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Internet-Enhanced Management of Fibromyalgia: A Randomized Controlled Trial

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1. Introduction

Fibromyalgia (FM) is a chronic pain condition with a prevalence of 2–4% in the general population [71]. Clinically, individuals with FM present with a variety of physical symptoms that include widespread pain, fatigue, sleep disturbance, decrements in physical functioning, and disruptions in psychological functioning (e.g., cognitive difficulties, mood disturbances, and lack of well-being) [8;38;70]. FM occurs more frequently in females [71] and is associated with higher than average healthcare utilization [9].

Pharmacological agents, particularly those classified as dual reuptake inhibitors and anticonvulsants possess the strongest evidence for efficacy in FM [27]. Despite wide use however, only about 40% of patients taking these medications experiences a clinically important reduction in pain [4]. For many patients, optimal care may require the combination of pharmacological and non-pharmacological interventions such as cognitive-behavioral therapy (CBT) and exercise [27].

Evidence supporting the efficacy of non-pharmacological treatment in FM is strong (e.g., [67;61;11;12;15;62]); yet the integration of non-pharmacological interventions into routine clinical care has been slow. Potential barriers to integration include: lack of physician

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Summary Statement

The Internet can be used to deliver evidence-based non-pharmacological interventions for fibromyalgia in rural settings. This trial demonstrated improvements in pain and physical functional status.

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knowledge or time to implement non-pharmacological approaches, limited access to qualified therapists, insufficient third party coverage of non-pharmacological approaches, and patient burden associated with traveling to and from therapy. Thus, most patients with FM do not receive these evidence-based components of care.

The Internet is increasingly used as a service delivery platform for many health and mental health conditions [19;66]. In many instances, efficacious face-to-face interventions are adapted for use on the Internet as a means of addressing the above mentioned barriers to care. Such adapted therapies frequently retain effect-sizes rivaling those of the more traditionally delivered interventions [41;28;19] with the added benefits of convenience, privacy, and providing clinicians with the ability to provide a full-spectrum of care to patients even in remote areas [29;48]. Several cognitive-behavioral oriented Internet interventions have been studied for use with chronic pain (e.g., [14;10;46]); but to date, no web-based interventions have been studied addressing the complicated issues associated with FM.

The current study evaluated the incremental utility of adding an Internet-based behavioral self-management program to the standard care of individuals with FM. The study used an intent-to-treat (ITT) randomized controlled trial design comprised of (a) a standard care group (STD) and (b) a standard care plus web-enhanced behavioral self-management (WEB-SM) program delivered to a mostly rural patient population.

2. Methods

2.1. Participants and setting

This study was conducted at the Avera Research Institute in Sioux Falls, South Dakota, United States. The Institute is home to a large telemedicine network linking 54 clinics covering a catchment radius of 500 miles in a five state region (i.e., South Dakota, North Dakota, Nebraska, Iowa, and Minnesota). Participants were referred to the study by their primary or specialist care physician, who received recruitment materials through their local provider network. The study was conducted in accordance with the Institutional Review Boards of Avera Health, the University of Michigan, and the Department of Defense (sponsor).

2.2. Inclusion/exclusion criteria

Inclusion criteria consisted of the following: (1) fulfillment of the American College of Rheumatology (ACR) research classification criteria for FM [72], (2) 18 years of age, (3) be under the standard medical care of a physician for at least 3 months prior to enrollment so as to minimize the initiation of new pharmacological agents across subjects, and (4) possess basic computer literacy and computer access. Subjects were excluded from participation if they had any of following: (1) A severe physical impairment that precluded receiving/using the website or using the self-management skills contained on the website, (2) Co-morbid medical illnesses capable of causing a worsening of physical functional status independent of FM (e.g., cardiopulmonary disorders, uncontrolled endocrine or allergic disorders, malignancy within 2 years), (3) Any present psychiatric disorder involving a history of psychosis, current suicide risk or attempt within 2 years of the study, or substance abuse within 2 years, (4) Prior CBT for pain management, and (5) A pending status associated with disability compensation or the receipt of disability compensation for less than two years.

2.3. Study flow

Using the flow diagram provided by the CONSORT statement [7], Figure 1 provides a schematic illustrating the progression of participants through the study design. As indicated, 140 individuals were assessed for eligibility with 22 being excluded based upon inclusion/exclusion criteria. The majority of exclusions were based upon failing to meet ACR criteria.

The study sample consisted of 118 participants. All participants continued to receive standard medical care from their primary or specialist physician but were randomly allocated to either standard care plus WEB-SM (n=59) or to standard care (n=59). Eight individuals from the standard care and 4 individuals from the WEB-SM intervention were lost to follow-up due to relocation, medical complications, or personal reasons for leaving the study prior to the final endpoint. The attrition rate for the study was 10.2%. An intent-to-treat approach was used in this study; therefore all 118 individuals who were randomized at baseline were included in the subsequent analyses.

2.4. Randomization procedure

Participants were randomly assigned to a treatment condition using a 1:1 ratio. A computerized randomization program assisted in the development of the allocation sequence for study. Allocation concealment was utilized to prevent selection bias and group assignment was given to both the participant and selected study staff only after completion of the baseline assessments.

2.5. Schedule of assessments

Following informed consent, each participant received a history and physical examination to verify diagnosis and to confirm study eligibility. Participants deemed eligible to participate, were asked to complete a battery of assessments in order to obtain baseline values of outcome measures. All patient-reported outcome measures were obtained by asking the participant to complete the questionnaires online in a supervised clinic setting. Participants in both arms of the study were asked to return to the clinic at the end of 6 months in order to complete the same battery for a second time (i.e., study endpoint). Study personnel assigned to assist participants in the clinic setting were blinded to participants' treatment assignment. As part of the WEB-SM program, participants in this arm of the study tracked their use of self-management skills on a monthly basis as a metric of adherence to this experimental addition to standard care.

2.6. Primary outcome measures

2.6.1. Physical Functional Status—The SF-36 Physical Functioning Scale [65] served as a primary outcome measure for the study. The SF-36 is a widely used measure of self-reported functional status and was developed as a generic measure capable of being used and compared across differing disease states. The use of this single subscale of the SF-36 is supported by recent literature as being a better measure of change for clinical trials than the composite summary scores that can be derived from this same measure [30;57].

2.6.2. Clinical Pain—The Severity Scale of the Brief Pain Inventory (BPI; [59] served as the other primary outcome variable for the study. The BPI is a multidimensional pain measure validated for use in chronic, nonmalignant pain. This scale takes into account current, worst, least, and average pain intensity levels over the past week.

2.7. Secondary outcome measures

Several common co-morbid symptoms were assessed as recommended by OMERACT, an international initiative to improve outcome measurement in rheumatology [37]. Co-morbid symptoms included fatigue, using the Multidimensional Fatigue Inventory (MFI; [54]), problems with sleep, using a composite of sleep problems from the MOS Sleep Scale (i.e., Index 2) [56], and mood as assessed by the Center for Epidemiological Studies Depression Scale (CES-D; [32] and by the State-Trait Personality Inventory (STPI;[55]) for anxiety.

In addition, both OMERACT and IMMPACT [21] recommend assessing patient global impression of change (PGIC) following a treatment trial. PGIC is a single-item measure

designed to capture patients' overall impression of improvement or worsening at the study endpoint compared to baseline. This single item has been used in many of the clinical trials supporting the efficacy of pharmacological agents in the treatment of FM (e.g., [5;18;25]). This measure was not originally part of the study but was added to the protocol mid-way through the trial so as to be consistent with the emerging recommendations and pharmacological clinical trial data. Both arms of the study initiated the use of this measure concurrently and thus these data are available for roughly half of the subjects in each arm of the study.

2.8. Participant characterization

A standardized demographics form (i.e., sex, age, race, marital status, educational status) and physical examination (e.g., including tender point exam, duration of FM, body mass index) was completed by a study physician or nurse practitioner prior to baseline assessments. Co-morbid psychiatric status was assessed using The Mini-International Neuropsychiatric Interview (MINI; [52]) and the presence of any Axis II co-morbid personality disorders was assessed using the Personality Disorders Scale of the Inventory of Interpersonal Problems (IIP; [47]).

2.9 Treatment Adherence

Treatment adherence in the WEB-SM arm was assessed on a monthly basis and at follow-up regarding the use of the behavioral self-management skills contained within the intervention. Participants were given access to a secure website that facilitated recording their use of the self-management skills on a monthly basis from their homes. Participants failing to make an entry into the website within 1 week of their expected monthly entry were reminded to monitor their skill use by study staff using email first and then by telephone. There were no unique intervention components that required monitoring in the standard care condition.

2.10. Treatment satisfaction and study manipulation check

Items from the Client Satisfaction Questionnaire (CSQ-12; [44]), were modified for FM and used to assess treatment satisfaction within the two treatment arms of the study. In order to verify that the WEB-SM arm in fact received and utilized content that differed from standard care, several questions were added to the CSQ-12 as a manipulation check of the study design.

2.11. Treatment regimens

2.11.1 Standard care—All participants in both arms of the study received their usual and customary care from their primary care physician. The only “care” that excluded participants from the study was prior CBT for pain management.

2.11.2. Web-Enhanced Behavioral Self-Management (WEB-SM)—A specialized website was constructed for this study that translated content from traditional face-to-face cognitive-behavioral therapy for FM into an educational self-help format. The website entitled “Living Well with Fibromyalgia” contained 13 modules segregated into three broad segments: (a) educational lectures providing background knowledge about FM as a disease state, (b) education, behavioral, and cognitive skills designed to help with symptom management, and (c) behavioral and cognitive skills designed to facilitate adaptive life style changes for managing FM (see Figure 2). Each of the 13 modules featured a video lecture on the topic by a clinician experienced in applying the selected topic with respect to FM, written summaries of the video lecture for reading or downloading, homework and self-monitoring forms for applying the behavioral strategies described in the video lecture, and supplemental educational materials unique to each topic (e.g., audio relaxation exercises and readings).

Multiple theoretical models support traditional face-to-face CBT including the theory of reasoned action [24], the theory of planned behavior [2], social-cognitive theory [6], control theory [16], the health beliefs model [33] operant conditioning [53] and the biopsychosocial model of pain [64]. The use of the Internet as an agent of change also has its theoretical underpinnings (e.g., [48]). Thus each of the 13 modules contained in the website possessed theoretical grounding and possessed empirical support from traditional face-to-face studies justifying their inclusion in this program (see Table 1).

Study participants assigned to the WEB-SM arm were encouraged to explore all aspects of the website and to select those modules that seemed to be of most relevance to their current situation. Participants were encouraged to practice and apply the behavioral skills on a regular basis and to revisit the site when new issues arose. So as to assess the value of a purely patient-driven, no-contact, behavioral self-management program, there was no additional coaching or professional contact with participants regarding the use of the WEB-SM program between baseline and the 6-month study endpoint. The standard care arm of the study similarly received no study-specific therapeutic contact during the 6 months of the study.

2.12. Statistical analysis plan

2.12.1 Sample size and power considerations—The current study was powered in order to detect a treatment effect on physical functioning, the target of a previous randomized controlled clinical trial of face-to-face CBT in FM upon which the content of this intervention was based [68]. Based upon this previous study, roughly 10% of the standard care control group and 30% of the WEB-SM group was expected to meet responder criteria for physical functioning. In order to have 80% power for responder analyses and primary group comparisons, 49 participants per arm was required. Allowing for 15% attrition, 113 individuals needed to be randomized for this study. This study was not powered to detect differences in the secondary outcomes.

2.12.2 Preliminary Analyses—Preliminary data analyses included descriptive statistics (e.g., frequencies, means, and standard deviations) and graphing so as to assess the normality of data and search for outliers in the outcome measures. A conservative approach to imputation (i.e., baseline observation carried forward (BOCF)) was used in ITT analyses for missing endpoint values due to early termination.

2.12.3. Baseline Characteristics—Baseline demographic and outcome measure values were assessed using means and standard deviations or percentages and counts as appropriate to the data. T-tests or Chi-square tests assessed differences between the groups despite the use of randomization.

2.12.4 Primary and Secondary Analyses—The primary analysis of this clinical trial was an “intent-to-treat” analysis based on the total randomized sample. Baseline-adjusted Analysis of covariance (ANCOVA), was used to evaluate change over time between the two arms of the study on all primary and secondary measures. For the two primary outcomes (i.e., pain and physical functioning), an additional responder analysis was conducted where a pain responder was considered to be anyone reporting a 30% improvement in pain between baseline and endpoint [23] and a physical function responder was defined as anyone reporting a 0.50 standard deviation improvement between baseline and endpoint. Statistical comparisons of responder rates in the two treatment arms were evaluated using Fisher’s exact test. For the PGIC measure, data was transformed into a dichotomous variable indicating “improvement” or “no change or worsening”. Fisher’s exact test evaluated proportional differences between categories for the two study arms. Fisher’s exact test, evaluating proportional differences

between groups, was also used to evaluate adherence, treatment credibility, treatment manipulation checks, and satisfaction with treatment.

3. Results

3.1 Sample characteristics

Baseline demographic, clinical status and co-morbid psychiatric status are detailed in Table 2. As a whole, the sample was predominantly female (95%), 50 years of age ($SD=11.5$), self-reported as being Caucasian (97%), and married (79%). Educational level of the sample extended over a broad range with 18% being high school graduates or less, 40% having some college training, 30% having received a college degree, and 12% possessing education extending beyond college graduation. The average participant had held a diagnosis of FM for 9.4 years ($SD=6.5$) and as a group, would be classified as being overweight possessing an average body mass index (BMI) of 28.7 ($SD=5.3$). Co-morbid psychiatric conditions included major depression (8%), panic disorder (20%), generalized anxiety disorder (10%), and post traumatic stress disorder (<1%). Based upon the IIP, a personality disorder was probable in 32% of the sample. The two groups did not differ from one another with respect to any of the sample characteristics or on baseline outcome measures (see Table 3) thus supporting the success of randomization.

3.2 Primary Outcomes

3.2.1 Pain—The group of individuals with FM receiving WEB-SM in addition to their standard care demonstrated significantly improved average pain intensity when compared to those receiving standard care only ($F_{(1,115)}=5.67$, $p<.01$). Additionally, the proportion of patients reporting a 30% decrease in mean pain score from baseline to endpoint (i.e., pain responders), was significantly greater in the WEB-SM group (WEB-SM: 29% vs. standard care: 8%; $p<.008$, Fisher's exact test). The number needed to treat (NNT) for the 30% responder rate was 5. Thus about 1 in 5 patients would be expected to receive this level of benefit from this web-based intervention between baseline and 6 months. Unadjusted baseline and 6-month follow-up data is displayed in Table 3.

3.2.1 Physical functional status—The WEB-SM group demonstrated statistically significant improvement in physical functional status compared to standard care only ($F_{(1,115)}=5.08$, $p<.03$). Using a responder criterion of 0.50 standard deviation improvement, the WEB-SM group again demonstrated more individuals improving (WEB-SM: 31% vs. standard care: 6%; $p<.002$, Fisher's exact test). The number needed to treat (NNT) in order to achieve a clinically meaningful improvement in physical functioning was again 5.

3.3 Secondary Outcomes

Summary measures of sleep, fatigue, and mood (i.e., depression and anxiety) failed to demonstrate significant differences between groups. Significant group differences were noted however on PGIC. Although available for only half of the sample (i.e., standard care, $n=33$, WEB-SM, $n=35$) there was a statistically significant difference in the numbers of individuals reporting at least minimal improvement (i.e., 57% of the WEB-SM recipients) but only 21% of standard care ($p<.003$, Fisher's exact test).

3.4 Adherence

For the WEB-SM group, monthly monitoring of behavioral skill usage revealed at least 1 module being used each month by 89%–94% of the sample. On average however, participants used 4 skills at any given time (see Table 4 for the percentage of participants using each skill by month). Adherence rates for each skill were compared between responders and non-

responders for the primary outcomes (i.e., pain and function). Functional status responders demonstrated significantly greater use of the exercise, pleasant activity, and problem solving modules than did non-responders ($t_{(48)}=2.19$, $p<.03$; $t_{(45)}=2.27$, $p<.02$; $t_{(33)}=2.26$, $p<.03$) respectively. No clear relationships were identified between adherence to specific skill use and responder status for pain reductions.

3.5. Study manipulation check

In support of the internal validity of the study, the the WEB-SM group did in fact differ from the standard care arm based on the content participants perceived themselves to have received. In response to the question, “Have you experienced an increase in self-management skills as a result of being in this study?”, 86% of the WEB-SM group answered affirmatively compared to only 42% of the standard care group (Fisher’s exact test, $p<.001$). The WEB-SM group also reported a greater increase in self-management skill use (WEB-SM: 77% vs. standard care: 33%; $p<.001$, Fisher’s exact test) and reported actual changes in behavior resulting in improvement (WEB-SM: 76% vs. standard care: 29%; $p<.001$, Fisher’s exact test).

3.6 Satisfaction

Ninety-one percent (i.e., 91%) of the WEB-SM participants reported receiving the type of service that they wanted compared to only 67% of the Standard Care group (Fisher’s exact test, $p<.001$). General satisfaction and satisfaction with the amount of help was endorsed by 91% and 82% of the WEB-SM group respectively; whereas general satisfaction with Standard Care was 73% and only 57% of standard care participants reporting receiving the amount of care wanted ($p<.01$, Fisher’s exact test for both questions). Seventy-nine percent (i.e., 79%) of the WEB-SM participants reported that the intervention actually helped compared to only 44% of the standard care group (Fisher’s exact test, $p<.001$) and 80% of the WEB-SM participants reported that they would use this type of help again compared to only 61% of the Standard Care arm (Fisher’s exact test, $p=.027$).

4. Discussion

This six-month, randomized controlled intent-to-treat trial, demonstrated that a no-contact educationally-based Internet self-management program significantly reduced pain and improved physical functioning in individuals with FM compared to a standard care control group. In fact, the standard care control group demonstrated no appreciable effect on patient’s pain or function as can be seen in Table 3. Improvement in overall well-being was also observed more frequently in the web-based group than in the standard care control. These findings are consistent with previous studies demonstrating the benefits of cognitive and behaviorally oriented approaches to managing FM delivered in traditional face-to-face formats [40;68;67; 61].

A review of which skills were preferred by the WEB-SM group revealed that exercise, a skill targeting both pain and function, was used most by study participants (i.e., 64–70% of participants over all 6 months of the study). The relaxation response, a skill aimed primarily at pain, was the second most highly utilized skill. The least favored skills were problem solving and reframing. Overall it appeared that participants favored the behaviorally-based skills over the more cognitively-oriented approaches when delivered in this format. This finding is consistent with a face-to-face study demonstrating greater improvements in pain and functional status being associated with interventions emphasizing behavioral over cognitive skills [61]. Support for the less-preferred but potentially potent cognitive strategies was found in this study however. Greater improvements in physical functional status was significantly associated with one of the cognitively-based skills (i.e., problem solving).

While adherence to module use in general was good (e.g., 3–4 modules used each month on average), only the use of exercise, pleasant activity scheduling, and problem solving uniquely differentiated responders from non-responders with regards to improvements in functional status. This suggests that despite the availability of all nine modules these three modules were the most consistently associated with functional status benefits when delivered to patients in this manner. Significant reductions in pain were also associated with the WEB-SM intervention as compared to standard care; however no specific set of modules were uniquely tied to the pain responders. It is possible that pain, being an experience rather than a behavior (e.g., like physical functioning), is influenced by multiple modalities that are unique to the individual experiencing the pain. Thus, no one module or set of modules played the leading role for the majority of pain responders when delivered in this manner. Whether this finding is unique to individuals with FM (i.e., a pain condition with numerous co-occurring somatic symptoms and limitations in functional status) is a question worthy of additional empirical investigation.

A strength of the current study was its use of outcome measures that were consistent with those being used in industry for the assessment of drug efficacy in FM. This methodology allows for more meaningful comparisons between pharmacological and non-pharmacological approaches to FM management. With treatment effect sizes being 0.64 for pain (i.e., Cohen's $d=0.64$, calculated using change scores and pooled change score (SD)), and 0.38 for function (i.e., Cohen's $d=0.38$), the magnitude of the therapeutic impact of this non-pharmacological intervention rivals or surpasses those for current pharmacological interventions available in the U.S.

Another strength of the current study was the objective of evaluating a purely web-based, no-contact intervention for use in the context of routine care. Such a no-contact intervention holds the advantage of being broadly available at relatively low cost once development costs are considered [60]. Further, such a program offers clinicians (particularly rural clinicians) high quality information for their patients without the requirement of finding a qualified local therapist (which in some settings, is unattainable). Patients also benefit as they can access self-management information in private and at their own convenience over the long term—which is an important consideration when managing a condition that by definition is chronic [48].

Several considerations should be noted when evaluating the merits of this study. First, some might question whether a standard care condition is the most appropriate comparison group. Two other potentially credible designs would have been the use of a sham website (i.e., controlling for content), or a face-to-face control (i.e., controlling for therapeutic delivery modality). As the efficacy of the cognitive and behavioral skills were not in question, and we were not challenging the potential superiority of face-to-face modalities when available, it was our intent to evaluate the WEB-SM program in the clinical context in which it would be most likely applied. From the perspective of translational clinical research, our use of a standard care control condition represents a preferred methodology for a study of this nature [20]. It should be noted however that the current design is limited if one wishes to attribute the outcomes exclusively to the specific content of the modules and not to other potential non-specific factors such as derivatives of increased internet use, or non-specific derivatives of having viewed the modules (e.g., increased self-focus, changes in daily routine etc).

Fatigue, sleep and mood domains (e.g., depressive and anxiety symptoms) were not impacted by this Internet intervention. At first this might be surprising given the efficacy of CBT in insomnia and mental health conditions [22;58]. However, while being theoretically grounded in common principles of behavioral and cognitive change, CBT works best when developed to target a specific type of change. In the current study, changes in pain and function were the primary objectives. It is likely that more specialized content, resources, and instruction may be needed to make meaningful changes in these secondary symptom domains. Relatedly, unlike

pain and functional deficits which were common to all participants, not all participants possessed difficulties with each of the secondary outcome measures.

A potential limitation of this study was our choice not to passively monitor actual web engagement (e.g., electronic tracking of webpage viewing or viewing duration). As part of the instructions to participants, we did not insist that all modules be accessed by all participants nor did we stipulate how long they should utilize the site. Rather our instructions permitted participants to access only those modules deemed most relevant at any given time (i.e., self-selected tailoring). Thus a tally of web pages viewed would not be a relevant metric of adherence for this study. Similarly metrics associated with duration of time spent on the website was not collected given that this metric can be confounded by factors such as internet connection speed, the ability of participants to access a page and leave the room, and the fact that more viewing is not linearly tied with better outcomes [20]. As a compromise we selected against the use of passive monitoring in favor of an older more traditional methodology for measuring adherence to behaviorally oriented treatments - homework monitoring [1]. As we reported, on average, 4 skills were used by each participant in the WEB-SM group over the course of the 6 month study supporting both the accessibility, relevance, and durability of the information contained within the modules for this patient population.

As is the case with pharmacological agents, not everyone with FM will benefit from this intervention. A no-contact intervention may not be sufficiently intense or structured to address the needs, complex sets of symptoms, and preferences of all patients. When greater needs arise, online behaviorally oriented programs need to “step up” the amount of support and tailored content being offered [3]. When “Living Well with FM” fails to meet the needs of specific patients, the website can also serve as a standardized self-help manual for clinicians or mid-level providers wishing to work more intensively with patients via email, telephony, or in more traditional face-to-face therapeutic formats. When used in this manner, the clinician would primarily tailor the standardized content to the individual patient.

In summary, sustained improvements in pain and physical functional status were demonstrated in a sample of individuals with FM using an Internet-based self-management program. The use of such a delivery platform has application in the context of primary care where clinical practice has not been able to take full advantage of evidence-based non-pharmacological interventions for FM. Given the magnitude of the effect sizes found in the WEB-SM group compared to standard care, such online programs have potential as a front line approach to the management of FM.

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Figure 1.
CORT Study Flow diagram

Figure 2.
Screen shot of “Living Well with Fibromyalgia”

Table 1**Living Well with Fibromyalgia Self-Management Modules**

Modules	Content
What is Fibromyalgia?	
About FM (Lecturer: Physician)	History of the FM Diagnosis [36]
Causes of FM (Lecturer: Physician)	Factors that trigger and maintain FM [69]
Multi-modal Treatment of FM (Lecturer: Physician)	Rationale for combined pharmacological and non-pharmacological interventions and the patients' role in FM management [27;17]
Symptom Management	
Medications (Lecturer: Nurse Practitioner)	Rationale for using various classes of medication in FM [27][17]
Exercise (Lecturer: Exercise Physiologist)	The role of aerobic fitness in health and how realistic exercise goals can enhance exercise use over time [51;11;12;15]
Sleep Hygiene (Lecturer: Psychologist)	Impact of poor sleep on pain and how behavioral patterns can help over time [39;22]
Relaxation (Lecturer: Social Worker)	Multiple methods for training the body to produce the relaxation response [42;13]
Pleasant Activities (Lecturer: Exercise Physiologist)	Rationale and skills for protecting personal time for self-growth and emotional well-being [34; 73]
Life Style Change	
Goal Setting (Lecturer: Psychologist)	Structured approaches to setting and achieving goals [45]
Problem Solving (Lecturer: Social Worker)	Structured approaches for overcoming barriers to effective FM management [43;50]
Graded Activation (Lecturer: Psychologist)	Structured approaches for gradually improving physical functional status [26;35;49]
Reframing (Lecturer: Social Worker)	Structured approaches for challenging negative automatic thinking styles[34;63]
Communication (Lecturer: Physician)	Structured approaches for improving communication with physicians, family, friends, and colleagues [31]

Table 2

Baseline Demographic and Clinical Characteristics of Individuals with FM

Characteristic	WEB-SM (n=59)	Std Care (n=59)	Total Sample (n=118)
Sex (n)			
Female	56	56	112 (95%)
Male	3	3	6 (5%)
Age (y)			
Mean (SD)	50.17 (12.34)	50.75 (10.58)	50.46 (11.45)
Race (n)			
White	58	57	115 (97%)
Other	1	2	3 (3%)
Marital Status (n)			
Single	8	5	13 (11%)
Married	45	48	93 (79%)
Separated, widowed, divorced	6	6	12 (10%)
Educational Status (n)			
Post graduate degree	7	7	14 (12%)
College Graduate	15	20	35 (30%)
Some college	25	22	47 (40%)
High school or less	12	10	22 (18%)
Body Mass Index (kg/m ²)			
Mean (SD)	29.32 (5.21)	28.03 (5.26)	28.66 (5.25)
Duration of FM (y)			
Mean (SD)	9.45 (6.85)	9.34 (6.10)	9.40 (6.46)
Axis I Psychiatric Diagnoses (n)			
Recurrent Major Depression	7	3	10 (8%)
Panic Disorder	11	13	24 (20%)
Generalized Anxiety Disorder	7	5	12 (10%)
Post Traumatic Stress Disorder	1	0	1 (<1%)
Axis II: Any Personality Disorder, (n)	19	19	38 (32%)

n=number of cases, y=years, %=percentage, SD=standard deviation

Table 3

Unadjusted statistics on primary and secondary outcomes by treatment condition over time

	<i>WEB-SM</i>	<i>STD CARE</i>
Primary Outcomes	<i>Mean (SD)</i>	<i>Mean (SD)</i>
Pain Severity–(<i>BPI</i>)		
• Baseline	5.1 (1.4)	4.9 (1.4)
• 6 months	4.3 (1.6)	4.9 (1.5)
Physical functioning– (SF-36 (PF))		
• Baseline	38.9 (8.6)	38.9 (9.5)
• 6 months	41.1 (8.7)	38.9 (8.6)
Secondary Outcomes		
Fatigue– (MFI total score)		
• Baseline	67.1 (11.7)	67.7 (11.7)
• 6 months	66.3 (11.0)	67.6 (12.2)
Sleep Disturbance–(MOS (Index 2))		
• Baseline	51.3 (16.1)	47.9 (16.6)
• 6 months	51.1 (16.5)	46.8 (16.7)
Depressed Mood– (CES-D)		
• Baseline	15.1 (10.1)	17.1 (11.5)
• 6 months	16.4 (11.9)	17.5 (11.5)
Anxious Mood– (STPI–state anxiety)		
• Baseline	17.1 (6.0)	16.9 (6.3)
• 6 months	18.1 (7.1)	18.4 (5.9)
PGIC		
• 6 months (improved)	n=20/35 (57%)	n=7/33 (21%)
• 6 months (no change or worse)	n=15/35 (43%)	n=26/33 (79%)

BPI=Brief Pain Inventory, SF-36=Short Form 36, MFI=Multidimensional Fatigue Inventory, MOS=Medical Outcomes Survey, CES-D=Center for Epidemiological Studies Depression Scale, STPI=State-Trait Personality Inventory, PGIC=Patient Global Impression of Change

Note. With the exception of PGIC, all other values are based upon the ITT sample (i.e., n=118) using BOCF when appropriate.

Table 4

Percentage of Cases Using Self-Management Skills by Month

Self-Management Skill	Month					
	1	2	3	4	5	6
Exercise	70	76	76	66	63	64
Relaxation Response	63	71	66	63	78	73
Sleep Hygiene	44	49	51	49	58	59
Pleasant Activity Scheduling	48	49	44	49	51	53
Goal Setting	37	42	36	34	42	34
Communication Skills	22	36	36	36	37	39
Graded Activation (pacing)	19	24	29	29	29	27
Problem Solving	19	25	20	25	17	25
Reframing	12	7	19	17	17	19
Percentage of participants using at least 1 skill	93	92	92	89	94	93
Mean number of skills used by participants	3.7	4.4	4.2	4.2	4.2	4.4