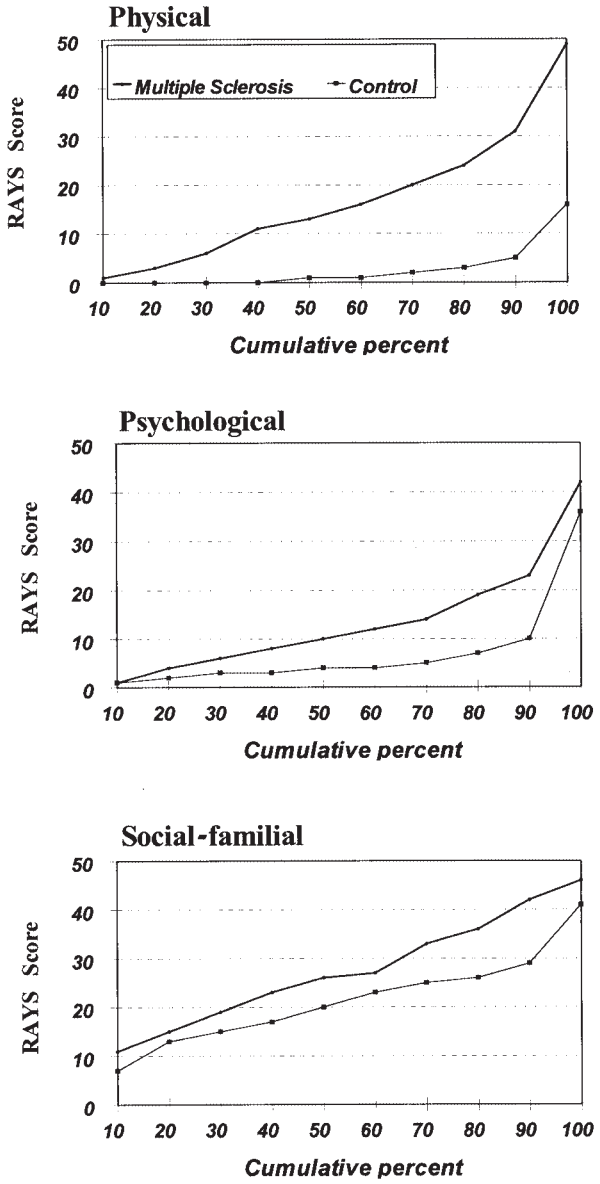

Figure 1 RAYS subscale scores presented as cumulative percentage of endorsement in MS patients and controls.

> 0.75 reflecting unidimensionality of the obtained subscales. Item total correlation exceeded 0.4 for all items.

Comparing the RAYS with the SF-36

Mean scores of MS patients on the SF-36 were on average 32% lower than norms reported for the general adult population [4], the only exception being the SF-36 bodily pain and vitality domains (Table 5). The most profound reductions among MS patients were found in the role of physical and social functioning domains of the SF-36.

As higher scores on the RAYS reflect lowered QoL, whereas higher scores on the SF-36 reflect better QoL, the relationships should be interpreted as follows: both lowered scores on the physical functioning and role-physical subscales of the SF-36 correlated with lowered physical subscale score on the RAYS. Both of these subscales of the SF-36 also correlated in the same direction with the psychological subscale of the RAYS, suggesting that impaired physical functioning and role adversely influence the psychological dimension of the RAYS. Increased score on the bodily pain subscale of the SF-36 correlated with lowered score on both the RAYS physical and psychological subscales, reflecting the adverse influence of pain on QoL perception. The social functioning subscale of the SF-36 correlated with both the physical and psychological subscales of the RAYS. However, it is interesting to note that MS patients do not attribute the decrease in social functioning to their physical and psychological limitations, and this is supported further by similar correlations between the physical functioning subscale of the SF-36 and the social–familial subscale of the RAYS, as well as the general health subscale of the SF-36 and the psychological subscale of the RAYS. The mental health subscale of the SF-36 correlated with the social–familial subscale of the RAYS, suggesting that better mood, less anxiety and increased levels of energy contribute to the patient's social–familial environment.

Neurological disability and QoL scales

EDSS score correlated with all the three RAYS subscales. physical: $r=0.47$, $P=0.0001$; psychological: $r=0.37$, $P=0.003$; social–familial: $r=0.32$, $P=0.002$. The relationship between the EDSS score and the SF-36 was statistically significant only for two of the SF-36 subscales. Physical functioning: $r=-0.74$, $P=0.0001$; role physical: $r=-0.35$, $P=0.006$.

Table 4 RAYS QoL Scale internal consistency

Dimension	Cronbach's α
Physical	0.89
Psychological	0.84
Social–familial	0.86

Table 3 RAYS QoL subscale median values, quartiles and inter-quartile range

	Median	25% Q1	Q3–Q1	75% Q3	*P*
Physical	13 (2)[1]	5 (0)	17 (3)	22 (3)	0.001
Psychological	11 (4)	6 (3)	10 (3)	16 (6)	0.003
Social–familial	27 (20)	18 (15)	16 (11)	34 (26)	0.02

[1] Values of control subjects are given in parentheses.

Table 5 RAYS and SF-36 scores and correlations

	SF-36		RAYS		
	Controls	MS patients	Physical	Psychological	Social–familial
Physical Functioning	84.1 ± 23.3	53.5 ± 26.7	−0.5**	−0.42**	0.36*
Role – Physical	81.0 ± 34.0	32.5 ± 21.9	−0.29*	−0.38**	0.07
Bodily Pain	75.1 ± 23.7	72.4 ± 26.6	0.46**	0.47**	−0.13
General Health	71.9 ± 20.3	51.6 ± 18.9	0.19	0.35*	−0.09
Vitality	60.8 ± 21.0	58.8 ± 21.5	−0.2	−0.05	−0.09
Social Functioning	83.3 ± 22.7	28.8 ± 12.2	0.38**	0.42**	−0.09
Role – Emotional	81.2 ± 33.0	46.6 ± 25.5	−0.2	−0.3	0.01
Mental Health	74.7 ± 18.0	62.4 ± 19.8	−0.2	−0.2	−0.27*

*$P < 0.01$; **$P < 0.001$.

Discussion

The measurement of QoL is an intermediate step between the impact of disease on the patient and the impact on the caregiver and society at large. In a public health perspective QoL data is useful and in fact becomes essential to demonstrate the broader impact of an intervention and to assess outcome comparatively. When it comes to the important step of determining effectiveness and establishing a social value for a newly approved intervention, QoL is one of the variables that has to be integrated into the decision algorithm [23].

The physical, psychological and social outcomes as a result of suffering from a chronic condition such as MS have recently become a focus of research. We have developed the RAYS scale as a specific tool to assess QoL in MS patients. Following identification of disease-specific items and evaluation of the tool according to identified criteria, a final version of the RAYS scale was established. The RAYS was compared with the SF-36 and the RAYS' three subscales were differentially correlated to various SF-36 subscales. The SF-36 is one of the most widely used generic QoL scales whereas the RAYS was designed as a disease-specific instrument, thus we did not expect many high correlations.

Physical aspects in the SF-36 clearly correlated with physical and psychological aspects measured by the RAYS. However, in two of the eight SF-36 subscales no significant correlations were found with the RAYS, probably because specific MS-related parameters, reflected mainly in the social–familial, and some of the physical items of the RAYS, were not expressed when endorsing the SF-36. Bodily pain and social functioning subscales of the SF-36 showed paradoxical correlation with QoL as reflected in the RAYS scale. This may suggest that MS patients do not perceive pain or social functioning as related to their physical or psychological limitations. This concept is supported further by similar paradoxical correlations between the physical functioning subscale of the SF-36 and the social–familial subscale of the RAYS, as well as the general health subscale of the SF-36 and the psychological subscale of the RAYS. In relation to bodily pain it should be noted that the mean score for MS patients did not differ significantly from that of normal controls, thus suggesting that this seemingly paradoxical correlation is irrelevant.

The RAYS scale proved to be a sensitive tool for assessing QoL in MS patients. Internal consistency was > 0.75 in all subscales indicating homogeneity of questions. In addition, the RAYS also proved valid as it significantly differentiated MS patients from healthy subjects. Moreover the significant correlations between the EDSS and all RAYS subscales further support the specificity of the RAYS for MS.

In contrast with the broad focus offered by generic QoL scales [24] the construction of the RAYS as a disease-specific instrument provides certain advantages. The RAYS provides precise and detailed information concerning the impact of MS on a variety of daily activities. Similar to the Canadian Burden of Illness Study Group, we found that physical function, role physical and the social function subscales were the best correlates with disease parameters. These results further support that a disease-specific tool is advantageous in providing further information on QoL, especially in light of the lack of correlation between several of the SF-36 subscales and disease parameters [8].

We suggest that adding the RAYS as a measure in both clinical and drug trials and on-going evaluations of comprehensive care, may aid in defining outcomes in terms of real life issues, such as whether or not a person feels well enough to perform daily activities.

The principal theoretical issue of QoL in MS research is accepting patients' perceptions as unique dimensions of their disability and satisfaction with management. In two recent studies [25,26] application of generic QoL scales for evaluation of MS patients added information beyond that provided by neurological evaluation. However, both studies concluded that the disease-targeted scales will provide unique data not captured by the generic measure. In the present study MS patients clearly indicated that physical, psychological and social–familial dimensions of their lives are impaired. We specifically adhered to their perceptions of the last week in endorsing the RAYS scale in order to receive precise answers related to their QoL that will be relevant, important and gen-

eralized [27]. As MS is a dynamic disease in which neurological changes may occur within days, it is necessary to capture the effect of the disease course on QoL during relatively short periods of time.

MS is a disorder of multiple functional systems and indeed in the present study the subjective impact of the disease was manifested in all aspects of life assessed by the RAYS. This finding is compatible with the results from the Medical Outcome Study reported for a variety of chronic conditions in the USA [28]. Patients with multiple conditions showed greater dysfunction and lower well being than those with only one condition. Thus, it is not surprising that MS patients scored significantly worse not only on the physical subscale of the RAYS but also on psychological and social–familial dimensions. It is noteworthy that the social–familial subscale reflected some dissatisfaction in the control group as well. We suggest that one possible interpretation for this finding may be that the well-being of patients and of healthy individuals within their social and familial environment is a sensitive measure that is easily disrupted. Future applications of the RAYS should take this phenomenon into account when interpreting results in the context of clinical drug trials, rehabilitation efforts or other interventions.

Patients' preferences regarding total managed care may differ from those of physicians and researchers. As novel drug therapies are introduced in the treatment of MS, QoL scales must become one of the central measures of efficacy. We suggest that the RAYS scale is a valid specific QoL measure in MS and may be incorporated in future studies as an outcome measure, after comparison with other existing MS-specific measures.

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Appendix

The RAYS – A Quality of Life Scale for multiple sclerosis patients

The following questions focus on the past week. We are interested in obtaining information about any problem or difficulty you have had during this period. Even if some of the questions seem redundant, they are in fact different so please answer all questions. However, if any question is impossible for you to answer please move to the next one.

We would like to emphasize that all questions refer to the effects of multiple sclerosis. If you feel that another factor has influenced your response please note that next to the specific item.

All questions relate to the last 7 days.

Physical domain

1. My driving is limited.
2. I have stayed in bed during the day.
3. I found it difficult to lift objects, bend, walk up stairs.
4. My walking is limited.
5. Difficulty in bladder control limited my activities.
6. I suffered pains or was uncomfortable.
7. I needed help to get up from a chair, get into a car, get out of bed.
8. I was unstable when walking.
9. I had difficulties with fine co-ordination of my hands (e.g. writing, buttoning, lacing my shoes).
10. I suffered blurred or double vision.
11. I felt tired.
12. I had 'accidents' such as: dropping objects, falls, bumping into things.
13. Warm weather exacerbated my condition.
14. I suffered from muscle cramps or rigidity.
15. Due to speech or voice difficulties others found it hard to understand me.

Psychological domain

1. I am a burden to others.
2. I laughed or cried suddenly for no reason.
3. I blamed or cursed myself.
4. I spoke hopelessly of the future.
5. I was afraid/frightened of what the near future holds for me.
6. I had difficulties remembering details.
7. I reacted slowly to things said or done around me.
8. I could not complete tasks started.
9. I found it difficult to solve problems, make decisions, plan or learn new information.
10. I had difficulties falling asleep and/or woke up in the middle of the night and/or awoke un-refreshed.
11. I did not enjoy activities that once brought me pleasure.
12. I devoted time and effort to grooming and personal appearance.
13. I felt sad or depressed.
14. Physical problems occupied or bothered me.
15. I felt changes in my appearance make me unattractive.

Social–familial domain

1. I worked/was employed.
2. I took part in household chores.
3. I took part in leisure time activities or hobbies.
4. I went out socially.
5. I used public transportation.
6. I participated in social gatherings.
7. I took part in managing family and parental duties.
8. My sexual activities declined.
9. I engaged in family and social conversations.
10. I was demanding, irritable and short-tempered to those around me.
11. I felt lonely.
12. I was satisfied with my achievements.
13. I listened to the news, read a newspaper, watched television.
14. I received emotional support from my family, friends, caretakers.
15. I was coping with my illness.

Additional concerns

1. I suffered/was bothered by side-effects of my treatment/medications.
2. My treating physician was available to answer my needs.
3. Generally I was satisfied with my quality of life.
4. I felt my illness makes me disabled.
5. I spoke with my family/friends about my illness.

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