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Research to Encourage Exercise for Fibromyalgia (REEF): Use of Motivational Interviewing Design and Method

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Abstract

Fibromyalgia (FM), defined as the presence of both chronic widespread pain and the finding of 11/18 tender points on examination, is an illness associated with major personal and societal burden. Supervised aerobic exercise is an important treatment modality to improve patient symptoms. Unfortunately, adherence to an exercise regimen after a structured supervised program is disappointingly low. Since FM is a chronic illness, studies are needed to test strategies that would enhance exercise adherence in these individuals. Individuals who are able to adhere to exercise almost always maintain the symptomatic benefits of exercise. The objective of this paper was to describe the protocol of the Research to Encourage Exercise for Fibromyalgia (REEF). REEF is a randomized attention-controlled trial that seeks to test the efficacy of 6 sessions of telephone delivered motivational interviewing (MI) that targets exercise adherence to improve FM-relevant clinical outcomes (i.e., physical function and pain severity). The trial has recently completed enrolling 216 subjects, and randomization has resulted in well balanced groups. Details on the study design, MI program, and treatment fidelity are provided in the paper. Outcome assessments at week 12, week 24 and week 36 will test the immediate, intermediate and long term effects of exercise-based MI on adherence (as measured by the Community Health Activities Model Program for Seniors/CHAMPS and accelerometer) and clinical outcomes. When completed, REEF will determine whether exercise-based MI could be utilized as a management strategy to sustain the clinical benefits of exercise for FM.

Keywords

Fibromyalgia; Exercise; Physical activity; Motivational interviewing; Physical function; Pain

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1. Introduction

Fibromyalgia (FM) is a illness that affects at least 2% of the general population and is characterized by the presence of both chronic widespread pain (CWP) and the finding of 11/18 tender points on examination[1,2]. Other than generalized pain, individuals with FM also report a substantial number of *other* "medically unexplained" symptoms, including fatigue, sleep disturbance, impairments in attention and other cognitive functions, irritable bowel, stiffness of muscles and joints and mood problems.

Over the last two decades, supervised exercise has been considered a major cornerstone in the management of patients with FM[3-5]. In multiple clinical trials, supervised exercise has been shown to improve symptom severity, physical function and global well-being[6-14]. Unfortunately, adherence to an exercise regimen after a structured supervised program is disappointingly low [13,15-18]. Incorporating a simple educational component to an exercise intervention does not appear to result in higher compliance with training sessions either [7,19]. After the supervised phase of an exercise program, exercise adherence declines and FM symptoms worsen [13,15-18]. Since FM is a chronic illness, studies are needed to test strategies that would maintain exercise adherence in these individuals. FM sufferers who consistently exercise are most likely to maintain initial benefits [7,13,17,20,21]; therefore, motivating FM patients to continue regular exercise is crucial for maintaining clinical benefits.

Miller and his colleagues [22] have developed an approach to clinician-client interactions that focuses on enhancing client's motivation to change. This approach, called motivational interviewing (MI), was initially developed to help problem drinkers cut down on or abstain from drinking alcohol. Within the principle of MI, motivation to change is viewed as something which is evoked in the patient, rather than imposed. It is a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence about a behavior (e.g., initiation and maintenance of exercise). In contrast to delivering simple advice, an MI practitioner helps a patient discuss the pros and cons of the target behavior; consequently, resolving the patient's ambivalence about the behavior.

This paper describes the protocol of the Research to Encourage Exercise for Fibromyalgia (REEF), a randomized attention-controlled trial to determine the efficacy of MI to encourage exercise (target behavior) in order to improve patient-oriented clinical outcomes (i.e., physical function and pain severity). A secondary objective of the trial is to determine the mediators between exercise-based MI intervention and improvement in clinical outcomes.

Figure 1 illustrates the conceptual model underlying REEF trial. MI will move FM patients toward the decision to adopt and/or maintain an exercise program by strengthening participants' intention- to-exercise - the final common pathway to behavior change (i.e., exercise adherence). MI will positively influence intention-to-exercise through 2 mechanisms: 1) by enabling participants to feel confident that they can exercise despite challenges (exercise self-efficacy), and 2) by tipping the balance of decisions favoring the positive features (pros) of exercise over the negative aspects (cons) of exercise (decisional balance).

2. Methods and Design

2.1 Overall Study Design

Study subjects were randomized to either the MI intervention group or the attention control (AC) group (Figure 2). The MI group received six telephone-delivered exercise-based MI

counseling calls spread over a 12-week period. The AC group received an equal number of telephone contacts to control for attention. Outcome assessments were conducted at baseline, week 12, week 24 and week 36. To get participants started on an exercise program, all study subjects (both MI and AC groups) received two supervised exercise training sessions and an individualized exercise prescription [23] before the telephone-counseling phase of the study. The two primary endpoints were improvement in the self-report physical impairment [as measured by the Fibromyalgia Impact Questionnaire (FIQ)] at week 36 and the proportion of study subjects who increased their weekly exercise duration by ≥ 30 minutes [as measured by Community Health Activities Model Program for Seniors (CHAMPS)] at week 36. Secondary outcomes included pain severity [assessed by the Brief Pain Inventory (BPI)], generic and FM-specific health related quality of life, the 6-minute walk test and the activity monitor (i.e., accelerometer). The study was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

2.2 Eligibility

All potential participants were referred from specialty or primary care clinics. Participants met the following entry criteria: (a) fulfilled the American College of Rheumatology (ACR) classification criteria for FM[1]; (b) FIQ-physical impairment score ≥ 2; (c) average BPI pain score ≥ 4; (d) had been on stable doses of medications for FM for ≥ 4 weeks; (d) willingness to limit the introduction of new medications for FM; and (e) age between 18-65 years old.

Excluded were individuals with (a) known cardiovascular disease; (b) moderate-severe chronic lung disease; (c) uncontrolled hypertension; (d) orthopedic or musculoskeletal conditions that would prohibit moderate-intensity exercise; (e) active suicidal ideation; (f) planned elective surgery during the study period; (g) ongoing unresolved disability claims; (h) inflammatory rheumatic conditions (i.e. rheumatoid arthritis, systemic lupus erythematosus, and other connective tissue disease); (i) current use of medications that may affect chronotropic response to exercise (i.e. beta-blocker or calcium channel blockers); (j) pregnancy; (k) schizophrenia or other psychosis; and (l) participation in moderate-vigorous exercise for 3 days a week or more.

2.3 Randomization

For each eligible subject a written informed consent was requested. Eligible subjects were then randomized to one of the two treatment arms, with randomization stratified by presence of depression [Patient health assessment-8 (PHQ-8) score ≥ 15], gender, and referral source (specialty vs. primary care). Allocation to treatment arm was carried out by a computer-generated randomization list with permuted block size of 2.

2.4 Supervised exercise training for all subjects

At week 1 of the study timeline, each subject (both MI and AC) watched a 15-minute video on the benefits of aerobic exercise for FM. Thereafter, participants had a one-to-one consultation with a fitness instructor. The fitness instructor provided an individualized exercise prescription based on the participants' severity of symptoms and prior exercise history.

The written exercise prescription included the initial intensity, duration and frequency, as well as, the progression of the exercise regimen over the next 36 weeks. Initial exercise duration was between 10 to 12 minutes, at an intensity of 40-50% of heart rate reserve (HRR). Using the Karvonen formula [24], the percent HRR was calculated by the following formula: [(220 – age) – (standing resting heart rate] x prescribed % + standing resting heart

rate. For all subjects, exercise duration increased up by 1 minute each week, to a maximum of 30 minutes, where it remained for the remainder of the study. Further, exercise intensity went up by an increment of 5% (e.g. from 40-50% to 45-55% of the HRR) every 4 weeks to attain a maximum of 65% of the HRR [25]. Exercise frequency was 2-3 times a week from week 1 to 4, 3 times a week from week 5 to 8, and 3 to 4 times a week from week 9 till the end of the follow-up period. To ensure that participants were within their target heart rate zone, each received a strapless heart rate monitor watch.

Also during the week 1 visit, each participant received an individualized supervised exercise training session from the fitness instructor. The exercise consisted of 10 minutes of stretching and 10 – 12 minutes of aerobic exercise. During the week 2 visit, the fitness instructor discussed any problems that the subject may have encountered while exercising in the past week, and then offered suggestions. On the same visit, the participants received their second individualized supervised exercise training session.

After the second supervised exercise training session, MI subjects received the phone-delivered exercise based MI counseling while the AC group received the phone-delivered education on fibromyalgia-relevant topics. Each subject had the same interventionist (MI-trained health practitioner or health educator) throughout the protocol.

2.5 Intervention

2.5.1 Exercise-based MI counseling—MI participants had 6 telephone calls throughout the study. The phone calls were scheduled at week 3, 4, 6, 8, 10 and 12 of the study (Table 1). The MI-trained health practitioner used an MI handbook, which was successfully pilot tested in our preliminary study[26].

The telephone-delivered MI intervention was divided into 3 phases:

1. First phase: The first two calls focused on strategies that enhance motivation to exercise. It involved eliciting from the patient statements (i.e. self-motivational statements) that supported the following: a) The patient's recognition of the full nature and extent of the problem, b) The patient's concern about how he or she is currently managing the problem, c) The patient's intention of changing in the direction of adaptive pain management, specifically, graded aerobic exercise and d) The patient's optimism that changes are possible.
2. Second phase: This phase was devoted to strategies that strengthen commitment to exercise regularly and consistently. Specifically, the third call included helping the patient develop a plan for change (i.e. shift from why the patient should consider change to how the patient will make changes) communicating free choice, and reviewing consequences of graded aerobic exercise versus inactivity. The fourth phone call involved asking for a commitment to exercise and a plan worksheet.
3. Third phase: The last 2 calls were for follow-through strategies to prevent relapse of inactivity. To review the changes that have occurred since the last session, the MI-trained health practitioner praised and reinforced any and all approximations of progress. She or he also reviewed behavioral indicators of motivation, patient's responses to questions concerning reasons for making or maintaining changes, and barriers to exercise adherence. The MI-trained practitioner again obtained a commitment to follow through on the new plan.

Procedures to assure MI fidelity included the following: 1) only health professionals with significant experience conducting MI-based health coaching delivered the intervention, 2) all phone contacts were audio taped to provide ongoing feedback and coaching to the MI health practitioner, 3) MI trainers, members of the Motivational Interviewing Network of

Trainers (MINT), provided on-going supervision and feedback to the MI health practitioner, 4) 25% of the audio taped phone contacts were formally evaluated for treatment integrity using the Motivational Interviewing Treatment Integrity (MITI) method - a focus tool to assess competence in the use of MI [27]. The MITI evaluators were blind to randomization.

2.5.2 Education attention control (AC)—Each AC call followed the same format as the MI call. During the AC call, study subjects received health information on important topics relevant to their illness. Specifically, there was one topic during each phone call that included the following: (a) overview of FM, (b) pain, (c) fatigue (d) sleep, (e) stress, and (f) living well with FM (Table 1). The AC calls were avenue to transfer relevant health information from the health educator to the study subject. The scheduled topics during each contact gave the call face validity (i.e., establish a credible pretense for the contact) while being neutral with respect to encouragement of exercise.

To ensure that the AC calls control for attention only, procedures to assure fidelity were taken. First, ongoing feedback and coaching was provided to the health educator to ensure that the phone calls remained focused on the topics included in the manual. Second, 15% of the audio taped phone contacts were formally evaluated by one of the investigators (SM) for quality assurance. It is important to note that the health educator has no prior experience in mental health counseling in general and MI in particular. Finally, the tapes were formally evaluated using the MITI method by the same MITI evaluators. A poor evaluation on the MITI guaranteed that the AC was implemented appropriately.

2.6 Outcome Measures

Table 2 outlines the data collection protocol, including the variables that were measured and when they were assessed. Except for the 6-minute walk test and the activity monitor data, all measures were self-report and self-administered online.

2.6.1 Primary efficacy measures

FIQ-physical impairment (FIQ-PI): As one primary outcome measure, FIQ-PI is the 10-item subscale of the Fibromyalgia Impact Questionnaire (FIQ) that inquires about the participant's ability to do 11 different types of physical activity; with each item rated on a 4-point Likert-type scale. The range of the score is between 0 and 9.99, where a higher score indicates a negative impact. The FIQ-PI correlates well (r= 0.65) with the Arthritis Impact Measurement Scale (AIMS) lower extremity physical function scale[28]. In a trial of pool therapy and education, Mannerkorpi found the FIQ-PI to be responsive, and correlated with improvement in the 6-minute walk test[29,30].

Community Health Activities Model Program for Seniors (CHAMPS): As a co-primary outcome measure, the CHAMPS was used as a measure of exercise adherence. The CHAMPS was developed to measure physical activity change in an intervention for older adults. The CHAMPS is a 15-minute survey that asks about the frequency and duration of physical activity in a typical week of the past month. From several community-based interventions for older women and men [31-33], CHAMPS has been shown to be sensitive to change. Two-week test-retest reliability has been shown to be 0.76 and construct validity is good[34]. Correlations with activity monitors and 6-minute walk tests have been reported to range from 0.40 to 0.57[34]. The approach is to provide a list of activities to prompt the memories of respondents. In the current study, the focused was on activities of moderate intensity or greater. The questionnaire provides measures of estimated hours per week in light, moderate and vigorously intense activities [32].

2.6.2 Secondary measures

Fibromyalgia Impact Questionnaire (FIQ): This is a reliable, validated self- assessment questionnaire widely used in clinical trials for FM[15,30,35-37]. In addition to the physical impairment subscale, it has 6 visual analog scales (VAS) for measuring sleep, *pain*, anxiety, morning stiffness and depression. It also measures work status, and overall well-being[28].

Brief Pain Inventory (BPI): The BPI is a pain assessment tool that has been proven reliable, valid and responsive to change among patients with chronic non-malignant pain [38,39]. BPI pain severity is the average of 4 items asking about worst, least, and current pain in the past week, and current level of pain.

6-minute Walk Test (6-MWT): To validate self-reported exercise activity, a 6-MWT was carried out for both the intervention and control groups. The 6-MWT is a clinically relevant aerobic endurance/fitness measure that is reproducible, sensitive to change, and significantly related to the total FIQ score in patients with FM[29,30,40,41]. To improve reliability, participants completed two trials of the 6-MWT with a 15 minute rest in between[41]. All distances were recorded in meters. From week 0 to week 36, an increase of at least 25 meters in the 6-MWT reflects exercise adherence[29,30].

Accelerometer: The GT1M ActiGraph accelerometer (or activity monitor) was used to objectively quantify the duration and intensity of physical activity in a given 7 day period. The GT1M ActiGraph is compact with a weight of 27 grams and dimensions of 3.8 × 3.7 × 1.8 cm. In laboratory and field settings, the ActiGraph has been shown to be a valid and reliable assessment tool of physical activity[42-46]. In adults, correlation coefficients ranged from 0.66 to 0.89 between ActiGraph counts and metabolic measures[42]. In 7-15 year old boys and girls, the ActiGraph was validated against heart rate telemetry with correlation coefficients between the two ranging from 0.50 - 0.74[47]. Comparisons with oxygen consumption during treadmill exercise and self-selected speed on a track found that the ActiGraph was highly related to both, and was sensitive to change in speed [48]. Importantly, the ActiGraph has been found to successfully detect bouts of moderate intensity physical activity[49]. In addition, the accelerometer has been used in various clinic populations including diabetes, obesity, chronic lung disease, chronic fatigue syndrome and FM[50-55]. The accelerometer provides measures of estimated weekly number of counts, steps and minutes of ≥ moderately intense physical activity. In the study, participants were required to have carried the activity monitor for at least 4 days in a week with a minimum of 10 hours each day during the waking hours. Additionally, participants were asked to clip the activity monitor on their waist (or their bra for those with higher body mass index) during each outcome assessment throughout the study.

Physical Component Summary Score (PCS): The PCS is part of the 36-item Medical Outcome Study Short-Form Health Survey (SF-36). The PCS score has been standardized to have a mean = 50, SD=10 in the general US population. Internal consistency reliability for the PCS is r=0.91 with test-retest reliability r=0.89. Low PCS scores are indicative of poor physical functioning. The PCS includes the following subscales: physical functioning, *bodily pain*, role-physical and general health [56]. The SF-36 is a brief, well-established, self-administered patient questionnaire for the assessment of health status. Despite being a generic health status assessment, the SF-36 has demonstrated responsiveness to both medical [57]and non-medical interventions[29,58]. In an RCT of tramadol/acetaminophen, patients in the treatment group demonstrated improvement on physical functioning and role-physical and bodily pain domains, as well as on the physical component summary score[36].

2.6.3 Mediators

Exercise self-efficacy (ESE): This is a 9-item scale designed to measure a person's perceptions of her confidence to engage in physical activity in various situations[59]. Response options are numbered from 0 ('not confident') to 10 ('very confident). Scoring is done by adding up the total score and dividing by the number of items [score range= 0 to 10]. The questionnaire's validity was supported by statistically significant lambda estimates that ranged from 0.61 to 0.87[59-61]. Further, a statistically significant relationship had been established between ESE and exercise[62-64]. The internal consistency estimate range from 0.92 to 0.95. In two previous exercise intervention trials, ESE was shown to be responsive to change[62,63].

Decisional balance: This is a 16-item inventory assessing perceived benefits (pros) and perceived barriers (cons) to physical activity participation[65]. High scores on the 'pros' scale indicate perceptions of high benefits from exercise; high scores on the 'cons' scale indicate unfavorable perceptions of exercise and reasons not to exercise. A decisional balance index is calculated by subtracting the cons score from the pros score. A higher (or positive) decisional balance score is associated with a higher motivational readiness to exercise[65-67]. This measure has been shown to have good internal consistency: Pros=0.90-0.95, Cons=0.67 to 0.79[68,69]. In several physical activity intervention trials, the decisional balance index was shown to be responsive to change[68-70].

Intention–to-exercise: Intention was assessed using a 3-item scale developed by Courneya and colleagues[71]. Scoring is done by adding up the item scores and dividing by the number of items [score range= 1 to 7]. Responses to each item are averaged to provide the intention scale. This 3-item scale has an internal consistency of 0.88. In a pre- and post cardiac exercise rehabilitation study, the scale was shown to be sensitive to change[72]. Among cancer survivors, Courneya et al reported preexisting *intention* to be a predictor of exercise behavior[73].

2.6.4 Covariates

Patient Health Questionnaire 8-item Depression Scale (PHQ-8): PHQ-8 is a brief self-administered scale which assesses major depressive disorder core symptoms and allows a score (range: 0 to 24) based on the total number and severity of depressive symptoms noted over the previous two-week period. Its validity and capacity to detect changes of depressive symptoms over time are well established [74-77]. A PHQ-8 score ≥ 10 represents clinically significant depression[78].

2.7 Statistical considerations

2.7.1 Sample size justification—Our 2 primary endpoints were:

- **a.** Improvement in physical function, as measured by the FIQ-PI, at week 36 compared to baseline. Using an alpha of 0.025 and a two-sample independent t-test, a sample size of 68 per group has 85% power to detect a minimum difference of 1.2 [29].
- **b.** Proportion of subjects who increase their weekly exercise adherence by ≥ 30 minutes (as measured by CHAMPS) at week 36 [16].

In a previously completed pilot study[26], the proportion of subjects at week 30 who reported ≥ 30-minute increment of exercise time per week was 40-42%. Using an alpha of 0.025 and a two-sample chi-square test with continuity correction, a sample size of 68 in each group has 80% power to detect a difference of 25% [40% (MI) vs. 15% (AC)]. To adjust for multiple primary endpoints, we will use the Bonferroni-Holm method since it is

less conservative and more powerful than the simple Bonferroni method[79]. To account for 35% attrition rate, we recruited 108 patients per group (N=216).

2.7.2 Statistical analyses—Baseline clinical and demographic data were compared among the two groups. Dichotomous and ordinal variables was examined using chi-square tests and continuous measures with two-sample test or two sample non-parametric Wilcoxon Rank Sum Test if the normality assumption was not met even after applying a suitable transformation. One of the two primary variables is whether a subject increases weekly exercise adherence by ≥ 30 minutes at week 36. However, we will also measure this outcome at weeks 12 and 24. For this dichotomous outcome, we will use a non-linear mixed-effects model. The fixed covariates will include treatment group, week and interaction term between treatment group and week. Two treatment groups will be compared at each of 12-, 24- and 36-week.The model will be fitted by the SAS procedure NLMIXED.

To compare the effect of MI intervention on the change in self-report physical function and pain severity from baseline to week 36 we will use all repeated measurements and the following mixed-effect model. We will use PROC MIXED available in SAS to fit this model. The fixed covariates will include treatment group, week and interaction term between treatment group and week. Two treatment groups will be compared at each of 12-, 24- and 36-week. Both models to analyze two primary outcomes will adjust for potential confounders if found unbalanced between two treatment groups at baseline. Intention-to-treat analyses will be used for both outcomes.

To determine the mediators of MI and changes in clinical outcomes, we will use Sobel test, which is found to be more powerful than other formal methods of assessing mediation[80]. We will test the mediating effects of the following: exercise self-efficacy, decisional balance, and intention to exercise. For statistical analysis, we will use the SAS codes available in the paper by Preacher and Hayes[81].

3. Results

A total of 996 patients were screened for inclusion in the ongoing study. Of these, 216 (21.6%) met the inclusion criteria, enrolled and were randomized to MI (n=107) and AC (n=109). The majority of screening failures were: 1) exercising for 3 days a week or more (30%), 2) medications that affects the chronotropic response to exercise (19%), 3) age over 65 years old (11.7%) and 4) presence of medical condition that contraindicated participation in an aerobic exercise program (11.2%). Most of the 216 participants were female (95.8%) and White (88.4%). The study cohort had a mean (± SD) age of 46 ± 11 years; 61% married, 78% had > high school education and 54% were employed. At study entry, the sample had mean disease duration of 9 ± 7 years; 33% were on opioid analgesics; 30% were on anticonvulsant; and 62% were on an antidepressant other than tricyclics. Clinically, the mean score for FIQ-total was 67 ± 12.7 and FIQ-physical impairment was 5.4 ± 1.6, suggesting a moderate-to-severely ill patient population. For self-report pain, the mean BPI pain severity score was 6 ± 1.3. As measured by CHAMPS, the average weekly number of hours that subjects were engaged in ≥ moderate level of physical activity was 1.7 ± 3.7 hours per week. For the activity monitor, the average weekly number of minutes of ≥ moderate level of physical activity was 105.5 ± 94.1 minutes per week. Although the perceived benefits of exercise outweighed the perceived barriers (mean decisional balance index= 25.5 ± 8.4), the 216 participants only had moderate degree of intention to exercise (median score=4, 1st quartile= 3 and 3rd quartile= 4.7) at study entry. Baseline characteristics were similar across treatment groups (p>0.2) except for body mass index (Table 3). Compared to AC, subjects in the MI group were slightly heavier (32.2 ± 7.6 vs. 30.5 ± 6.6, p=0.07).

4. Discussion

In the past 17 years, the FM exercise literature has largely focused on the 'specifics' (i.e. intensity, frequency, duration of exercise, pool vs. land-based exercise, etc.) of exercise that would result in clinical benefits for patients. However, patients' adherence to exercise remains problematic. The graduation from a supervised to an unsupervised environment is associated with loss of effectiveness because adherence is poor. The use of MI to maintain exercise adherence is a promising tool in sustaining clinical benefits of exercise, in terms of pain reduction and improvement in physical functioning.

Many studies have reported success with MI interventions to elicit behavior changes[82-97], but the use of MI to encourage exercise is relatively new. A recent meta-analysis showed medium effect sizes (0.53) of MI for increased physical activity in the general medical patient population[98]. MI has also been effective in increasing exercise among diabetic patients and patients with chronic heart failure[99,100]. Unlike other patient population, chronic pain patients are fearful that exercise might exacerbate their existing pain or result in a new injury or pain site, which may interfere with their planned physical exercise program [16,17]. Fear of pain is a potent inhibitory factor in getting patients with chronic pain into regular exercise regimens[101]. Most people need more than advice to exercise – they need assistance overcoming the barriers to exercise. Exercise-based MI may encourage patients to initiate and maintain exercise, even when such barriers as pain could provide an excuse to quit.

The principle of MI is not based on any specific theory. Rather, Miller drew from social psychology[102], cognitive dissonance[103], empathic processes from the methods of Rogers[104,105], and self-efficacy[106,107]. The Trans-theoretical Model (TTM) of behavior change emerged in parallel with MI and provided a useful framework for understanding the change process; with MI providing a mean of facilitating this change process. MI also appears to be consistent with a number of models of health behavior, such as Theory of Planned Behavior, and Social Cognitive Theory[108]. All of these models, despite differences in their terms and emphasis, share two common constructs. These are the patient's expectations about the consequences of engaging in the behavior, and the influence of the patient's perception of, or beliefs about, personal control over the behavior. The MI practitioner uses four main principles: 1. express empathy, 2. develop discrepancy – explore the gap between future goals and current behavior, 3. roll with resistance – deflect and reframe patient statements; lessens resistance and 4. support self efficacy. The patient is seen as responsible for choosing and carrying out personal change, but at the same time he or she must have a belief in his or her ability to change.

The protocol described here has several unique features. First, the MI intervention in REEF was telephone administered and therefore has the advantage of reducing delivery cost and improving patient compliance with the program. Second, REEF consisted of only 6 sessions over a 12-week period. Weekly phone sessions then tapered off into less frequent sessions. Such a program that decreases in intensity as it advances may train the participant to continue the behavior even without the telephone calls serving as prompts or motivators. Further, a 6-session program is potentially more cost effective compared to the typical 10-12 week program. Third, the inclusion of physical activity assessment and training prior to the intervention guaranteed that participants started their exercise program well informed of the benefits and complications of exercise. REEF trial provided an exercise prescription tailored for the participant's needs and health condition. An individualized exercise prescription is especially important in FM populations as over exertion early on may sabotage further participation in an exercise program.

REEF has successfully enrolled 216 FM patients whose baseline socio-demographic and clinical characteristics were comparable to other published non-pharmacologic clinical trials in FM[7,16,29,109]. Randomization has produced balanced groups in all variables including factors such as exercise self efficacy, decisional balance and intention to exercise. Outcome assessments at week 12 and week 36 will test the immediate and long term effects of exercise-based MI on FM-relevant clinical outcomes and exercise adherence (as measured by self-report CHAMPS and accelerometer). At the completion of this study, we expect to have a treatment approach that targets exercise adherence, which might then lead to improvements in clinical outcomes. The attractive elements of telephone communication (i.e., increased convenience of availability and access and increased time efficiency) could potentially make the MI intervention more accessible to the greater majority of FM patients. Additionally, the currently ongoing study is expected to elucidate on the mechanistic pathway of how MI impacts clinical outcomes. The knowledge gained will be important in refining future treatment approach to further sustain the benefits of exercise.

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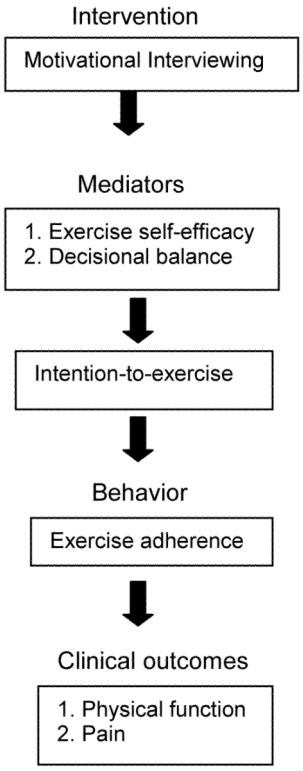

Figure 1.
Conceptual Model Underlying REEF Trial

Figure 2.
Schematic overview of the REEF study design

Table 1

Intervention Schedule

Study timeline	Motivational Interviewing (MI)	Attention-control (AC)
Week 1: Visit 1	2. Watch video: FM and benefits of exercise	
	3. Individualized exercise prescription and supervision	
Week 2: Visit 2	1. Review of exercise prescription	
	2. Individualized exercise supervision	
Week 3: Phone session 1	Self-motivational statements	Overview of FM
Week 4: Phone session 2	Optimism about change and intention to change	Pain*
Week 6: Phone session 3	Communicating free choices	Fatigue
Week 8: Phone session 4	Commitment to exercise	Sleep
Week 10:Phone session 5	Reinforce any approximation of progress & review reasons for maintaining changes	Stress
Week 12: Phone session 6	Barriers to exercise adherence	Living well with FM

*Included a short discussion on the general benefits of exercise for fibromyalgia.

Table 2

REEF outcome assessment: measures and schedule of administration

Outcome	Measure	Schedule			
		Baseline	Week 12	Week 24	Week 36
Primary Efficacy	Clinical: FIQ* physical impairment	X	X	X	X
	Adherence: CHAMPS¶	X	X	X	X
Secondary	BPI† pain severity	X	X	X	X
	FIQ pain and FIQ total	X	X	X	X
	6-minute walk test	X	X		X
	Activity monitor	X	X	X	X
	SF-36 physical component	X	X		X
Mediators	Exercise self-efficacy	X	X	X	X
	Decisional balance	X	X	X	X
	Intention-to-exercise	X	X	X	X
Covariates	PHQ-8‡ depression	X	X		X
	Demographics	X			
	Disability status	X	X		X
	Number of comorbid illnesses	X	X		X
	Body mass index	X	X		X
	Season of the year enrolled	X			
	Exercises at home or fitness facility	X	X	X	X
	Exercises solo or in a group	X	X	X	X
Others	Number and types of pain medications	X	X		X
	Number and types of non-study health care visits	X	X		X

*FIQ= Fibromyalgia impact questionnaire

¶CHAMPS= Community health activities model program for seniors;

†BPI= Brief pain inventory

‡PHQ-8= Patient health questionnaire-8

Table 3

Baseline characteristics of 216 subjects enrolled in the REEF study

	Motivational interviewing (n=107)	Education attention control (n=109)
Age in years, mean (SD)	46.0 (11.4)	45.7 (11.0)
Gender, % female	96.3	95.4
Ethnicity, % non-Hispanic	99.1	98.2
Race, % white	90.7	86.2
Education, % > high school	76.6	78.9
Marital status, % married	57.9	64.2
Employment, % employed	57.9	49.5
Body mass index, mean (SD)	32.3 (7.6)	30.5 (6.6)
Duration of fibromyalgia diagnosis in years, mean (SD)	8.9 (6.4)	9.1 (7.6)
PHQ-8 depression (range 0-24), mean (SD)	12.4 (4.8)	12.7 (5.1)
BPI pain intensity (range 0-10), mean (SD)	5.9 (1.2)	6.0 (1.4)
FIQ-physical impairment (range 0-10), mean (SD)	5.3 (1.5)	5.4 (1.7)
FIQ total (range 0-100), mean (SD)	67.5 (12.0)	66.6 (13.5)
Exercise self-efficacy (range 0-10), mean (SD)	5.4 (1.9)	5.3 (2.0)
Decisional balance: benefit-barrier (range -20 - 44), mean (SD)	26.0 (8.7)	25.0 (8.2)
Intention to exercise, (range 1-7)†	4 (2.7, 4.7)	4 (3.0, 4.7)
Medications, % prescribed Non-tricyclic antidepressants Anticonvulsants Opioid analgesics	 66.4 31.8 32.7	 57.8 27.5 33.0
CHAMPS, mean (SD) Light only (hrs/wk) Moderate only (hrs/wk) Vigorous only (hrs/wk)	4.9 (4.4) 1.4 (2.4) 0.1 (0.8)	5.2 (5.0) 1.7 (4.1) 0.2 (0.7)
Activity monitor, mean (SD) Counts/wk $\times 10^4$ Steps/wk $\times 10^4$ Min/wk of ≥ moderate activity	 125.0 (55.5) 2.9 (1.2) 99 (86)	 133.3 (62.4) 2.9 (1.1) 112 (101)
Meters walked in 6 minutes, mean (SD) ‡	479.5 (75.5)	486.5 (84.7)

Abbreviations: PHQ-8 = Patient Health Questionnaire-8; BPI = Brief Pain Inventory; FIQ = Fibromyalgia Impact Questionnaire; CHAMPS = Community Health Activities Model Program for Seniors; n = number of patients; SD = standard deviation.

Note: For PHQ-8, BPI and FIQ scales, a higher score indicates a worse state of health.

† Median score (1^{st}, 3^{rd} quartiles).

‡ Average of two 6-minute walk tests.