

## MENTAL QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS TREATED AND NON-TREATED WITH INTERFERON BETA-1B (IFNB-1B)\*

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*Abstract:* In order to detect the influence of immunomodulatory treatment with interferon beta (IFN $\beta$ ) on the mental quality of life in patients with relapsing-remitting multiple sclerosis, its characteristics were examined in patients treated (n = 25) and non-treated (n = 25) with interferon beta-1b. Using the Time Sampling Diary in which the subjects entered their answers to 8 questions in randomly-chosen time intervals over a period of 14 days the following results were obtained: a) Treated and non-treated patients differed significantly (ANOVA) regarding their mental quality of life expressed as an average of the 5 point response scale with the extreme poles of I feel very bad (1) and I feel very good (5). However, the detected difference was true only of treated and non-treated females and not of males: the treated females felt significantly better subjectively. This finding was also confirmed by configuration-frequency analysis (CFA) of individual response categories. b) From the analysis of the description of how a person feels it is evident that the subjects most often felt tired (29.65%), often experienced pain (16.01%), and joy (16.85%). When comparing the frequency of these states among treated and non-treated females it has been demonstrated that the treated females experience joy more often and sadness less often than non-treated females. The detected differences are interpreted in a way showing that the treatment has a mediating effect upon the mental quality of life: it enabled the treated females to be more active, or to stay in the presence of unknown persons more frequently, which may have resulted in improved values of variables of mental quality of life.

*Key words:* mental quality of life, multiple sclerosis, interferon beta-1b, Time Sampling Diary

### INTRODUCTION

Multiple sclerosis (MS) is the prototype inflammatory autoimmune disorder of the central nervous system (CNS) and, with a lifetime risk of one in 400, potentially the most common cause of neurological disability in young adults. As with all complex traits, the disorder results from an interplay between as yet unidentified environmental factors and susceptibility genes.

Together, these factors trigger a cascade of events, involving engagement of the immune system, acute inflammatory injury of axons and glia, recovery of function and structural repair, post-inflammatory gliosis and neurodegeneration. The sequential involvement of these processes underlies the clinical course characterised by episodes with recovery, episodes leaving persistent deficits, and secondary progression. The aim of treatment is to reduce the frequency, and limit the lasting effects, of relapses, relieve symptoms, prevent disability arising from disease progression, and promote tissue repair.

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Despite limited success in each of these categories, everyone touched by multiple sclerosis looks for a better dividend from applying an improved understanding of the pathogenesis to clinical management (Compston, Coles, 2002). At the centre of attention at present is finding the earliest possible reliable indications for an MS diagnosis and the initiation of immunomodulatory treatment. The controlled prospective studies have confirmed the successful application of interferons beta (IFN $\beta$ ) in MS treatment and the optimum treatment is considered to be the use of more efficient interferons beta (IFN $\beta$ -1b 250  $\mu$ g administered every other day, IFN $\beta$ -1a 44  $\mu$ g three times weekly) (Hurwitz, 2005).

The effect of immunomodulatory treatment on the course of relapsing-remitting MS (RRMS) has recently been judged not only on its ability to decrease the frequency of occurrence of relapses and to reduce the activity of the illness evaluated on the basis of magnetic resonance results (MR diagnosis), but also on some other criteria. One of them is, to begin with, the patient's subjective quality of life. This criterion indicates how patients experience and subjectively endure their health state, how they feel, how they live through their ordinary days and how they establish their social relationships (see for example Lorenz, Koller, 2002). As stated by Schumacher, Klaiberg and Brähler (2003), the quality of life of patients known as Health-Related Quality of Life (HRQOL) has to date no universally accepted and binding definition and has not been sufficiently delimited from the neighbouring concept of subjective well-being. It has been generally agreed upon, however, that HRQOL is a multidimensional construct with the following dimensions or components (Patrick, Erickson, 1988): 1) physi-

cal difficulties caused by illness, 2) mood in the sense of emotional set-up or overall subjective well-being, 3) functional limitations of everyday life caused by illness related to work, household and leisure time, 4) weakening of interpersonal relationships and social interaction. Because authors tend to differ in giving types of dimensions of quality of life, the results of different studies are difficult to compare. The current study BEST (Betaferon in Early relapsing-remitting multiple sclerosis Surveillance Trail) involving 3000 patients studies, besides the clinical parameters of MS, the health-related quality of life by means of two different instruments - FAMS (Functional Assessment of Multiple Sclerosis) and the 5-dimensional questionnaire EuroQol (European Life Quality Questionnaire). From the running assessment of results obtained from 591 patients after one year's treatment it has become evident that, in comparison with the year before the treatment, the IFN $\beta$ -1b treatment has led in this group to a fall in the average yearly occurrence of relapses from 0.9 to 0.44. According to the FAMS results, only in patients with progression of health impairment (9%) was the quality of life lowered (by 16.5 points); in patients without that progression the quality of life moderately increased (by 1 point of the overall score). According to the EuroQol data (n = 365) the quality of life of the monitored patients was stable. In the assessment of "the momentary health state" in IFN $\beta$ -1b treatment with the use of visual analogue scale an improvement was detected from 68 to 71.9 points. The preliminary results of the BEST study can be summarised as follows: a) IFN $\beta$ -1b treatment is safe and well-tolerated, it does not have negative impact upon the quality of life of patients, b) worsening of the health-related quality of life is connected

with the SM progression, c) in patients treated with IFN $\beta$ -1b the monitored indicators of the quality of life (FAMS, EuroQol) do not tend to worsen (Lellwitz, 2004).

Using the FIS scale (Fatigue Impact Scale) Metz, Patten, Archibald et al. (2004) examined the effect of immunomodulatory treatment with IFN $\beta$  and glatiramer acetate (GA) on fatigue in MS. The range of fatigue was measured by using the scale at the beginning of the treatment and 6 months later. In MS patients fatigue is a much more frequent symptom, the origin of which has not yet been completely clarified and which influences their quality of life. It is known that fatigue is often worse during attacks of the disease, when there is active CNS inflammation. The quoted authors hypothesised that if reduced inflammation is associated with improved fatigue, fatigue may represent a marker of disease activity or an indicator of patient's response to immunomodulatory treatment. Even if this association cannot be demonstrated, a reduction in fatigue would be a treatment benefit. Out of 218 SM patients, 86% having relapsing-remitting disease, GA was used by 61% and IFN $\beta$  by 39%. At baseline, total FIS and subscale scores were comparable in the two groups. More patients improved on GA than on IFN $\beta$  on total FIS (24.8% vs 12.9%,  $p = 0,033$ , adjusted odds ratio 2.36, 95% confidence interval 1.03 to 5.41) and on physical (28.6% vs 14.1%,  $p = 0.013$ ) and cognitive subscales (21.1% vs 10.6%,  $p = 0.045$ ). Logistic regression analysis confirmed the association between GA use and amelioration of fatigue, around twice as great as with IFN $\beta$ . Confirmation of this result is required. It is unclear why GA is more likely to ameliorate fatigue than IFN $\beta$ , given that both reduce CNS inflammation.

In our research we adhere to the definition of the quality of life of the World

Health Organization (WHOQOL-Group, 1995) which presupposes the existence of 6 domains of the quality of life: 1) physical quality of life, 2) mental quality of life (especially including experiencing positive and negative emotions), 3) independence, 4) social relationships, 5) social and physical environment and 6) domain of personal values and spirituality. Our research focused only on the domain of mental quality of life that was detected by measuring the so-called on-line experiencing with the help of the Time Sampling Diary (TSD, Brandstätter, 2001).

The research objective was to analyse the mental quality of life of RRMS patients and to investigate its characteristics in patients treated and non-treated with IFN $\beta$ -1b. Our intention was to detect whether there were any differences in the mental quality of life between patients treated with IFN $\beta$ -1b (250  $\mu$ g administered subcutaneously by autoinjector every other day) and patients who were not treated with IFN $\beta$ -1b.

## METHOD

### *Participants*

The research sample consisted of males and females with clinically definite relapsing-remitting MS (according to Poser's criteria). The sample members were patients of an MS centre as well as members of clubs of patients with MS in the region of Eastern Slovakia. The group of treated patients included 30 patients (12 males, 18 females) who by the time of selection had been treated with IFN $\beta$ -1b for a minimum of one year (maximum of two years). The group of non-treated consisted of 30 patients (13 males, 17 females) who had not undergone the immunomodulatory treatment with IFN $\beta$ . The persons included in

both groups were chosen randomly from the list of all treated/non-treated patients in the area stated above. Out of the total number of 30 selected treated patients 25 delivered their diaries, while out of the selected sample of 30 non-treated patients 26 patients delivered their diaries (total 51 persons). The data of one of the non-treated group patients were not complete, for which reason only the data obtained from 50 patients were statistically analysed (for the descriptive data of the research sample see Table 1).

#### *Research Instrument*

To measure the mental quality of life the Time Sampling Diary (TSD) was used (Brandstätter, 2001) which makes it possible to monitor people's subjective feelings and the possible personal and external factors of their states. The persons examined are supposed to answer the eight questions of the TSD. 1) How do I feel at the moment? The answer scale offers the possibilities of very bad (1) - bad (2) - neither good nor bad (3) - good (4) - very good (5). We consider the answer to this question to be the indicator of a person's mental quality of life. 2) How would I describe my current state in greater detail?

Persons answer by underlining one or more states: anger, feeling of guilt, pleasure, embarrassment, physical vigour, anxiety, pain, joy, sadness, happiness, shivering, fatigue, boredom, laziness. In case they experience a state which is not given in the list, persons can provide their own description. 3) Why do I feel this way? (Persons provide subjective explanations). 4) Where am I? 5) What am I doing? 6) What was I doing before? 7) Who else is also present? (The persons present are asked about, not their names). 8) What medication have I used since I made my last entry in the diary?

On the reverse side of the diary examined persons have at their disposal a schedule of times when they are supposed to make their diary entries; there they are also instructed to set an alarm clock or to remember the next time they are scheduled to answer diary questions.

The given combination of data and their statistical analysis makes it possible to obtain information about various aspects of mental quality of life. Usually a person's subjective feeling is analysed (answers to questions 1 and 2), subjective interpretation of one's own feeling (answer to question 3), probable factors responsible for subjective feeling (answers to question

Table 1. Research sample - treated and non-treated persons according to their sex and average age (in years and months), EDSS and Duration of SM (in years and months)

	Treated				Non-treated				Total
	n	Age	EDSS	Duration of SM	n	Age	EDSS	Duration of SM	
Males	12	38.3 (25-45)	3.25	4.9	8	45.1 (29-55)	4.18	10.9	20
Females	13	36.4 (24-46)	2.31	4.3	17	41.7 (38-58)	3.62	11.3	30
Total	25	37.21	2.82	4.9	25	46.04	3.64	10.9	50

Note: EDSS - Expanded Disability Status Scale (Kurtzke, 1983)

4-8). From the combination of answers to questions 1 and 2 and 4-8 information can be acquired about the degree of involvement of various objective variables (place where a person spends his/her time, presence of other persons, activity performed by a person) in the subjectively perceived quality of life, or in the subjectively interpreted causes of one's own feeling. The study presents only part of the results obtained relating to the subjective feeling - mental quality of life of the two compared groups.

#### *Procedure*

25 treated and 25 non-treated persons kept their Time Sampling Diaries for the period of 14 days - they provided answers to 8 questions a maximum of 6 times a day at randomly-chosen time points. By means of a written instruction on the right-hand margin the aim of the research and the way entries were to be made were explained to each respondent. During the entire course of the research patients had an opportunity to ask for clarification of uncertainties via

telephone by calling the phone number provided. The patients were given the diaries personally, during which time their neurological status was registered (using Kurtzke's Expanded Disability Status Scale, Kurtzke, 1983) along with their demographic data (age, sex, duration of illness since the final statement of diagnosis, other accompanying autoimmune diseases). Participation in the research was voluntary and patients were recompensed for keeping their diaries.

## RESULTS

### *Frequency of Analysed Entries in the Time Sampling Diary (TSD) - Descriptive Analysis*

Table 2 presents the numbers of entries of the examined persons over the period of 14 days.

Note: According to the schedule, persons were allowed to make up to 84 entries during the two week period (the schedule of randomly generated entry times allowed for a maximum of 6 entries daily).

Table 2. The number of entries of subjects in the Time Sampling Diary

Non-treated		Treated	
Person	Number of entries	Person	Number of entries
1	57	27	76
2	62	28	61
3	73	29	79
4	54	30	70
5	68	31	76
6	50	32	81
7	45	33	84
8	63	34	67
9	74	35	83
10	56	36	66

Table 2 continues

Table 2 (continued)

Non-treated		Treated	
Person	Number of entries	Person	Number of entries
11	60	37	84
12	81	38	55
14	59	39	76
15	67	40	57
16	79	41	71
17	78	42	84
18	42	43	84
19	70	44	57
20	56	45	84
21	66	46	83
22	57	47	84
23	70	48	67
24	60	49	84
25	77	50	83
26	65	51	83
N = 25	1589	N = 25	1879

Note: Because of the insufficient number of entries (29), Person No. 13 was excluded from the analysis and not included in the Table

As can be seen from Table 2, over the period of two weeks individual persons made between 42 entries minimum (Person 18) and 84 entries maximum (Persons 33, 37, 42, 43, 47 and 49). From the total number of 3468 entries made by all persons, 82% (2853) were made at times determined by the schedule, the rest of them (17%) were made with a delay.

*Mental Quality of Life of Treated and Non-Treated Patients - Analysis of Variance Results (ANOVA)*

The mental quality of life is represented by the answer to the first question in the

Diary "How do I feel at the moment"? The subjects provided answers on the response scale between the poles of very bad (1) and very good (5). The results are given in Table 3.

Using the analysis of variance (Table 3) one significant main effect was identified (treatment) and statistically significant interaction. The subsequent comparison of individual means of the subgroups using t-tests (Table 4) showed that there is no significant statistical difference between treated and non-treated males. There is a significant difference in the mental quality of life between treated and non-treated females ( $t = -8.155$ ,  $df = 2310$ ,  $p < .001$ ).

Table 3. Results of analysis of variance for sex and treatment as independent variables and mental quality of life as dependent variable

Source of variance	Sum of squares	df	F	sign.
Main effects:				
Sex	0.016	1	.026	.872
Treatment	12.101	1	18.144	< .001
Interaction: Sex X Treatment	16.681	1	25.425	< .001
Error	2199.29	3352		
Total	42237	3356		

Table 4. Average values of mental quality of life with regard to sex and treatment

	Treatment		Total
	Non-treated	Treated	
Male	3.46	3.44	3.45
Female	3.30	3.58	3.44
Total	3.38	3.51	

There is, furthermore, a statistically significant difference between non-treated males and non-treated females - males experience higher values of mental quality of life than females ( $t = 3.563$ ,

$df = 1563$ ,  $p < .001$ ) and treated males experience, in comparison with treated females, statistically lower levels of mental quality of life ( $t = -3.566$ ,  $df = 1789$ ,  $p < .001$ ).

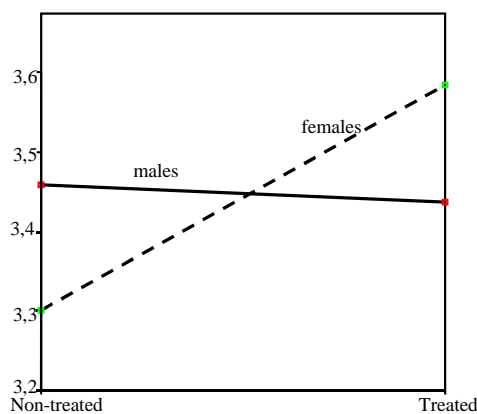


Figure 1. Average values of mental quality of life depending on treatment and sex

Graphic representation of individual averages (Figure 1) further supports the results of variance analysis: while treated and non-treated males do not differ from each other in the values of mental quality of life (almost horizontal line), treated females and non-treated females do differ significantly - the treated females experience statistically significant values of mental quality of life.

*Mental Quality of Life of Treated and Non-Treated Patients - Results of Configuration-Frequency Analysis (CFA)*

While the ANOVA calculation uses average values of response scale to compare groups, CFA calculation works with the frequency number of each response degree individually. It enables the acquisition of information about which concrete response degrees the compared groups differ in. First we compared treated and non-treated

persons, then males and females and finally treated males and treated females separately. CFA values concerning the comparison of treated and non-treated persons are presented in Table 5 and Figure 2.

As can be seen from Table 5, non-treated and treated patients differ significantly in how often they feel bad and how often they feel good: non-treated patients feel bad markedly more often (standardised residual = 3.6) than treated patients (standardised residual = -3.4), treated patients feel very good markedly more often (standardised residual = 3.3) than non-treated patients (standardised residual = -3.6). This result is illustrated in Figure 2: the difference between non-treated and treated patients in the categories very bad (14 vs. 18), neither bad nor good (522 vs. 545) and good (726 vs. 920) is not statistically significant; there are significant differences in the categories bad (251 vs. 178) and very good (52 vs. 130).

Table 5. Mental quality of life as number of individual response categories of treated and non-treated patients

			Mental quality of life					Total
			Very bad	Bad	Neither bad nor good	Good	Very good	
Treatment	Non-treated	Count	14	251	522	726	52	1565
		Expected	14.9	200.1	497.6	767.6	84.9	1565.0
		St. residuals	-0.2	3.6***	1.1	-1.5	-3.6***	
	Treated	Count	18	178	545	920	130	1791
		Expected	17.1	228.9	569.4	878.4	97.1	1791.0
		St. residuals	.2	-3.4***	-1.0	1.4	3.3***	
Total	Count	32	429	1067	1646	182	3356	
	Expected	32.0	429.0	1067.0	1646.0	182.0	3356.0	
Chi-Square = 54.740, df = 4, p < .001								

Note: \* = p < 0.05, \*\*\* = p < 0.01, \*\*\*\* = p < 0.001



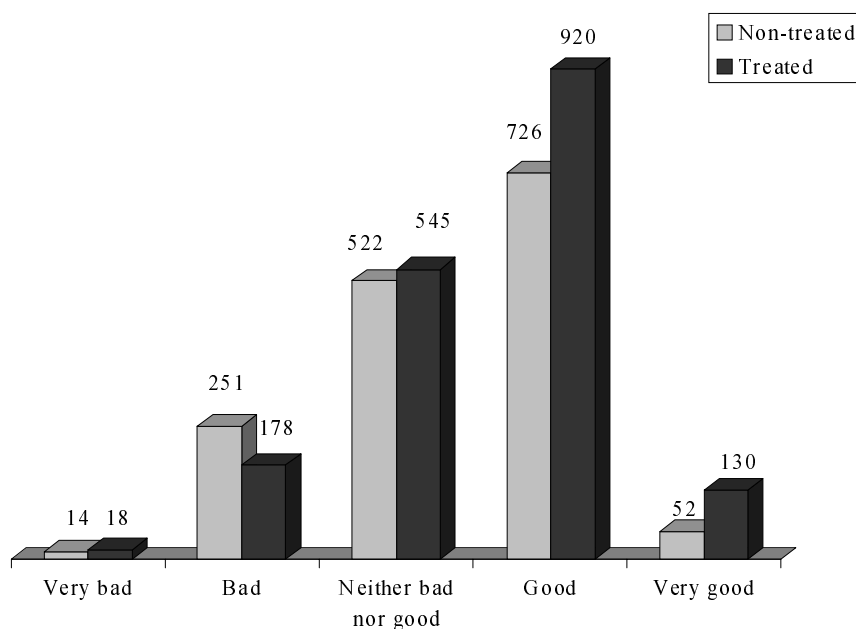


Figure 2. Mental quality of life as the number of individual response categories of treated and non-treated patients

Using ANOVA, differences in mental quality of life were identified between non-treated and treated patients. However, significant interaction of gender and treatment meant that this difference is not applicable to males but only to females. For this reason we repeated the calculation using CFA while taking this finding into consideration: we made the comparison of frequency of experiencing individual categories that describe mental quality of life separately for non-treated and treated females and for non-treated and treated males. The results for non-treated and treated females are presented in Table 6 and in Figure 3. Because no statistically significant differences in categories of mental quality of life were detected when compar-

ing non-treated and treated males, they are not presented in the form of a table.

The data in Table 6 suggest that non-treated females feel statistically significantly bad (standardised residual = 5.2) more often than treated females (standardised residual = -4.8) and significantly very good less often (standardised residual = -3.7) than treated females (standardised residual = 3.4). This result is represented in Figure 3: the difference between non-treated and treated females in the categories very bad (6 vs. 12), neither bad nor good (352 vs. 389) and good (455 vs. 620) is not statistically significant; there are significant differences in the categories bad (208 vs. 107) and very good (43 vs. 120).

Table 6. Mental quality of life as the number of individual response categories of treated and non-treated females

			Mental quality of life					Total
			Very bad	Bad	Neither good nor bad	Good	Very good	
Treatment	Non-treated	Count	6	208	352	455	43	1064
		Expected	8.3	145.0	341.0	494.7	75.0	1064.0
		St. residuals	-.8	5.2***	.6	-1.8	-3.7***	
	Treated	Count	12	107	389	620	120	1248
		Expected	9.7	170.0	400.0	580.3	88.0	1248.0
		St. residuals	.7	-4.8***	-.5	1.6	3.4***	
Total		Count	18	315	741	1075	163	2312
		Expected	18.0	315.0	741.0	1075.0	163.0	2312.0

Chi-Square = 83.819, df = 4, p < .001

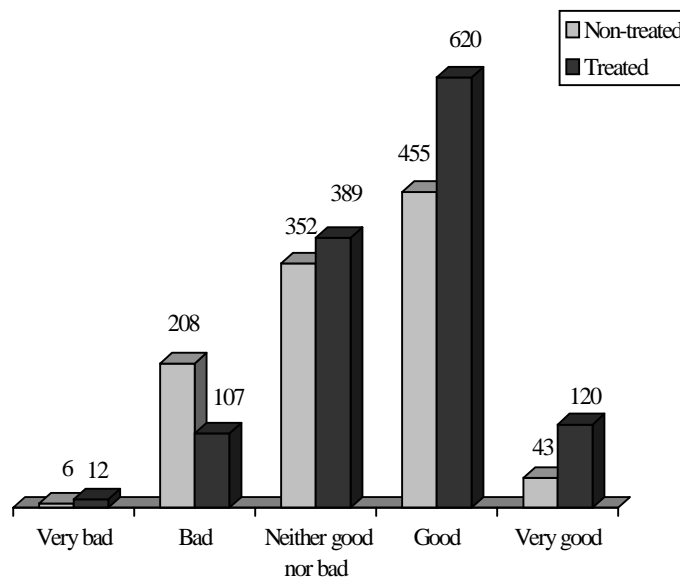


Figure 3. Mental quality of life as the number of individual response categories of treated and non-treated females

In conclusion, females treated with immunomodulation therapy with IFN $\beta$  feel subjectively better than non-treated females. This finding is not valid for males - regardless of whether they are treated or not males do not differ as regards the mental quality of life.

*Quantitative Analysis of Descriptions of Mental Quality of Life*

Besides the answer to the first question, how subjects feel at the time of diary entry, TSD makes it possible to obtain a more detailed idea about concrete states of subjects, which we consider a quantitative indicator of mental quality of life. Answers to the second question, viz. "How would I describe my current state in greater de-

tail?", and their analysis makes it possible to determine the number of concrete positive and negative emotional states of the compared groups. To describe their state the subjects were able to use one or two (of the total number of 14) concrete descriptive words, of which 4 described positive emotions and states (pleasure, vigour, joy and happiness) and 10 negative emotions and states (anger, guilt, embarrassment, anxiety, pain, sadness, shivering, tiredness, boredom and laziness). Table 7 presents the overall number of positive and negative descriptions in the whole sample. As persons were able to use more than one descriptive word (they used a maximum of 4 descriptions) to describe their states, Table 7 presents the frequency of all descriptions which the subjects used.

Table 7. Frequency of experienced states in the total sample

	Description 1	Description 2	Description 3	Description 4	Total	Per cent
1 Anger	199	1	0	0	200	4.39
2 Guilt	10	3	0	0	13	0.28
3 Pleasure	110	0	0	0	110	2.42
4 Embarrassment	6	2	0	0	8	0.18
5 Vigour	372	16	0	2	390	8.57
6 Anxiety	66	8	2	2	78	1.71
7 Pain	606	106	5	14	731	16.01
8 Joy	559	183	5	20	767	16.85
9 Sadness	102	91	26	3	222	4.88
10 Happiness	76	134	33	0	243	5.33
11 Shiver	51	73	22	2	148	3.25
12 Tiredness	653	475	203	19	1350	29.65
13 Boredom	54	34	6	0	94	2.06
14 Laziness	75	90	29	3	197	4.33
15 Other	0	1	0	0	1	0.02
Total	2939	1217	331	65	4552	100.00

From Table 7 it is evident that the list of descriptive words which TSD provides for the description of a person's current states can be considered satisfactory because the possibility of giving a different state from the ones provided in the Diary was used only once. The data in Table 7 point out the fact that some of the states, such as guilt, embarrassment, anxiety, boredom, pleasure and shivering, were experienced relatively rarely. We omitted these states from further analysis. In the context of the finding that only non-treated and treated females differed in experiencing mental quality of life (this is not true for males), we carried out a comparison of non-treated and treated females from the point of view of the given positive and negative descriptions. Figure 4 presents the occurrence of 3 positive (vigour, joy and happiness) and 5 negative descriptions

(pain, sadness, anger, tiredness and laziness).

The frequency of experienced states presented in Figure 4 points to the differences between treated and non-treated females. Using the Chi-square test we found out that the treated females experience joy statistically significantly more often than non-treated females (Chi-square = 44.769,  $p < .001$ ); however, the two groups did not differ in the frequency of experiencing other positive states (vigour and happiness). As to negative states, the treated females experience tiredness (Chi-square = 23.695,  $p < .001$ ), anger (Chi-square = 18.256,  $p < .001$ ) and laziness (Chi-square = 29.120,  $p < .001$ ) statistically significantly more often. Conversely, sadness is experienced by the non-treated females statistically significantly more often than the treated females (Chi-square = 8.421,  $p < .001$ ).

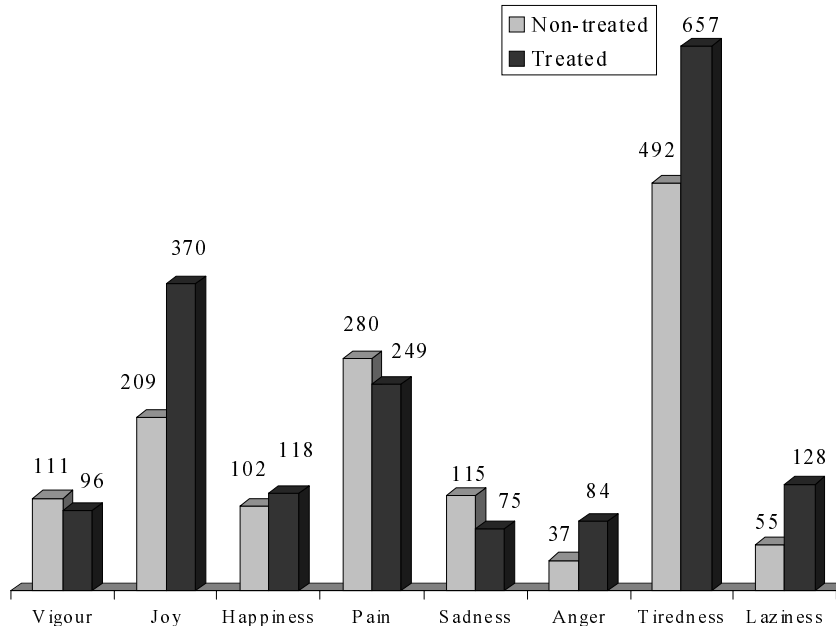


Figure 4. The number of positive and negative states in non-treated and treated females

## DISCUSSION

We can summarise the results obtained as follows: a) The non-treated and treated patients differed statistically significantly (ANOVA) in the mental quality of life, expressed as an average of the five-degree response scale with the two poles being very bad (1) and very good (5). The difference, however, was related to the non-treated and treated females, not to males: the treated females felt subjectively significantly better. b) This finding was also supported by the configuration-frequency analysis (CFA): the non-treated patients feel significantly worse than the treated ones, who in turn feel very good significantly more often than the treated ones. The repeated CFA calculation done separately for males and separately for females demonstrated that this difference applied only to females and not to males. c) It follows from the analysis of descriptions of state that the subjects most often felt tired (29.65%), often experienced pain (16.01%) and joy (16.85%). When comparing the frequency of experiencing these states by treated and non-treated females it became clear again that of the positive states the treated females experience joy more often and of negative states sadness less often than the non-treated females. Tiredness, anger and laziness were experienced more often by treated than by non-treated females. Among males these differences were statistically insignificant.

The immunomodulatory treatment with IFN $\beta$ -1b carried out in patients with relapsing-remitting MS has shown itself to be a factor which is related to patients' mental quality of life. Those patients who had opted for this treatment differed sig-

nificantly from those who had not, even though this difference applied only to females. The fact that this positive effect manifested itself only in females (not in males) is surprising and requires further verification. Several explanations are offered by the analysis of answers to other questions in the diary. When we tried to find out where the persons were staying at the time of making their diary entries (answer to Question 4) it appeared that most of them were staying at home (81.4% of all entries); 17% of entries were made outside subject's homes. The comparison of the examined person's quality of life at home and outside their homes has led to the conclusion that they feel statistically significantly better outside their homes. When the comparison was made how often the treated and non-treated females spent their time in and outside their homes it became evident that it was the treated females who statistically significantly spent more time outside their homes. This fact could have been one of the reasons for the positive values of mental quality of life, since there were no differences found in males regarding the place where they stayed. Whether staying outside home had any direct influence on the mental quality of life of females or the fact that the treated females, due to having undergone the treatment, felt so physically fit that they could spend more time outside home (at work, etc.) than non-treated females remains an open question. In such a case this would not be a direct effect of treatment whose consequences would positively reflect in values of mental quality of life but rather a mediated effect of treatment which enabled the treated females to carry out reasonable activities which resulted in positive values of mental quality of life. From the analysis of situations demonstrating in whose presence the examined per-

sons were (answer to Question 7) it became evident that they were in the presence of their spouses in 35.8% of cases, in 25.8% of cases they were alone, they were with other family members in 24.7% of entries and they were in the presence of unknown persons in 10.1% of entries. The analysis of mental quality of life in these four types of situation revealed that the subjects feel best when they are in the presence of unknown persons. The comparison of males and females again confirmed that the treated females found themselves statistically significantly more often in situations where unknown persons were also present while non-treated females rarely found themselves in this situation. This finding does not apply to males. This factor also seems to have had an effect upon the mental quality of life either directly or indirectly through being a mediator of the effect of treatment that enabled the treated females to stay in the presence of others more often.

Our cross-sectional research cannot explain causal relationships among the examined variables and the findings obtained must be interpreted with regard to this fact. Even though our research sample was representative and randomly selected, creating equivalent groups from the viewpoint of relevant indicators was not satisfactory: values on the EDSS scale in treated and non-treated patients cannot be considered comparable (on average they are higher in non-treated patients). Also the length of illness, another possible factor, was not the same in both groups (in treated persons it was shorter). Taking these factors into consideration also, it is

necessary to replicate the research findings.

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## PSYCHICKÁ KVALITA ŽIVOTA PACIENTOV SO SCLEROSIS MULTIPLEX LIEČENÝCH A NELIEČENÝCH INTERFERÓNOM BETA - 1B (IFN $\beta$ -1B)

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*Súhrn:* S cieľom zistiť vplyv imunomodulačnej liečby interferónom beta (IFN $\beta$ ) na psychickú kvalitu života pacientov s relabujúcou/remitujúcou sclerosis multiplex boli skúmané jej vlastnosti u liečených (n = 25) a neliečených pacientov (n = 25) interferónom beta-1b. Pomocou Denníka časových snímok, do ktorého skúmané osoby odpovedali na 8 otázok v náhodne zvolených časových intervaloch počas 14 dní, boli získané tieto výsledky: a) Neliečení a liečení pacienti sa štatisticky významne líšili (ANOVA) v psychickej kvalite života vyjadrenej ako priemer päť bodovej odpovedovej stupnice s krajnými pólmi cítim sa veľmi zle (1) a cítim sa veľmi dobre (5). Zistený rozdiel však platil iba pre neliečené a liečené ženy, nie pre mužov. Významne lepšie sa subjektívne cítili liečené ženy. Toto zistenie bolo potvrdené aj pomocou konfiguračno-frekvenčnej analýzy (KFA) frekvencie jednotlivých odpovedových kategórií. b) Z analýzy opisov vlastného stavu vyplynulo, že skúmané osoby sa najčastejšie cítili unavené (29.65%), často prežívali bolesť (16.01%) a často prežívali radosť (16.85%). Pri porovnaní početností prežívania týchto stavov liečenými a neliečenými ženami sa ukázalo, že liečené ženy prežívajú z pozitívnych stavov častejšie radosť a zriedkavejšie smútok ako neliečené ženy. Získané rozdiely sú interpretované v tom zmysle, že liečba má na psychickú kvalitu života sprostredkovaný vplyv (moderátorový efekt): umožnila liečeným ženám väčšiu aktivitu, resp. častejší pobyt v prítomnosti iných osôb, čo mohlo mať za následok zlepšené hodnoty v premenných psychickej kvality života.