

# Predictors of Adherence to an Integrated Multimodal Program for Fibromyalgia

PATRICIA L. DOBKIN, RALUCA IONESCU-ITTU, MICHAL ABRAHAMOWICZ, MURRAY BARON, SASHA BERNATSKY, and AURELIO SITA

**ABSTRACT.** *Objective.* To describe treatment adherence to a multimodal integrated program for patients with fibromyalgia (FM), identify predictors of adherence to treatment recommendations, and examine the relationship between adherence and patient outcomes.

*Methods.* Sixty-three patients with FM were followed while participating in a 3-month outpatient program including physiotherapy, occupational therapy, nursing, and cognitive-behavior therapy. Patients completed a battery of psychosocial questionnaires pre- and post-treatment. At the end of each month of the treatment, patients completed 2 adherence questionnaires (for general and specific adherence) and 1 questionnaire about barriers to adherence to treatment. Generalized estimating equations extension of multivariable linear regression analyses for repeated measures examined predictors of general and specific adherence. Conventional linear regression analyses examined the relationships of general adherence with post-treatment FM disability and pain intensity.

*Results.* In general, adherence to treatment recommendations was good (mean general adherence score of 62 points, on a 0 to 100 scale), with no significant changes in mean level of general or specific adherence over the 3-month period. The main predictor for both general and specific adherence was barriers to adherence to treatment. Increased general adherence was significantly associated with lower pain at post-treatment.

*Conclusion.* The items described in the questionnaire for barriers to treatment are the main problem when it comes to adhering to a multimodal treatment program for FM. Healthcare professionals are advised to discuss these barriers directly with patients and assist in overcoming them. (First Release Oct 15 2008; J Rheumatol 2008;35:2255–64; doi:10.3899/jrheum.071262)

## Key Indexing Terms:

PATIENT COMPLIANCE

FIBROMYALGIA

MULTIMODAL TREATMENT

Fibromyalgia (FM) is a disorder characterized by widespread musculoskeletal pain and fatigue<sup>1</sup>. Associated symptoms include cognitive disturbance, nonrestorative sleep, and psychological distress<sup>2</sup>. There is a growing consensus that symptom management is best achieved through an integrated multimodal approach<sup>3–7</sup>. However, the evidence for the clinical effectiveness of multimodal interventions in FM remains equivocal<sup>8</sup>.

Mixed results for treatment efficacy are likely due to individual differences in patient responses to various inter-

ventions as well as in their adherence to medical recommendations. Psychosocial factors may influence, at least in part, who adheres to, and subsequently, who benefits from treatment<sup>9</sup>. As shown by Dobkin, *et al*<sup>10</sup>, about half the women with FM failed to take medications as prescribed. Those with lower psychological distress and higher affective pain ratings were more likely to adhere to their prescriptions. Adherence has an ongoing significant effect on patients' well-being, as shown by Lemstra and Olszynski<sup>7</sup>. Patients with FM who maintained the exercise component of their multimodal intervention program during a 15-month followup period experienced better health-related outcomes in terms of pain, disability, mental health, and nonprescription medication use than those that did not.

Most studies involving patients with FM use "attendance at treatment sessions" as an indicator of adherence<sup>4,7,11,12</sup>. However, the construct of adherence is not one-dimensional. First, the extent of treatment adherence may vary within and between treatment modalities. Second, a patient's adherence is likely to vary over the course of treatment, and thereafter. Third, coping skills are learned in a classroom setting but their application occurs outside the clinic. Finally, adherence can be affected by barriers; Dobkin, *et al*<sup>13</sup> found that an increase in barriers to exercise (e.g., stressors) during a 12-week home-based exercise program pre-

---

From the Department of Medicine and Department of Epidemiology, Biostatistics and Occupational Health, McGill University; Department of Rheumatology, Jewish General Hospital; and Clinique AGIRE, Montreal, Quebec, Canada.

Supported by the Social Sciences and Humanities Research Council of Canada.

P.L. Dobkin, PhD, Associate Professor, Department of Medicine; R. Ionescu-Ittu, PhD Candidate; M. Abrahamowicz, PhD, James McGill Professor, Department of Epidemiology, Biostatistics and Occupational Health, McGill University; M. Baron, MD, Department of Rheumatology, Jewish General Hospital; S. Bernatsky, MD, PhD; A. Sita, PhD, Clinique AGIRE.

Address reprint requests to Dr. P. Dobkin, McGill University Health Centre, 687 Pine Ave. West, "V" Building, Montreal, Quebec H3A 1A1, Canada. E-mail: patricia.dobkin@mcgill.ca

Accepted for publication June 23, 2008.

---

Personal non-commercial use only. The Journal of Rheumatology Copyright © 2008. All rights reserved.

dicted worse maintenance of exercise at the 3-month followup.

Our goals in this prospective study were: (1) to describe adherence to an integrated multimodal treatment program provided to patients with FM; (2) to identify predictors of adherence; and (3) to examine the relationship between adherence and outcomes.

## MATERIALS AND METHODS

Patients were attending a 3-month multimodal treatment for FM at the Jewish Rehabilitation Hospital (JRH) in Montreal, Canada, which is part of universal medical care. The inclusion criteria were: (1) adult patients with a history of widespread pain for at least 3 months; and (2) pain upon palpation of at least 11 of 18 FM tender points<sup>1</sup>. The exclusion criteria were: (1) cognitive impairment; (2) serious mental illness; and (3) language barriers. A clinical psychologist determined the patients' status prior to the study start. The majority of patients were French-Canadians and all were referred to the rehabilitation program by a physician.

**Procedures.** All patients who registered for the FM rehabilitation program at the JRH and met study criteria were invited to participate by a JRH staff member. The research project coordinator then contacted all interested patients and provided them with information regarding study procedures. Written consent was obtained along with baseline questionnaires. Sociodemographic information was obtained at baseline, while clinical and psychosocial factors were measured both at baseline and at the end of the treatment. Assessment of general and specific adherence and barriers to treatment was carried out at the end of each month during the 3-month treatment period. The questionnaire package for baseline and for Month 3 was administered at the JRH. The questionnaires regarding the adherence and barriers to adherence were mailed at the end of each month during treatment. Our study was approved by the McGill University Institutional Review Board and the ethics committee of the JRH.

**Multimodal treatment program.** The JRH provided an outpatient program consisting of 2 to 4 sessions per week of roughly 2 to 4 h, which included the following in a small-group setting: physiotherapy (7 sessions), occupational therapy (8 sessions), nursing (6 sessions), and cognitive-behaviour therapy (CBT; 8 sessions). These sessions were held as closed groups (i.e., did not admit new members once begun), with each treatment modality delivered by a different health professional. All patients received the same treatment. The program aims to educate patients about FM, prepare them to manage symptoms, improve sleep and coping skills, teach stress management, and to develop a fitness program that progresses slowly over time. For example, the nurse would inform patients about medications and their potential side effects, give tips for improving sleep (e.g., positions), and answer questions about diet. The physiotherapist would demonstrate stretching and muscle strengthening exercises. The occupational therapist would discuss the importance of pacing and taking breaks, activity planning, and good posture. The psychologist would teach relaxation techniques, stress management, effective communication/assertiveness skills, and ways to improve memory and concentration.

### Measures

**Sociodemographic characteristics.** Self-reported information pertaining to age, maternal language, education, employment status, and marital status was collected at baseline.

**Clinical.** The clinical status of patients was assessed both by a physician (at baseline) and using questionnaires completed by the patients (at baseline and at the end of the treatment) by 3 measures: (1) physician assessment of disease activity, (2) disability, and (3) perceived pain.

**Physician assessment:** At baseline, a rheumatologist assessed the number of tender points, the duration of symptoms, and the time since diagnosis of FM. The physician also recorded disease activity using a 100 mm

visual analog scale (VAS)<sup>14</sup>. End descriptors for the VAS were 0 corresponding to no activity to 100 corresponding to very high activity. A review of 24 randomized clinical trials in FM identified the VAS measure of disease activity as the outcome most likely to respond to treatment<sup>15</sup>.

**Disability:** The Fibromyalgia Impact Questionnaire (FIQ)<sup>16</sup> is a reliable, validated self-administered measure of functioning in the past week. The first 10 items address the ability to carry out tasks that require physical strength; 2 items ask respondents to circle the number of days they felt good, as well as the number of days of missed work. Seven items (e.g., pain, fatigue) are measured on 100 mm VAS. A total FIQ score is calculated as an average of 19 items, with higher scores indicating greater disability (range = 0–100). Test-retest reliability coefficients for each item range from 0.56 to 0.95.

**Perceived pain:** The Short Form of the McGill Pain Questionnaire (MPQ-SF)<sup>17</sup> was administered to assess the overall intensity of pain using its VAS, with 0 corresponding to “no pain” and 10 to the “worst possible pain.”

**Psychosocial.** The psychosocial characteristics of the patients were assessed at baseline and at the end of the treatment; these included measures of self-efficacy, pain catastrophizing, perceived stress, and depression.

Self-efficacy was measured with 2 of the 3 subscales of the Arthritis Self-Efficacy Scale<sup>18</sup>: (1) self-efficacy for pain management, and (2) self-efficacy for other (FM) symptoms. Higher scores indicate the person is more confident in her ability to manage her illness. The construct and concurrent validity of this scale has been demonstrated<sup>19</sup>. Higher self-efficacy assessed with this scale has been linked to better outcomes among patients with FM<sup>20</sup>.

**Pain Catastrophizing Scale (PCS):** The PCS<sup>21</sup> consists of 13 items describing different thoughts and feelings that individuals may experience when they are in pain. The PCS instructions ask patients to reflect on past painful experiences, and to indicate the degree to which they experienced each of the 13 thoughts or feelings when experiencing pain, on a 5-point scale with 0 corresponding to “not at all” and 4 corresponding to “all of the time.” The PCS score ranges from 0 to 52, higher scores indicating more ruminating about and magnifying the pain experience, and/or feeling helpless. The PCS has good psychometric properties<sup>21</sup>.

**Perceived Stress Scale (PSS):** The PSS is a 10-item instrument that was used to assess the degree to which patients felt overwhelmed by stressful life situations that had occurred during the past month<sup>22</sup>. Items are scored on a 5-point scale in which 0 corresponds to “never” and 4 corresponds to “very often.” Higher scores mean more stress (range = 0 to 40). In our sample, Cronbach's  $\alpha$  was 0.82 at baseline and 0.76 at 3 months, indicating high internal consistency.

**Depression:** The Center for Epidemiologic Studies-Depression Mood Scale (CES-D) is a 20-item scale that was designed to detect depression in the general population; it is also useful in clinical and psychiatric settings<sup>23,24</sup>. It has good reliability and concurrent and discriminant validity. Scores range from 0 to 60, higher scores indicating greater depression. A CES-D cutoff of 16 is used to screen for depression in the general population.

**Barriers to Treatment Adherence Questionnaire (BTAQ; Appendix A):** The BTAQ<sup>25</sup> was developed by our team to assess barriers to each treatment component (physiotherapy, occupational therapy, nursing, and CBT). The items are the same across treatment components (e.g., lack of time, too much effort, stressful events, weather, fatigue, work). Each item is rated on a 3-point scale as either a small, medium, or large barrier. A separate column was checked if the item was not a barrier. Instructions for all 4 treatment modalities are prefaced with “during the last week” so as to minimize recall bias. Global scores on the BTAQ are computed by summing across the 17 items (1, 2, 3 for small, medium, or large, with 0 for “not a barrier”), and range from 0 to 51. First, separate BTAQ scores representing the magnitude of barriers for each modality were computed for each month over the 3-month treatment period. Next, the means of modality-specific scores were computed, resulting in a total barriers score for each month.

**Adherence.** Attendance at treatment sessions: Medical charts were consulted to determine the number of sessions attended by each patient for each treatment modality throughout the treatment program.

**General Adherence Scale (GAS):** The GAS<sup>26</sup> was used to measure the patient's general tendency to adhere to the skills learned and the recommendations made during the multimodal treatment program. Patients were asked to respond to 5 questions about their general level of difficulty in following treatment recommendations across all 4 treatment modalities and the frequency with which they followed these recommendations. Each question is scored using a Likert scale, with 1 indicating "none of the time" and 6 indicating "all of the time." The instruction to this questionnaire is prefaced with "during the past month." To score the GAS, the 5 items are averaged and then transformed linearly, resulting in a score of 0–100, higher scores indicating more adherence to treatment. Validity has been reported<sup>26</sup>, and the Cronbach's  $\alpha$  was 0.80<sup>27</sup> and 0.88 in a more recent study on adherence to hypertensive medications<sup>28</sup>. In our study, each patient had 3 consecutive scores representing general tendency to adhere to the multimodal treatment program for each of the 3 months. Cronbach's  $\alpha$  coefficients for Months 1, 2, and 3 were 0.72, 0.66, and 0.75, respectively.

**Specific Adherence Scale (SAS; Appendix B):** This questionnaire was developed by our team using the same process described for the BTAQ. Various recommendations of the program were listed (e.g., did aerobic exercises, paced activities) and patients responded on a 4-point Likert scale ranging from 0, corresponding to rarely or none of the time, to 3, most or all of the time. The instruction to this questionnaire is prefaced with "in the past week." A total score was computed as a mean of the 17 items, for each time period (Month 1, 2, and 3), with a range from 0 to 3. For the multivariable analyses, the SAS score was rescaled on a 0 to 100 scale to facilitate comparison with the general adherence scores. We did not examine specific recommendations according to each treatment modality because of an overlap in what different health professionals recommended (e.g., nurses and psychologists encouraged the use of relaxation practice); this is consistent with interdisciplinary treatment principles. If a patient indicated that an item was not recommended, this was taken into consideration by omitting the item from the mean score computation.

**Statistical analyses.** Descriptive statistics, including proportions, means and standard deviations (SD), medians and interquartile ranges (IQR), and Pearson correlations were calculated. The mean change from baseline to Month 3 (post-treatment) was estimated for various measures and tested for statistical significance with paired 2-tailed t-tests. We report when the statistical significance of the tests is affected by the Bonferroni correction. Multivariable analyses addressed the second and the third objectives of our study, with different methodologies.

The analyses related to the second objective investigated the potential predictors of general adherence to treatment (GAS) across post-baseline assessments. The analysis employed a generalized estimating equations (GEE) model with an exchangeable covariance structure<sup>29</sup>, to account for the intra-subject correlations between repeated outcome measurements. The GEE model included GAS measurements at Months 2 and 3 as the dependent variable and 5 *a priori* selected independent variables: the total barriers score (BTAQ), perceived stress (PSS), pain catastrophizing (PCS), self-efficacy for other FM symptoms, and physician assessment of disease activity (VAS). Given that we had repeated monthly measurements for the total barriers score, we used the barrier score at a given month to predict GAS observed in the next month. Thus, total BTAQ score at Months 1 and 2 was used to predict, respectively, GAS at Months 2 and 3. For the other 4 predictors, we used their baseline value to predict GAS at both Months 2 and 3. All 5 predictors were kept in the final model and reported regardless of their statistical significance. The model adjusted also for potential changes over time in adherence, by including a binary indicator of Month 3, with Month 2 as reference. The same multivariable GEE analysis was then replicated using the SAS as the dependent variable.

The analyses related to the third objective investigated the potential association between the general adherence (GAS) measured in the first month of treatment and the magnitude of the change from baseline to

Month 3, separately for each of the 2 clinical outcomes: (1) disability (FIQ), and (2) pain intensity (MPQ). For each outcome, we used a multiple linear regression model, where the effect of adherence was adjusted for the following potential confounders: (1) for the disability outcome: pain catastrophizing, self-efficacy for other FM symptoms, physician assessment of disease activity and baseline disability; and (2) for the pain outcome: pain catastrophizing, self-efficacy for pain, physician assessment of disease activity, and baseline pain. The potential confounders were selected based on the results for the predictive model for adherence (Objective 2) and the clinical expertise of the investigators. We decided *a priori* to keep in the final models both the GAS and the baseline value of the corresponding clinical outcome (respectively, disability or pain intensity) regardless of their statistical significance, while the other potential confounders were excluded if their effects were statistically nonsignificant at  $p < 0.05$ , using the backward elimination technique.

Independent variables included in both types of multivariable analyses (GEE and conventional linear regression) were standardized by subtracting the mean and dividing by 2 SD. Accordingly, each estimated regression coefficient represents the adjusted difference in outcome scores (GAS, SAS, FIQ, and MPQ) between 2 hypothetical subjects, one with the score for the predictor variable 1 SD below the mean and one with the score for the predictor variable 1 SD above<sup>30</sup>.

There were 2 types of missing data in our study. First, some subjects completed a questionnaire, but missed some items within the questionnaire. Second, a couple of subjects did not complete an entire questionnaire. Missing data for subjects who omitted an item in a particular questionnaire were handled by imputing the mean of the corresponding item scores for all subjects who did not miss that item. For subjects who did not complete a questionnaire at a particular monthly followup assessment, we carried forward the corresponding score from the last available questionnaire of the same subject. Finally, based on outlier diagnostics<sup>31</sup> for the adherence outcomes, we identified 2 potential outliers with exceptionally high values of the influence statistics (DF-beta). Further analyses revealed that both subjects had an unusual combination of very low pain catastrophizing scores and very low adherence scores and/or apparently inconsistent patterns of change in specific versus general adherence (data not shown). Accordingly, these 2 subjects were excluded from the analyses for general and specific adherence. All analyses used SAS statistical software (version 8 02; SAS, Cary, NC, USA).

The model selection strategies described above for the second and third objectives were employed to avoid the risk of model overfitting that may occur when the sample size is not large and the multivariable model includes many measures. However, this parsimonious model selection strategy may miss some potential predictors and/or confounders (e.g., sociodemographic factors, such as age or marital status, may be associated with both adherence and outcomes). Therefore, we performed sensitivity analyses in which we considered additional variables available in our database: age at recruitment, marital status (married vs single, divorced, or widowed), education (post-secondary or more vs less than post-secondary), FM duration (yrs since the first FM diagnosis), and working status (working vs non-working, retired, or student). We then relied on a backward elimination technique to gradually eliminate the least significant sociodemographic variables, so that each sensitivity analysis final model for adherence predictors included all 5 *a priori* selected variables (regardless of their statistical significance) and only those sociodemographic variables that were significant at  $p < 0.05$ . Similarly, each sensitivity analysis final model for outcomes included the 2 *a priori* selected variables (regardless of their statistical significance) and only those sociodemographic variables that were significant at  $p < 0.05$ .

## RESULTS

**Participants.** Among women who were initially approached, only a few declined to participate; the most common reasons for unwillingness to enter the study were lack of time, par-

ticipating in another study, not interested in completing questionnaires (data not shown). Of the 70 women who provided consent, 7 (10%) dropped out before completing the baseline assessment. Table 1 presents the sociodemographic and clinical information collected at baseline for the 63 women included in the final analyses. The age ranged from 28 to 74 years, with a mean of 51 years. Given that all were required to have a minimum of 11 tender points to be eligible for the program, the mean of the tender point counts for the whole group is high (16 tender points).

**Description of adherence (Objective 1).** Median attendance was 87% (IQR 75%-100%) for physiotherapy; 100% (IQR 83%-100%) for nursing; 86% (IQR 64%-86%) for CBT; and 83% (IQR 80%-100%) for occupational therapy. Thus, overall participation in the multimodal 3-month program was very good.

Table 1. Descriptive statistics for the sample at baseline.

Variables	Total Subjects, n	N (%) or mean $\pm$ SD (range)
<b>Sociodemographic</b>		
Age, yrs	58	51.5 $\pm$ 10.7 (28–74)
Ethnicity (Caucasian %)	60	57 (95.0)
Maternal language (French %)	61	47 (77.0)
Education, yrs	61	12.1 $\pm$ 3.1 (5–22)
Marital status (%)	62	
Married		39 (62.9)
Single		11 (17.7)
Separated/divorced		10 (16.1)
Widowed		2 (3.2)
Employment status (working %)	58	27 (46.5)
<b>Clinical</b>		
Duration of FM symptoms, yrs	58	15.0 $\pm$ 11.8 (2–51)
Diagnosis duration, yrs	62	7.7 $\pm$ 5.6 (1–20)
Tender points	63	15.8 $\pm$ 3.6 (4–18)
MD VAS	63	74.4 $\pm$ 19.8 (7–97)

FM: fibromyalgia; MD VAS: physician assessment visual analog scale.

The mean general adherence (GAS) score (over all 3 measurements at Months 1, 2, and 3) was 62 on a 0 to 100 scale. Figure 1 presents the changes over time in general adherence, specific adherence, and barriers for adherence to treatment scores. Changes from Month 1 to post-treatment were statistically nonsignificant at  $p < 0.05$  for specific adherence and barriers, but were significant ( $p = 0.03$ ) for general adherence. Even though the latter change became marginally nonsignificant after the Bonferroni adjustment for multiple testing, it is worth noting that this trend toward increasing general adherence scores was concomitant with a decreasing trend in the barriers to adherence.

As expected, there was a statistically significant correlation between general adherence and specific adherence scores at all timepoints, with a slightly higher correlation in the first month of the treatment (Pearson's  $r = 0.58$ ,  $p < 0.0001$ ) than near the end of the treatment ( $r = 0.45$ ,  $p < 0.0001$ ).

Pain and fatigue were the 2 barriers most frequently mentioned across all treatment components. The BTAQ was also able to determine that some barriers were more commonly experienced for certain treatment components. Stressful events were barriers for all components except physiotherapy. Too much effort was a barrier for all components except nursing. For example, the presence of other illness and adherence requiring too much effort were barriers more commonly cited for physiotherapy and occupational therapy; whereas lack of time and stressful events were perceived as important barriers to CBT.

**Predictors of adherence.** Figure 2 presents the results of the multivariable GEE analyses for the 5 *a priori* selected potential predictors of general adherence (Panel A) and specific adherence (Panel B). The numerical values for point estimates and  $p$  values are shown in Figure 2. The 2 panels of Figure 2 indicate that the composite BTAQ measure for barriers to treatment was the most important predictor for both adherence measures. Specifically, independently of the

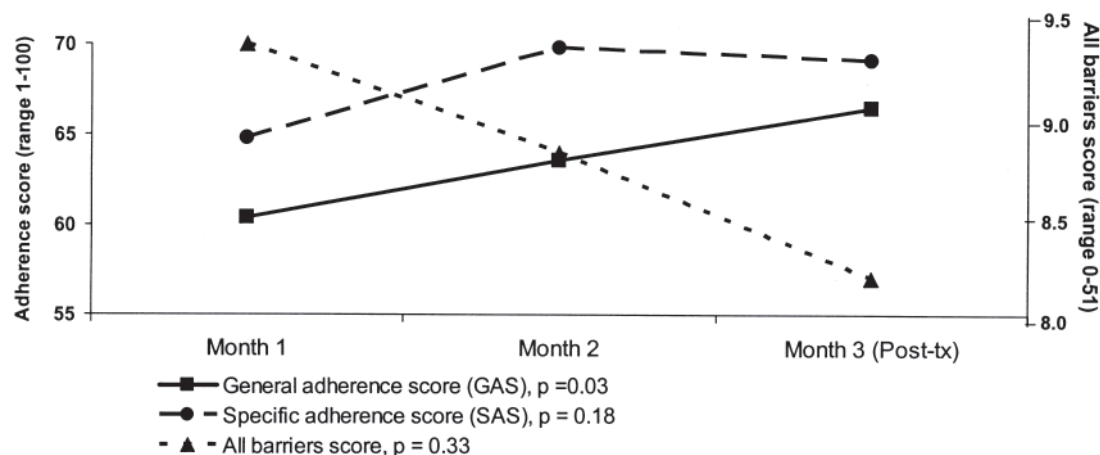


Figure 1. Adherence during treatment.

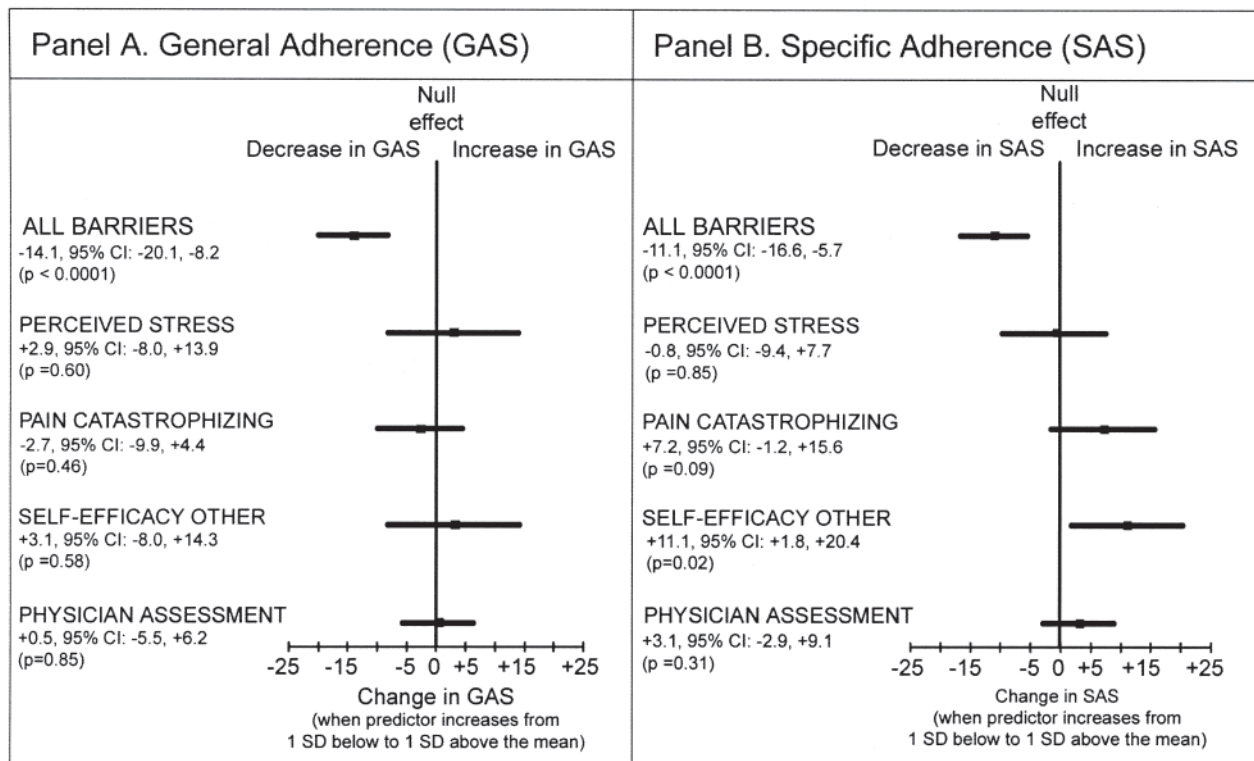


Figure 2. Predictors of adherence to treatment. General and specific adherence were measured on a 0–100 scale. Estimates are based on GEE multivariable linear regression models that take into account repeated measures. Black squares represent point estimates for the adjusted association between a given independent variable and adherence; horizontal line marks the corresponding 95% CI. Numerical values for the point estimates, 95% CI, and p values are shown to the left. When the line does not cross zero, the effect is statistically significant at  $\alpha = 0.05$  ( $p < 0.05$ ). GAS: General Adherence Scale, SAS: Specific Adherence Scale.

other variables shown in Figure 2, the adherence scores of patients with a high barriers score (1 SD above the mean) in the preceding month were, on average, more than 10 points lower than those of subjects with a low barriers score (1 SD below the mean) ( $p < 0.0001$  for both models). Most other potential predictors had no statistically significant associations with either general or specific adherence (Figure 2). The only exception was that higher self-efficacy for other FM symptoms was a statistically significant predictor of higher specific adherence (Figure 2B,  $p = 0.02$ ); further, higher pain catastrophizing had a marginally nonsignificant association with specific adherence ( $p = 0.09$ ).

*Changes in clinical and psychosocial factors from baseline to post-treatment.* Table 2 summarizes the changes from baseline to post-treatment for the clinical and behavioral measures that were assessed at both times. All changes were in the expected direction and remained statistically significant even after the Bonferroni correction. The improvement in depression was clinically significant, as the mean CES-D dropped from 26 to 17, where 19 is the accepted cutoff for patients with chronic pain.

*Association between general adherence on post-treatment disability and pain.* Figure 3 presents the results of the multivariable analyses investigating the associations of general

Table 2. Changes in predictors from baseline to Month 3 post-treatment.

Predictors	Mean Baseline (95% CI)	Mean at Month 3 (95% CI)	Change (95% CI)
Self-efficacy (other)	48.9 (43.5, 54.4)	67.7 (63.8, 71.5)	+18.7(+12.1, +25.4)*
Self-efficacy (pain)	42.3 (37.1, 47.4)	63.7 (59.1, 68.3)	+21.5 (+14.6, +28.3)*
Pain catastrophizing	29.5 (26.5, 32.5)	18.0 (15.0, 21.1)	-11.4 (-15.6, -7.2)*
Perceived stress	22.8 (21.1, 24.6)	18.5 (16.8, 20.1)	-4.5 (-6.8, -1.9)**
Depression	26.0 (22.8, 29.1)	17.1 (14.2, 20.0)	-8.9 (-13.2, -4.6)*
Perceived pain	6.5 (5.9, 7.1)	5.2 (4.6, 5.9)	-1.26 (-2.2, -0.4)**
Disability	64.7 (60.9, 68.6)	52.2 (47.3, 57.0)	-12.6 (-18.6, -6.5)*

\*  $p < 0.0001$ ; \*\*  $p < 0.01$ .

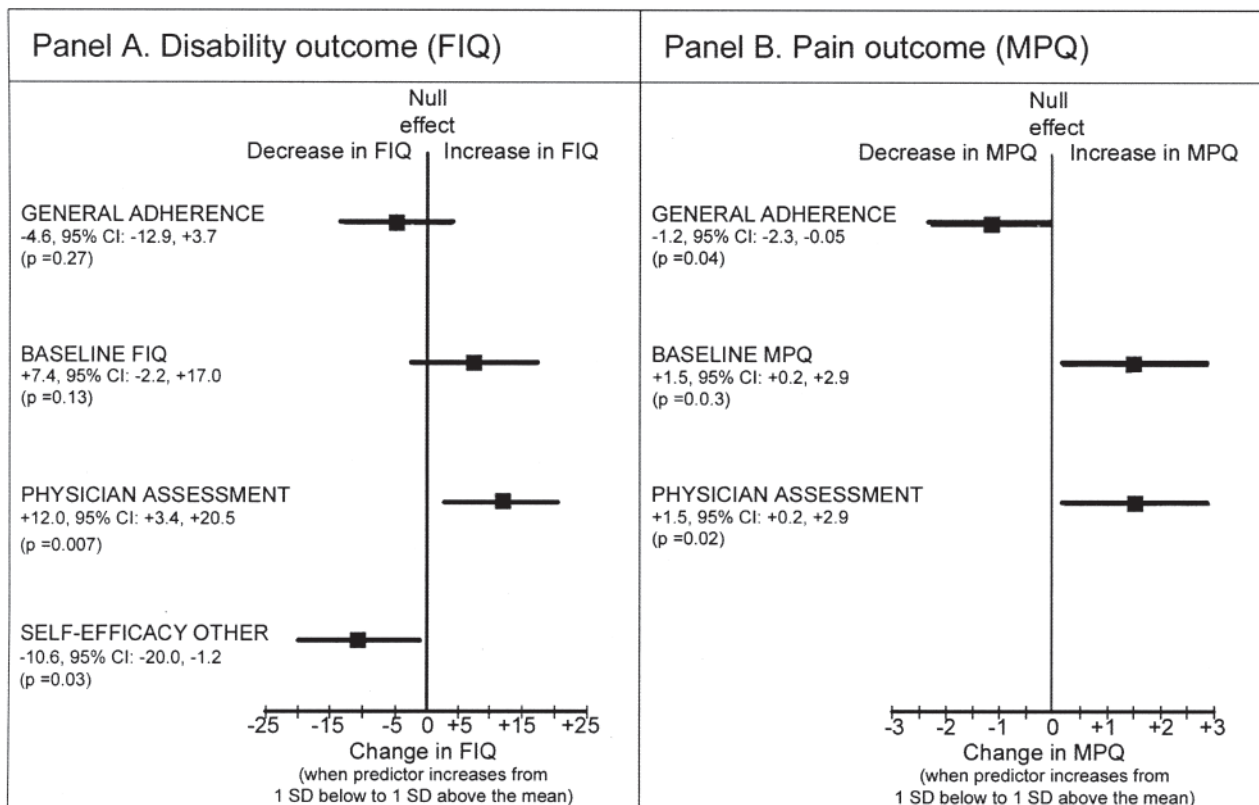


Figure 3. Association between general adherence and post-treatment outcomes. Disability (Fibromyalgia Impact Questionnaire, FIQ) was measured on a 0–100 scale. Pain (McGill Pain Questionnaire, MPQ) was measured on a 0–10 scale. Estimates are based on conventional multivariable linear regression models. Interpretation of results is the same as in Figure 2.

adherence to treatment with post-treatment disability FIQ (Panel A) and pain MPQ (Panel B). Interpretation of results in Figure 3 is the same as in Figure 2. After adjusting for potential confounders, general adherence measured in the first month was not a statistically significant predictor of disability at post-treatment (lines in Panel A cross zero,  $p = 0.27$ ). However, higher general adherence (GAS) in the first month predicted pain intensity at post-treatment (Panel B,  $p = 0.04$ ), even after adjusting for baseline MPQ, physician assessment of disease activity, and self-efficacy. Other statistically significant predictors of lower disability at post-treatment included higher baseline self-efficacy for other FM symptoms ( $p = 0.03$ ) and lower baseline FM activity, based on the physician's assessment ( $p = 0.007$ ). Specifically, the disability score is about 15 points lower among patients who had high baseline self-efficacy, and the disability score is about 15 points higher among patients who had high disease activity. Similarly, decreased pain intensity post-treatment (1 point lower) was associated with lower pain intensity at baseline and lower FM activity (the pain intensity was about 1.5 points higher among patients with high physician-rated scores).

**Sensitivity analyses.** None of the sociodemographic variables had a significant association with general adherence (GAS), post-treatment disability (FIQ), or post-treatment

pain (MPQ), so that sensitivity analyses did not change the results for these outcomes (data not shown). However, age at recruitment was identified as a predictor of specific adherence (SAS), with an average 3 points increase in SAS score per decade increase in age ( $p = 0.02$ ). Additional adjustment for age did not change the statistical significance of the association between specific adherence and any of the 5 *a priori* selected variables. Specifically, higher score on all barriers ( $p = 0.0006$  and lower self-efficacy  $p = 0.03$ ) remained a significant predictor of lower specific adherence (data not shown).

## DISCUSSION

In this study, we showed that among patients with FM participating in a multimodal program, attendance to classes and general and specific adherence to treatment scores were quite good throughout the 3-month treatment program.

For general adherence, the most important predictor was all barriers, while pain catastrophizing was marginally significant. Specifically, more barriers and more use of this maladaptive coping style predicted lower adherence. The finding with regard to barriers is consistent with Dobkin, *et al*<sup>10</sup>, who found that an increase in barriers to a home-based exercise program during treatment predicted worse maintenance of aerobic exercise in the 3-month period following

treatment; this was not the case, however, during treatment with the same patients<sup>32</sup>. Perhaps this discrepancy is explained by the different measures employed, as well as the fact that a multimodal program was being studied (rather than only exercise). As for pain catastrophizing, this cognitive style can immobilize a patient with regard to taking positive steps to manage chronic pain. It involves rumination, magnification of pain, and feeling helpless. These thoughts and feelings can block efforts towards action, including adherence to a pain treatment program. To our knowledge, this is the first study to examine the relationship between this coping style and adherence in FM.

For specific adherence, the predictors were barriers to treatment and self-efficacy for other FM symptoms, and older age. Older patients adhered better. Barriers interfered with adherence whereas self-efficacy positively affected adherence; i.e., the more confident a patient felt with regard to handling other symptoms (e.g., fatigue), the more likely she was to follow specific treatment recommendations. This latter finding concurs with Lynch, *et al*<sup>12</sup>, who noted that self-efficacy was a predictor of adherence to an 8-week mindfulness-based stress reduction program; but in that study, adherence was measured by attendance to classes.

When comparing predictors of general and specific adherence, a few comments are in order. First, the General Adherence Questionnaire covers the “past month,” whereas the Specific Adherence Scale covers the “past week.” This may explain, in part, some variance in predictors identified for the 2 outcomes. Despite the different timeframe, these 2 measures correlated well, as expected ( $r$  values = 0.45–0.57;  $p$  values = 0.0001). Indeed, higher barriers were associated significantly with lower scores on both adherence measures. This highlights the need to directly discuss with patients obstacles that prevent them from doing what is recommended. The Barriers to Adherence to Treatment questionnaire could easily be brought into the consultation room so that the patient and healthcare provider could work together to solve problems that prevent the patient from engaging in the treatment plan. Treatment needs to be discussed, taking into account the patient’s lifestyle.

As is evident in Table 2, the patients improved on all measures pre- to post-treatment (decreases in disability, depression, stress, pain catastrophizing; increases in self-efficacy). While this was not an efficacy study and the results cannot be attributed to the treatment *per se*, these encouraging results make interpretation of the next set of analyses more meaningful. While adherence tended to increase over the 3-month period of treatment, what we really wanted to know was, does adherence to treatment matter?

When the outcome was FM disability, there was a trend for higher general adherence to be related to lower disability scores at post-treatment, but it was not statistically significant. Nonetheless, 2 statistically significant predictors were identified: more self-efficacy for other FM symptoms and

higher physician assessment of FM activity at baseline. This makes sense, as these patients probably felt less overwhelmed by their FM, adhered better to treatment, and improved. Interestingly, on average, the disability score was about 15 points higher among patients who had high physician-rated disease activity at baseline. Thus, physicians appear to be able to judge who will do better or worse with FM. This finding is also consistent with a study by Sewitch and colleagues<sup>33</sup>, who found that the higher overall non-adherence in patients with FM was predicted by higher physician-patient discordance during the medical visit. In our study, rheumatologists’ relatively high estimates of FM activity may have given patients the impression that they were taken seriously and not dismissed as exaggerating their symptoms; this could positively influence adherence.

Higher general adherence was a statistically significant predictor of lower pain intensity at post-treatment. On average, the pain intensity score was 1 point lower (on a 1 to 10 scale) for patients with high adherence, compared to low adherence patients with the same pre-treatment pain score. Physician assessment of disease activity was also a predictor in that, on average, the pain intensity score was about 1.5 higher in patients who had a high physician-rated disease activity, at baseline.

It is difficult to compare these results to others’ data as so little work has been done in the domain. We were able to find embedded in a few studies some attention to adherence and its relationship to outcomes for patients with FM. For example, Williams, *et al*<sup>34</sup> employed a brief form of CBT and asked patients to keep daily diaries with regard to 9 skills taught in therapy. A research assistant telephoned the patient once a month for 1 year to retrieve these data. Aggregate ratings were then classified for each skill that indicated the pattern of adherence to each skill (e.g., never met the goal in 12 months or met the goal sometimes, etc.) Success in improving physical functioning was not directly associated with the level of adherence.

While our study adds to the growing literature on adherence in FM, a few limitations need to be taken into account. First, the sample size was moderate, restricting the number of variables that could be examined in the statistical analyses. As ours was a descriptive study, carried out in a public health center, there could not be a control group. However, it was not a randomized clinical trial, nor was the purpose of our study to determine efficacy of the program. It did successfully answer the questions it was designed to address. Finally, it is possible that there was a selection bias in that those who agreed to participate in the study may be more compliant in general. This is true for any study of adherence. Thus, these results pertain to patients who attend programs, such as this one, and are willing to be monitored.

The clinical implications of our study are as follows. Since barriers are important for adherence and adherence is related to outcomes, using a questionnaire concerning barriers

ers (such as the BTAQ) as a platform to discuss these issues is recommended. The SAQ may be useful if its items reflect the program offered; it could be modified to fit the approach used. While it has not been examined closely for its psychometric properties, the data from our study suggest it is related to both general adherence and barriers. Our study alerts researchers and clinicians to the fact that not all patients

adhere to healthcare professionals' recommendations and one should not assume a treatment is not helpful without examining adherence to it first.

## REFERENCES

1. Wolfe F, Smythe HA, Yunus MB, Bennett RM, Bombardier CH, Goldenberg DL. 1990 criteria for the classification of fibromyalgia:

## Appendix A. (A separate form was provided for each treatment modality.)

### Barriers to Treatment Adherence (CBT)

The JRH FM Program involves making changes in your life-style and health-related behaviours. Change is not always easy because **barriers** may block the way. Listed below are some possible reasons why patients have not been able to make the recommended changes for the psychology component of the treatment program. Please check only if the items listed pertain to **you**, with regard to the psychologist's recommendations. Circle S (small), M (medium), or L (large) to indicate how big the barrier was for you **during the past week**. Put a mark in the right hand column if the item was not a barrier.

Barriers	Psychology			Not A Barrier
1. Limited time	S	M	L	
2. Too much effort	S	M	L	
3. Inconvenient (e.g., travel)	S	M	L	
4. No child care	S	M	L	
5. Stressful events	S	M	L	
6. Weather	S	M	L	
7. Not enjoyable	S	M	L	
8. No social support	S	M	L	
9. Other illness	S	M	L	
10. Too costly	S	M	L	
11. Fatigue	S	M	L	
12. Pain	S	M	L	
13. Lack of motivation	S	M	L	
14. Work	S	M	L	
15. Limited community	S	M	L	
16. No FM group support	S	M	L	
17. Other, specify	S	M	L	

## Appendix B. Specific Adherence Scale (SAS)

Project: FM III  
Form: SPECAD  
I.D.  
Date:

Below is a list of things that the JRH FM team may have recommended you do as part of your **treatment for fibromyalgia**. Please indicate **how often you have done each of the following in the past week**, by circling one number on each line. Indicate if it was **NOT** recommended by putting an **X** in the final box.

	Rarely or none of the time 0 (<1 day)	Some or little of the time 1 (1-2 days)	Occasionally or a moderate amount of the time 2 (3-4 days)	Most or all of the time 3 (5-7 days)	Not part of my treatment recommenda- tions
1. Took prescribed medication, as directed	0	1	2	3	
2. Used effective sleep habits	0	1	2	3	
3. Did aerobic exercises	0	1	2	3	
4. Performed stretching exercises	0	1	2	3	
5. Performed strengthening exercises	0	1	2	3	
6. Used pacing techniques	0	1	2	3	
7. Kept scheduled appointments with health professionals	0	1	2	3	
8. Took rest breaks, as needed	0	1	2	3	
9. Practiced proper rest and sleeping positions	0	1	2	3	
10. Took time to organize a daily schedule in order to balance activity and rest	0	1	2	3	
11. Took time to practice relaxation techniques (e.g., deep breathing, self-hypnosis techniques)	0	1	2	3	
12. Socialized more	0	1	2	3	
13. Gave and received social support	0	1	2	3	
14. Paid attention to posture	0	1	2	3	
15. Used community services and resources	0	1	2	3	
16. Followed diet recommendations	0	1	2	3	
17. Used memory and concentration activities	0	1	2	3	

- Report of the multicenter criteria committee. *Arthritis Rheum* 1990;33:160-72.
2. Crofford LJ, Clauw DJ. Where are we a decade after the American College of Rheumatology Classification Criteria were developed. *Arthritis Rheum* 2002;46:1136-8.
3. van Santen M, Bolwijn P, Verstappen F, et al. A randomized clinical trial comparing fitness and biofeedback training versus basic treatment in patients with fibromyalgia. *J Rheumatol* 2002;29:575-81.
4. Cedraschi C, Desmeules J, Rapiti E, et al. Fibromyalgia: a randomised, controlled trial of a treatment programme based on self management. *Ann Rheum Dis* 2004;63:290-6.
5. Turk DC, Sherman JJ. Treatment of patients with fibromyalgia syndrome. In: Turk D, Gatchel R, editors. *Psychological approaches to pain management: a practitioner's handbook*. 2nd ed. New York: Guilford; 2002.
6. Luedtke CA, Thompson JM, Postier JA, Neubauer BL, Drach S, Newell L. A description of a brief multidisciplinary treatment program for fibromyalgia. *Pain Manag Nurs* 2005;6:76-80.
7. Lemstra M, Olszynski WP. The effectiveness of multidisciplinary rehabilitation in the treatment of fibromyalgia: a randomized controlled trial. *Clin J Pain* 2005;21:166-74.
8. Karjalainen KA, Hurri H, Jauhiainen M, et al. Multidisciplinary rehabilitation for fibromyalgia and musculoskeletal pain in working age adults (Cochrane Review). *The Cochrane Library* 2005;4:1-17.
9. Schachter CL, Busch AJ, Peloso PM, Sheppard MS. Effects of short versus long bouts of aerobic exercise in sedentary women with fibromyalgia: A randomized controlled trial. *Phys Ther* 2003;83:340-58.
10. Dobkin PL, Sita A, Sewitch MJ. Predictors of adherence to treatment in women with fibromyalgia. *Clin J Pain* 2006;22:286-94.
11. Edinger JD, Wohlgenuth WK, Krystal AD, Rice JR. Behavioral insomnia therapy for fibromyalgia patients: a randomized clinical trial. *Arch Intern Med* 2005;165:2527-35.
12. Lynch GV, College E, College H. Patient variables associated with treatment completion in a mindfulness meditation-based stress reduction (MBSR) treatment for fibromyalgia: Implications for prescriptive matching and participation enhancement [thesis]. Louisville, KY: Department of Psychological and Brain Sciences, University of Louisville; 2004.
13. Dobkin PL, Abrahamowicz M, Fitzcharles MA, Dritsa M, Da Costa D. Maintenance of exercise in women with fibromyalgia. *Arthritis Rheum* 2005;53:724-31.
14. Price DD, McGrath PS, Rafii A, Bucklingham B. The validation of visual analogue scales as ratio scale measures for chronic experimental pain. *Pain* 1983;17:45-56.
15. White KP, Harth M. An analytical review of 24 controlled clinical trials for fibromyalgia syndrome (FMS). *Pain* 1996;64:211-9.
16. Burckhardt CS, Clark SR, Bennett RM. The Fibromyalgia Impact Questionnaire: Development and validation. *J Rheumatol* 1991;18:728-33.
17. Melzack R. The short-form McGill Pain Questionnaire. *Pain* 1987;30:191-7.
18. Lorig K, Chastain RI, Ung E, Shoor S, Holman HR. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. *Arthritis Rheum* 1989;32:37-44.
19. Lorig K, Holman HR. Arthritis self-efficacy scales measure self-efficacy. *Arthritis Care Res* 1998;11:155-7.
20. Buckelew SP, Huyser B, Hewett JE, et al. Self-efficacy predicting outcome among fibromyalgia subjects. *Am Coll Rheumatol* 1996;9:97-104.
21. Sullivan MJL, Bishop S, Pivik J. The Pain Catastrophizing Scale: Development and validation. *Psychol Assess* 1995;7:524-32.
22. Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Soc Behav* 1983;24:385-96.
23. Radloff LS, Locke BZ. Community surveys of psychiatric disorders. In: Weisman NM, Myers JK, Ross CE, editors. *The Community Mental Health Assessment Survey and the CES-D scale*. New Brunswick, NJ: Rutgers University Press; 1986.
24. Martens MP, Parker JC, Smarr KL, Hewett JE, Slaughter JR, Walker SE. Assessment of depression in rheumatoid arthritis: a modified version of the Center for Epidemiologic Studies Depression Scale. *Arthritis Rheum* 2005;49:549-55.
25. Dobkin PL, De Civita M, Bernatsky S, Filipski M, Sita A, Baron M. Preliminary validity of the Barriers to Treatment Questionnaire in fibromyalgia: Combining quantitative and focus group data. [unpublished].
26. Sherbourne CD, Hays RD, Ordway L, DiMatteo MR, Kravitz RL. Antecedents of adherence to medical recommendations: Results from the Medical Outcomes Study. *J Behav Med* 1992;15:447-68.
27. DiMatteo MR, Sherbourne CD, Hays RD, et al. Physicians' characteristics influence patients' adherence to medical treatment: results from the Medical Outcomes Study. *Health Psychol* 1993;12:93-102.
28. Hamilton GA. Measuring adherence in a hypertension clinical trial. *Eur J Cardiovasc Nurs* 2003;2:219-28.
29. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika* 1986;73:13-22.
30. Gelman A, Hill J. *Data analysis and multilevel/hierarchical models*. New York: Cambridge University Press; 2007.
31. Todarello O, Taylor GJ, Parker JDA, Fanelli M. Alexithymia in essential hypertensive and psychiatric outpatients: A comparative study. *J Psychosom Res* 1995;39:987-94.
32. Dobkin PL, Da Costa D, Abrahamowicz M, Dritsa M, du Berger R, Fitzcharles MA. Adherence during an individualized home based 12-week exercise program in women with fibromyalgia. *J Rheumatol* 2006;33:333-41.
33. Sewitch MJ, Dobkin PL, Bernatsky S, et al. Medication non-adherence in women with fibromyalgia. *Rheumatology Oxford* 2004;43:648-54.
34. Williams D, Cary M, Groner K. Improving physical functional status in patients with fibromyalgia; a brief cognitive behavioral intervention. *J Rheumatol* 2002;29:1280-6.