

# A Study of Standard Care in Fibromyalgia Syndrome: A Favorable Outcome

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**ABSTRACT.** *Objective.* A longitudinal prospective study was undertaken to examine the outcome of fibromyalgia (FM) with standard medical care, as well as factors that might either predict or influence this outcome. *Methods.* Eighty-two women with clinical FM were evaluated at baseline and 70 were followed for a mean of 40 months. Patients continued their usual management for FM as prescribed by their own physicians. The primary outcome variable was patient's overall status compared to baseline on a 7 point Likert scale (range 1 = much worse, 7 = much better). Secondary outcome measures included measurements for pain, fatigue, and patient and physician global assessment on a visual analog scale. Additional functional measures were the disease-specific Fibromyalgia Impact Questionnaire (FIQ), and the generic Health Assessment Questionnaire (HAQ). *Results.* Of 70 (85%) patients who were followed up at 3 years, 33 (47%) reported overall moderate to marked improvement, and the remaining 53% reported either slight improvement, no change, or deterioration. The improved group (n = 33) compared to those that remained the same or worsened (n = 37) showed significant differences for change of score from baseline for tender point count, patient global assessment, sleep disturbance, fatigue, pain, FIQ and HAQ, and were younger, 46 versus 51 years. No other baseline demographic or disease variables discriminated between the 2 groups. The only baseline predictors for a favorable outcome were younger age and less sleep disturbance. *Conclusion.* The overall outcome in this group was favorable, with almost half the sample reporting clinically meaningful improvement in overall FM status. These findings are discussed in terms of their implications regarding current theory on the pathogenesis of FM. (J Rheumatol 2003;30:154-9)

*Key Indexing Terms:*  
FIBROMYALGIA

OUTCOME

After almost 2 decades of interest in the diffuse musculoskeletal pain syndrome fibromyalgia (FM), this disorder remains an enigma, with little knowledge of cause, treatment, or outcome. Current understanding points toward dysregulation of central pain processing mechanisms and associated neuroendocrine alterations in response to some triggering mechanism<sup>1</sup>. Although studies to date indicate improvement<sup>2-4</sup> as well as continued symptoms of FM over time, the overall impression is of an ongoing process that results in considerable functional impairment<sup>5-9</sup>. In that the syndrome of FM is characterized by subjective symptoms, without abnormality on standard clinical testing, physicians and patients alike

share the concern that FM may predate some other rheumatologic process. For this reason longer followup studies in FM are necessary to understand the natural history, identify predictors of outcome, and determine whether this condition is indeed a distinct entity.

The varied presentation and heterogeneity of FM is increasingly recognized. Patients with FM differ considerably in terms of severity of symptoms of pain and fatigue, as well as functional ability. Factors that might predict the outcome and disease course in FM are largely unknown. A knowledge of the likely natural history in an individual patient would be helpful in counseling a patient about planning treatment interventions, as well as likely outcomes for functional and work ability. Much anxiety is caused by uncertainty and thus a more definitive prognosis would be reassuring. The few studies that describe the natural history of FM have shown conflicting results, and factors that may influence outcome are speculative<sup>2,4,8,9</sup>. This study of patients with a clinical diagnosis of FM followed longitudinally with no predetermined treatment interventions was undertaken to document the outcome of FM and to identify factors that might have prognostic significance.

## MATERIALS AND METHODS

The study was approved by the local Research Ethics Committee. Between February 1995 and July 1995, 82 women with a primary clinical diagnosis of FM were enrolled in a prospective longitudinal study. No men fulfilled study entry criteria during the enrolment period. All patients were required to have

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a previously confirmed diagnosis of primary FM by American College of Rheumatology (ACR) criteria, but it was not required that ACR criteria regarding tender points (TP) be fulfilled at the time of entry<sup>10</sup>. This allowed participation of patients at various stages of disease and undergoing variable treatments. Inclusion criteria were as follows: (1) age 18 years or older; (2) previous diagnosis of FM by ACR criteria, with current presence of widespread pain; (3) fluency in English or French; (4) patient gave written informed consent. The exclusion criterion was FM as a secondary diagnosis to some other rheumatological disease.

The study population comprised 70 female patients who had baseline and followup data available at a mean of 40 months. Patients were referred for inclusion in the study mostly by primary care physicians or other rheumatologists, and the study site was either a university tertiary care rheumatology center or a university affiliated community rheumatology practice, whichever was closest to the patient's home. Patients continued to receive usual standard care as prescribed by their referring rheumatologist and/or primary care physician. In addition, patients may have used interventions not prescribed by a health care professional. No specific directions on management for FM were given to the physicians caring for the patients or to the patients at the time of the study visits.

Patients were evaluated upon entry to the study (T1), and reassessed at least 3 years later (T2); each examination consisted of a detailed interview, examination, and assessment of functional status. Throughout the study, clinical assessments were made by one author (MF). Demographic and clinical variables measured at baseline included age, years of education, marital status, current employment status, disability status, annual family income (Canadian dollars), duration of symptoms of FM, and time since diagnosis of FM. Treatments received for FM in the preceding 6 months were recorded, including medications prescribed, substances bought over the counter and not prescribed, and visits to physicians and nonphysician practitioners. The weekly physical activity was recorded as the number of hours per week spent walking, either outside or indoors, specifically for exercise purposes, as well as the number of hours spent each week doing sporting activity, including both aerobic and water sports.

All patients were assessed at least 3 years after entry; the primary outcome variable was overall status of FM by patient report on a 7 point ordinal scale, with 1 = much worse, 7 = much better. In addition the following clinical and functional measures were studied: a 10 cm VAS with 0 = very good, 10 = very severe was used for sleep disturbances, fatigue, pain, and global assessment of disease by patient and physician. Functional status was measured by the Health Assessment Questionnaire (HAQ)<sup>11</sup> and the Fibromyalgia Impact Questionnaire (FIQ)<sup>12</sup>.

*Statistical analysis.* Descriptive statistics including means, medians, and standard deviations were calculated for all variables. Repeated measures t tests were used to examine differences over time for continuous variables, while the McNemar test was used for dichotomous data. To examine factors related to improved status, patients were grouped based on their responses to a 7 point ordinal scale assessing overall FM status (1 = much worse, 7 = much better). Patients were categorized as definitively improved (Group 1) if they reported a 6 or 7, while those reporting 5 or less were considered minimally improved, stable, or deteriorated (Group 2). Group differences on study variables were examined using independent sample t tests for continuous data and chi-square for dichotomous data. Pearson correlation coefficients were used to examine associations between baseline variables, change scores (T2 minus baseline), and FM status at followup.

A multiple regression was computed to test the importance of baseline study variables on FM status at the 3 year followup. Variable selection was based on theoretical relevance, pattern of correlation with the outcome variable and other potential predictor variables, and the assumptions underlying multiple regression analysis. Variables were entered together in one block in what is known as a simultaneous entry<sup>13</sup>. This method was selected as it is the method recommended when there is no a priori theoretical rationale for entering variables in a specific order<sup>14</sup>. The ratio of subjects to predictor variables did not exceed 10:1, as recommended by Tabachnick and Fidell<sup>14</sup>.

## RESULTS

Of the 82 female patients with a clinical diagnosis of FM evaluated at baseline, 70 completed the reassessment at the 3 year followup (85.4%). While all 70 patients included in the final sample reported widespread pain at study entry, 9 had a TP count < 11 at study entry (mean TP count 7.3, SD 2.8). These patients were not excluded from the final sample as they were similar to the 61 who fulfilled criteria on baseline characteristics with the exception of having a higher household income ( $p < 0.005$ ), fewer sleep difficulties ( $p < 0.05$ ), and less functional disability (HAQ,  $p < 0.05$ ). The 12 women who were lost to followup were similar in baseline disease characteristics to those who remained in the study, including duration of FM symptoms, employment status, FIQ, and HAQ, but tended to be younger (mean 38.6 yrs, SD 10 vs mean 49.1 yrs, SD 8.8).

Demographic characteristics of the 70 patients with followup data are shown in Table 1. Table 2 shows baseline and followup measurements for clinical status, symptom reporting, functional and psychosocial status, exercise activity, and treatments for the sample. Significant improvements at followup compared to baseline were shown for the following: number of patients with widespread pain (70 vs 45;  $p < 0.0001$ ), tender point count (13 vs 10;  $p < 0.001$ ), number of patients fulfilling ACR criteria at followup (61 vs 33;  $p < 0.0001$ ), sleep disturbance ( $p < 0.0001$ ), fatigue ( $p < 0.001$ ), pain ( $p < 0.0001$ ), patient global ( $p = 0.003$ ), FIQ ( $p < 0.0001$ ), and anxiety, measured with the Arthritis Impact Measurement Scale<sup>15</sup> ( $p < 0.0001$ ). There was a nonsignificant trend toward more time spent in exercise activity at the 3 year followup. A significant decrease in the regular use of analgesics and muscle relaxants was found, while the use of alternative products increased. At the 3 year followup, 3 patients had developed some other disease process that might have accounted for the pain syndrome, which included rheumatoid arthritis, polymyalgia rheumatica, and peripheral neuropathy.

*FM status at 3 year followup.* At followup, patients were grouped according to the primary outcome measure into definitively improved (ordinal scale 6, 7; Group 1:  $n = 33$ ) or minimally improved, stable, or deteriorated (ordinal scale 1–5; Group 2:  $n = 37$ ). Significant differences on baseline variables included age ( $p = 0.003$ ), income ( $p = 0.035$ ), tender

Table 1. Demographic characteristics of 70 women with FM. Unless otherwise stated numbers represent the numbers of patients and percentage.

Age, yrs, mean (SD)	49.1 (8.8)
Education, yrs, mean (SD)	13.7 (3.3)
Marital status	
Married	57 (81)
Single/divorced/widowed	13 (19)
Employed	30 (43)
Not employed because FM	24 (34)
Receiving disability payments	13 (19)
Duration of FM, yrs, mean (SD)	11.7 (11)
Time since diagnosis of FM, yrs, mean (SD)	2.9 (3.1)

Table 2. Clinical characteristics at baseline and followup in 70 women with FM. Unless otherwise stated numbers represent the means and standard deviations.

	Baseline (T1)	Followup (T2)	p	95% CI
Widespread pain, n (%)	70 (100)	45 (64)	< 0.0001	
Tender point count	13.3 (3.3)	10.2 (5.9)	< 0.001	1.9, 4.2
FM (ACR criteria), n (%)	61 (87)	33 (47)	< 0.0001	
Sleep disturbance	69.5 (25.6)	52.7 (26.3)	< 0.0001	9.3, 24.3
Fatigue	68.2 (25.1)	56.9 (26.3)	< 0.001	4.9, 17.6
Pain	67.6 (26.0)	54.4 (27.6)	< 0.0001	6.5, 19.8
Patient global	60.5 (25.1)	50.5 (26.2)	0.003	3.4, 16.5
FIQ	56.1 (20.3)	46.2 (20.2)	< 0.0001	5.4, 14.3
HAQ	0.99 (0.70)	0.94 (0.79)	NS	-0.02, 0.92
AIMS-Depression	3.3 (1.7)	2.8 (2.0)	NS	-0.05, -0.16
AIMS-Anxiety	5.3 (1.9)	4.4 (2.1)	< 0.0001	0.42, 1.3
Exercise				
Total physical activity, h/wk (walking and sports)	3.8 (3.4)	4.5 (5.0)	NS	-0.37, 1.8
Walking, h/wk	2.3 (2.7)	2.7 (3.3)	NS	-1.3, 0.61
Treatments				
Alternative products, n (%)	22 (31)	38 (54)	0.005	
Analgesics, n (%)	47 (67)	34 (49)	0.011	
NSAID, n (%)	24 (34)	14 (20)	NS	
Antidepressants, n (%)	30 (43)	21 (30)	NS	
Muscle relaxants, n (%)	24 (34)	10 (14)	0.001	
Narcotics, n (%)	11 (16)	11 (16)	NS	
Tranquilizers, n (%)	21 (30)	18 (26)	NS	
Estrogens, n (%)	23 (33)	18 (26)	NS	

ACR: American College of Rheumatology; FIQ: Fibromyalgia Impact Questionnaire; HAQ: Health Assessment Questionnaire; NSAID: nonsteroidal antiinflammatory drug.

point count ( $p = 0.003$ ), and number of patients fulfilling ACR criteria ( $p = 0.007$ ), with Group 1 scoring more favorably compared to Group 2. At followup, more women in Group 1 were employed (69.7%) compared to Group 2 (27%). Similarly, Group 1 compared to Group 2 at the 3 year followup had lower TP counts ( $p = 0.0001$ ) and were less likely

to fulfill ACR criteria ( $p = 0.0001$ ) (Table 3). Details of the symptoms and functional and psychological status at baseline and followup for the 2 groups are shown in Table 4. Significant differences at the followup visit were found for the following variables: sleep disturbance ( $p = 0.002$ ), fatigue ( $p = 0.002$ ), pain severity ( $p = 0.002$ ), patient global assessment

Table 3. Clinical characteristics in FM patients grouped according to overall status of FM at baseline and followup. Unless otherwise stated all values represent the mean and standard deviation.

	Group 1, Improved n = 33	Group 2, Stable or Deteriorated, n = 37	p	95% CI
Age, yrs	45.9 (7.5)	51.9 (9.0)	0.003	-6.1, 2.0
Duration FM diagnosis, yrs	2.2 (2.3)	3.4 (3.6)	NS	-2.6, 0.33
Education, yrs	14.4 (3.7)	13.1 (3.0)	NS	-0.32, 2.8
Annual family income, \$1000 Cdn	65.7 (34.1)	49.9 (27.2)	0.035	1.1, 30.4
Employed, n (%)				
Baseline	17 (51.5)	13 (36.0)	NS	
Followup	23 (65.7)	12 (34.3)	0.002	
Widespread pain, n (%)				
Baseline	33 (100)	37 (100)	NS	
Followup	15 (33.3)	30 (66.7)	0.002	
Tender point count				
Baseline	12.2 (3.7)	14.5 (2.7)	0.003	-3.9, -0.81
Followup	7.7 (5.5)	12.7 (5.2)	0.0001	-7.6, -2.3
FM (ACR criteria), n (%)				
Baseline	25 (75.8)	36 (97.3)	0.007	
Followup	8 (24.2)	25 (75.8)	0.0001	

Table 4. Symptom severity and functional status variables for FM patients grouped according to overall status of FM at baseline and followup. Unless otherwise stated all values represent the mean and standard deviation.

	Group 1, Improved n = 33	Group 2, Stable or Deteriorated, n = 37	p	95% CI
Sleep disturbance				
Baseline	63.6 (24.9)	74.7 (25.4)	NS	-23.1, 0.90
Followup	42.2 (25.4)	61.7 (25.1)	0.002	-30.5, -6.8
Fatigue				
Baseline	65.8 (22.4)	70.3 (27.4)	NS	-16.5, 7.6
Followup	46.4 (24.7)	65.9 (25.6)	0.002	-30.4, -6.8
Pain				
Baseline	60.5 (28.5)	73.9 (22.2)	0.031	-25.5, -1.2
Followup	36.3 (22.2)	70.0 (23.0)	0.0001	-42.9, -21.4
Patient global				
Baseline	54.6 (22.9)	65.7 (26.0)	NS	-22.8, 0.72
Followup	33.6 (22.5)	65.1 (21.1)	0.0001	-40.4, -19.8
FIQ				
Baseline	52.7 (19.4)	59.1 (20.9)	NS	-16.0, 3.3
Followup	35.3 (19.0)	55.8 (16.7)	0.0001	-28.3, -11.5
HAQ				
Baseline	0.88 (0.69)	1.1 (0.70)	NS	-0.56, 0.11
Followup	0.66 (0.69)	1.2 (0.82)	0.005	-0.87, -0.15
AIMS-Depression				
Baseline	3.2 (1.8)	3.3 (1.7)	NS	-0.97, 0.70
Followup	2.4 (1.8)	3.2 (2.2)	NS	-1.7, 0.13
AIMS-Anxiety				
Baseline	5.3 (1.8)	5.3 (2.0)	NS	-0.95, 0.88
Followup	4.1 (2.1)	4.7 (2.1)	NS	-1.6, 0.34

( $p = 0.0001$ ), FIQ ( $p = 0.0001$ ), and functional disability ( $p = 0.005$ ).

Complete clinical and functional status data at 12 and 24 months after study entry were available on 60 of the 70 (86%) women followed up at the 3 year assessment. For the group that had improved at the 3 year followup, 26 (79%) had completed followups at both the 12 and 24 month period. Of these women, 16 (61.5%) would have been categorized as improved at *each* yearly assessment, while an additional 5 (19%) women would have been categorized as improved in only one of the prior yearly assessments. For the group that was categorized as stable or worsened at the 3 year followup, 33 (89%) completed followups at both the 12 and 24 month assessment after study entry. Twenty-four (73%) women in Group 2 at the 3 year followup would have been categorized into this group at *both* the 12 and 24 month followups, while an additional 8 (24%) would have been categorized in that group for only one of the 2 prior assessments.

Repeated measures ANOVA were carried out to examine group by time differences on the clinical and functional status variables on the subset of 60 women with available yearly data. A significant group-by-time interaction was shown for the FIQ ( $p = 0.004$ ), HAQ ( $p = 0.015$ ), patient global assessment ( $p = 0.007$ ), and tender points ( $p = 0.004$ ). Post hoc examination of the means using pair-wise t tests for each

group was then computed. For the group that had improved at the 3 year followup, significant improvements compared to baseline were also noted at the 12 and 24 month followup on the following variables: FIQ, HAQ, patient global, and tender point count. In comparison, the group that remained stable or had worsened at the 3 year followup improved only on tender point count at the 12 and 24 month followup compared to baseline. Only group differences were shown for sleep, fatigue, and pain, with Group 1 consistently scoring more favorably on these variables compared to Group 2. No group or group-by-time effects were shown for depression, anxiety, and total weekly physical activity.

*Predictors of FM status.* A standard multiple regression was computed to determine baseline predictors of improved FM status at 3 year followup. As shown in Table 5, the baseline variables entered into the equation were age, years since FM diagnosis, TP, sleep difficulties, and HAQ score. Twenty-eight percent of the variance in FM status at the 3 year followup was explained by the set of predictors entered, with younger age ( $p = 0.009$ ) and fewer sleep difficulties ( $p = 0.03$ ) contributing significantly to the equation.

## DISCUSSION

This study was undertaken to examine the outcome as well as predictors for FM, without any specific recommendations

Table 5. Multiple regression results predicting improved FM status at the 3 year followup.

Baseline Variables	Beta	t	95% CI
Age	-0.30	-2.67**	-0.11, -0.02
Years since diagnosis	-0.21	-1.88 <sup>†</sup>	-0.27, 0.01
Tender point count	-0.22	-1.84 <sup>†</sup>	-0.26, 0.01
Sleep disturbance	-0.25	-2.16*	-0.04, -0.001
HAQ	0.10	0.79	-0.43, 0.99
R <sup>2</sup> = 0.26, adj R <sup>2</sup> = 0.28, F (5, 64) = 5.03***			

<sup>†</sup> p < 0.10, \* p < 0.05, \*\* p < 0.01, \*\*\* p < 0.001.

regarding treatment intervention other than standard medical care. Almost 50% of patients in this study reported a clinically meaningful improvement in overall status of FM. A younger age and higher income were the only demographic variables, and a higher TP count was the only clinical measure, differentiating the 2 groups. It is notable that 8 out of 9 patients who had less than 11 TP at study entry were in the improved group. It could be argued that these 9 patients either had FM in a milder form and thus were more likely to have a better outcome, or if criteria are rigidly observed, that their diffuse pain syndrome might represent a process different from FM. No other demographic, clinical, or functional variable differentiated between the groups. The only predictors of improved FM status over time were a younger age and less sleep disturbance at study entry. It is notable that 3 patients developed a more clearly definable disease over the study period. This could have been an entirely coincidental occurrence, or the diffuse pain syndrome that was clinically recognized as FM may have been the first symptom of some other rheumatological condition.

The natural history of FM is unclear. Studies to date have suggested that symptoms persist over time<sup>5-9</sup>, with ongoing functional impairment, high health care utilization, and continued medication use. Recently, however, there have been reports of a more favourable outcome for FM in children<sup>16</sup>, in community rheumatology practice<sup>4</sup>, and in a hospital setting<sup>2</sup>. Macfarlane, *et al*<sup>3</sup> reported that chronic widespread pain had either improved or disappeared completely in 65% of community subjects evaluated after 2 years, suggesting that widespread chronic pain may not persist indefinitely. The understanding of the natural history and outcome of FM, albeit with current suboptimal treatments, has important implications with regard to defining outcome measures that are meaningful, particularly when evaluating any treatment intervention. The improvement observed in almost half of patients in our study is encouraging, but remains unexplained. We acknowledge that this study was observational, without rigorous control of treatment interventions or a placebo group as pertains to clinical trials. We observed a favorable outcome for FM by multiple measures over the 3 year duration of this study. The group as a whole reported improvement in many of the major

symptoms of FM, as well as showing improved functional status and less medication use. Thirty-six percent of patients no longer reported widespread pain, and 53% no longer fulfilled criteria for FM. These findings are similar to those reported for FM in adults in Australia and children in Israel<sup>4,16</sup>. In parallel to an overall subjective report of improvement in our patients, the TP count, the only examination abnormality in FM, was also noted to improve. Although the reliability of the TP count has been questioned in FM<sup>17</sup>, we believe this to be a useful measure in that it may reflect the overall reduction in pain threshold.

The reasons for the overall improvement observed in this group of patients with FM are speculative. The only predictors for a better outcome in our patients were a younger age and fewer sleep difficulties at baseline. Our patients, like those reported by Wolfe, *et al*<sup>9</sup> who did not fare as well, were all seen in a specialist rheumatology setting, which might suggest bias toward a patient population manifesting more severe disease<sup>9</sup>. Our findings are, however, in agreement with other studies reported from a rheumatology referral practice in Australia<sup>4</sup>, a hospital based study in Mexico<sup>2</sup>, and a community based study in the United Kingdom<sup>3</sup>. Simply participating in a study may have sufficient positive psychological effect to influence symptom reporting and favorably affect outcome. The poor outcome reported for patients in both the United Kingdom and the United States is difficult to explain<sup>8,9</sup>. The followup in the latter multicenter study was by mailed questionnaires, and the attrition rate varied over time and by center, as did the number of assessments at individual sites<sup>9</sup>. In contrast, most other studies including the present study evaluated patients clinically<sup>2,4</sup>. None of the factors previously reported to contribute to a poorer outcome in FM, including higher pain levels<sup>6,7,9,18</sup>, less education<sup>3,18</sup>, and psychological<sup>6,9,18</sup> and poorer health and functional status<sup>6,9</sup>, were identified in the present study. Media reporting, patient awareness and education about a disease, and compensation issues may vary in different countries, and may be an important factor in influencing patient outcome.

Reasons for the improvement observed may be due to modulation of disordered pain perception mechanisms over time, with adaptation of the organism and resetting of the pain threshold. Another possible explanation could be the more realistic individual outcome goals set by patients. It is also likely that individual patients have identified mechanisms and interventions that have positive effect upon symptoms. The reassurance of a definitive diagnosis might focus efforts toward healing strategies rather than continued investigation and a search for a diagnosis. It is also possible that patients who improve no longer consult physicians, leaving patients in poorer health to continue to consult. The role of exercise in modulating symptoms of FM is increasingly recognized. McCain, *et al* reported that exercise improved pain symptoms in FM in a study of cardiovascular fitness training<sup>19</sup>. Although the patients in our study reported exercise activity of 4 hours

a week, with increase over the period of the study, we are unable to attribute improvement simply to this activity.

There are limitations of the study that should be addressed. The sample size of 82 patients is small, although the attrition rate of only 15% over 3 years represents a successful followup. Our examination of prognostic factors was a secondary and exploratory objective, and while the variables selected were clinically and theoretically meaningful, our findings are preliminary and require replication in a larger study. This study also presents findings from patients recruited from a single city and thus results may not be applicable to other groups of patients. The patients were seen in either a tertiary care or a university affiliated rheumatology clinic setting, suggesting that those with more severe symptoms might have been included. We believe, however, that our patients do represent the full spectrum of severity of FM, albeit without any male patients, and may well be more reflective of the usual patient with FM, and be a reason that studies to date report an overall poor outcome in FM. As the present sample was drawn from FM patients willing to participate in a prospective study for research purposes, inference about the outcome of FM in general should be made with caution.

The encouraging and striking overall improvement in symptoms and functional ability in this particular group might indicate an overall better outcome in FM than is commonly believed. In that the current theory regarding the pathogenesis of FM is focused toward central dysregulation of pain processing mechanisms, it is possible that with time alone there could be a resetting of pain threshold. Some treatment interventions may facilitate the shift of pain threshold toward normality.

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