

Fibromyalgia Health Promotion Program: Background Evidence

Fibromyalgia is a chronic disease that is three times more common in women and characterized by amplified pain sensations that result in more pain than would be expected by a given stimulus.^{1,2} Fibromyalgia has disabling effects that lead to decreased quality of life and increased healthcare costs indicating that a health promotion program for women with fibromyalgia would be beneficial.²⁻⁴ The purpose of this section is to provide background evidence for the interventions, behavior change theories, and outcome measures implemented in this proposed program.

Based on a study by Nielson et al., a multi-modal intervention that includes exercise and behavior change theory is effective for patients with fibromyalgia.⁵ The intervention in the study included physical and occupational therapy as well as cognitive-based interventions to alter patient attitudes, beliefs, and behaviors.⁵ These interventions addressed the perceived susceptibility, severity, and barriers which are characteristic of the health belief model while the self-regulation strategies such as the enlistment of social support that were used are more closely tied to the social cognitive theory. The results of the intervention showed improved self-efficacy which is emphasized in both the health belief model and the social cognitive theory.⁵ The use of behavior change theory for patients with fibromyalgia is particularly important as they commonly have psychosocial factors that can decrease their compliance with exercise including pain catastrophizing and fear of movement.² O'Dwyer et al. conducted a systematic review of behavior change interventions that targeted physical activity in patients with fibromyalgia and found that four of the five studies that found a positive

effect were based on a behavior change theory while none of the studies without a theoretical basis found a positive effect.¹ Among the behavior change theories used were the health belief model and social cognitive theory.¹ Based on the evidence above, this proposed program is multi-modal and is based on the health belief model and the social cognitive theory. The health belief model is based on the idea that optimal behavior change will occur when perceived barriers, benefits, threats, and self-efficacy are addressed.⁶ The social cognitive theory also includes the self-efficacy as an important aspect of behavior change but also includes social support, self-regulation, and self-reflection as important components.⁷ As the definitions of these behavior change theories imply, the health belief model and social cognitive theories primarily work at the individual and interpersonal levels. Due to the importance of self-efficacy in both of these theories, the Self-Efficacy for Exercise Scale (SEES), which is both valid and reliable, will be used to measure self-efficacy change in the participants in the program.⁸ Due to a lack of an established MCID and MCD for the SEES, the program designer has chosen to use a 10% improvement as an estimated meaningful improvement in this population.

Aerobic and strength exercises are pillars of the proposed health promotion program for women with fibromyalgia. A systematic review by Bidonde et al. found that aerobic exercise interventions significantly improved short-term health-related quality of life, pain, stiffness, and physical function.⁴ The aerobic exercise parameters found in effective programs in the literature varied which does not allow for optimal parameters to be defined for this population.⁴ However, we can use the averages of the interventions as a rough guide to estimate effective aerobic exercise parameters. The

average frequency was three times per week with an average of 35 minutes per bout with gradual increases in intensity for about 15 weeks.⁴ A health-promotion program that also incorporates behavior change interventions based on the health belief model and the social cognitive theory is likely to improve long-term compliance with aerobic exercise and lead to the benefits being maintained over time. A 15-week intervention tested by Larsson et al. showed that resistance training in women with fibromyalgia significantly improved their strength, endurance, fibromyalgia symptoms, and chronic pain acceptance.⁹ In this study, the resistance training was performed targeting large muscle groups twice per week with a progressive increase in load based on an estimated 1-repetition maximum.⁹ The load used was reassessed by the clinician every 3-4 weeks.⁹ The intervention utilized a person-centered approach and group training sessions which were likely to improve the self-efficacy and social support of the participants which align with the social cognitive theory of behavior change.⁹ The six-minute-walk test will be used as an outcome measure for exercise capacity in the patients in the health promotion program as this test is reliable, sensitive and has been shown to correlate to the fibromyalgia impact questionnaire.¹⁰ The minimal clinically important difference (MCID) in this population has been indicated to be 156 meters when analysis was performed using the 14% (MCID) improvement in the fibromyalgia impact questionnaire (FIQ).¹⁰

Yoga and mindfulness meditation has also been shown to be effective for patients with fibromyalgia and is another component of this multi-modal health promotion program. An intervention for patients with fibromyalgia conducted by Van Gordon et al. utilized meditation/mindfulness education, group discussion, and

practice.¹¹ When compared to a control group that utilized cognitive behavioral therapy, the intervention group showed a strong positive effect on fibromyalgia symptoms, pain, psychosocial measures, sleep, and civic engagement.¹¹ This intervention seemed to be particularly promising as these benefits were maintained or improved at the 6-month follow up.¹¹ A study examining the efficacy of the Yoga of Awareness program which includes stretching, mindfulness meditation, breathing practice, and education also showed impressive results in patients with fibromyalgia as the FIQ score improved by 31.4%.¹² These two interventions primarily used the health belief model and social cognitive theory through the removal of barriers and perceived threats as well as the improvement of self-efficacy and social support.^{11,12} While there will not be a specific measure selected to isolate the impact of the yoga and mindfulness portion of the program, the FIQ will be a primary outcome measure used to evaluate the program as a whole with an improvement of $\geq 14\%$ indicating a clinically important difference.¹³ As shown from the studies mentioned above, effective yoga and mindfulness interventions have been shown to improve the FIQ score.^{11,12}

The final component of this health promotion program for women with fibromyalgia is a sleep hygiene intervention. Orlandi et al. implemented an intervention that included education regarding the timing of sleep, the sleep environment, sleep and physical activity-related nutrition tips, and more.¹⁴ The intervention group also received a sleep diary to track the number of hours of sleep and the quality of sleep.¹⁴ After the study, the group that received the intervention reported improved subjective sleep quality, improved pain, and a better ability to fall asleep easily after waking in the night compared to the control group.¹⁴ The self-monitoring aspect of the intervention reflects

the social cognitive theory while the sleep hygiene handout may serve as a cue to action which aligns with the health belief model. This program seeks to improve upon the intervention and results seen in the above study through increased levels of follow-up, education, and social support regarding sleep hygiene. The Pittsburgh Sleep Quality Index (PSQI) will be used to measure the change in sleep quality as a cut of global score of >5 has been shown to distinguish good vs. poor sleepers.¹⁵

In conclusion, the available evidence indicates that there are effective non-pharmacological lifestyle interventions including exercise, yoga, mindfulness training, and sleep hygiene education that may help reduce the symptom burden experienced by women with fibromyalgia and improve their quality of life. This multi-modal intervention program will primarily use principles of the health belief model and social cognitive theory as these are plentiful in the literature. Finally, the success of the program will be measured using the Self-efficacy for Exercise Scale, the six-minute walk test, the FIQ, and the PSIQ.

Fibromyalgia Health Promotion Program Goals

This health promotion program designed for women with fibromyalgia aims to meet the following objective goals:

1. From baseline to the 15-week post-intervention assessment, the average group Self-Efficacy for Exercise Scale score will improve by ≥ 9 points as evidence of improved self-efficacy during the program.⁸
2. From baseline to the 15-week post-intervention assessment, the average group 6-minute walk test will improve by >156m as this would indicate a meaningful clinical difference for exercise capacity in this population.¹⁰

3. From baseline to the 15-week post-intervention assessment, the average group FIQ score will increase by $> 14\%$ as evidence of a clinically meaningful improvement in fibromyalgia symptom burden.^{10,16}
4. From baseline to the 15-week post-intervention assessment, the average group PSQI will be < 5 as a score of ≥ 5 has been shown to indicate poor sleep.¹⁵
5. From baseline to the 15-week post-intervention assessment, the program attrition rate will be $\leq 20\%$ as evidence of an acceptable program design to the target population.

Fibromyalgia Health Promotion Program Methods

Before the beginning of this health promotion program for women with fibromyalgia, participants will be recruited with a maximum of 15 participants included in the program to allow for a group dynamic while keeping the numbers small enough to allow for individualization and create an environment that is conducive to sharing in group discussion. The primary means of recruitment and referral for the program will be communication with local MDs and rheumatologists who treat a high volume of women with fibromyalgia. Women of all ages are eligible for inclusion in the program and have a confirmed diagnosis of fibromyalgia from their primary care provider or rheumatologist. Participants must also be willing to attend $>80\%$ of the sessions and express a desire to improve their health behavior through participation in the program. Lastly, patients with dangerous comorbidities including uncontrolled diabetes, recent myocardial infarction, unstable angina, and severe hypertension ($>180/110$ at rest) will be excluded as participation in the program may be unsafe for these individuals.¹⁷

The program will last for 15 consecutive weeks and meet three times per week for approximately 1-hour sessions. The program will be conducted on Mondays, Wednesdays, and Fridays from 5:00 – 6:00 pm. The program design is primarily driven by the health belief model and the social cognitive theory as perceived barriers are addressed, perceived benefits are emphasized, social support is promoted, and self-efficacy is cultivated. The cost of the program will be \$300 per participant which equates to just under \$7 per session. The duration, frequency, and timing chosen are based on previous effective interventions in the literature. This duration and frequency should allow sufficient time for training adaptations to occur and for self-efficacy to develop which is likely to lead to an improved long-term impact of the program. While it can be difficult to accommodate the varying schedules of clients, the timing of the program was chosen to allow both first shift, third shift, and unemployed participants to attend. However, this time may be modified to best fit the needs of the participants identified through the recruiting process. Some modifications were made to the exercise protocol to improve the feasibility of the program including decreasing the frequency of resistance training from twice per week to once per week.^{4,9} Due to the program size, there will be significant equipment, space, and staffing requirements. The aerobic training intervention will require 15 combined treadmills (or a designated walking area such as a track), stationary bikes, and ellipticals. The resistance intervention will ideally utilize a leg press, knee extension and knee flexion resistance machines, and free weights ranging from 2.5 lbs. to 30 lbs.⁹ However, this may be modified to accomplish the goal of progressively loading the major muscle groups of the body using the available equipment. The yoga and meditation portion of the program requires the

space of a typical group exercise class at a gym so that there is enough room for 15 yoga mats to be spread out to allow for stretching without encroaching on others' space. The group discussions and sleep hygiene education can also take place in the group exercise room as no additional space is needed compared to the yoga/meditation intervention. Lastly, two private consultation rooms are required for the periodic individual consultations that will be incorporated into the program. Based on the outlined equipment and space needs, this optimal site for this type of program would be at an established gym with ample space such as the YMCA. The ideal staffing for the program includes two physical therapists and a yoga/mindfulness instructor. The use of two therapists rather than one is designed to allow for greater attention and individualization for the participants during the exercise portions of the program.

One week before the start of the program, all prospective participants will attend a 1-hour session that aims to identify any contraindications to participating in the program and allow participants to complete the baseline 6-minute walk test, the self-efficacy for exercise scale (SEES), the FIQ, and the PSQI. The typical weekly format for the program will consist of a dynamic warm-up, 30 minutes of aerobic exercise training followed by 30 minutes of yoga and meditation training on Monday and Friday sessions. The aerobic training time will be held constant through the 15-week program while the type of exercise and intensity of exercise will be altered for a greater training effect. Participants will be assigned randomly to begin with either treadmill/track walking, stationary cycling, or the elliptical. For the first five weeks, the participants will slowly increase the intensity of their assigned activity until an RPE of 11-12 is reached which correlates to fairly light activity.¹⁸ The initial goal is to start slow and complete the 30

minutes of aerobic activity without exacerbating fibromyalgia symptoms. This is likely to improve the self-efficacy of the participants and decrease the attrition rate from participants who might be fearful of more intense exercise. After the 5th week of the program, the participants will change modes of exercise to either of the modes not yet utilized. During weeks six through ten, the intensity of the exercise will be increased to an RPE of 13-14 which equates to somewhat hard exercise, unless fibromyalgia symptoms are exacerbated which would indicate a return to exercise at an RPE level of 11-12.¹⁸ During the last five weeks of the intervention, the participants will switch to the last mode of exercise that has not yet been performed. They will again increase their intensity to an RPE of 15-16 which equates to hard exercise.¹⁸ With any exacerbated fibromyalgia symptoms, the intensity will be decreased to the previous highest tolerable intensity. The yoga and meditation component of the program consists of gentle stretching, mindfulness meditation, and breathing techniques.¹² While the amount of time spent per session is decreased from the typical Yoga of awareness program to improve the feasibility of this comprehensive program, it is hypothesized that the increased duration of this health promotion program will allow for similar health benefits from this modified intervention.¹² The Wednesday program sessions will consist of 40 minutes of resistance training followed by either 20 minutes of sleep hygiene education or group discussion regarding coping with fibromyalgia symptoms to improve social support. The sleep hygiene and group discussion will occur on alternating weeks. The strength training intervention will target the major muscle groups of the body utilizing progressive increases in exercise parameters. The aim of the first week of the strength intervention will be to estimate the 1-repetition maximum (1RM) for each participant by

having them perform the maximal number of repetitions on each exercise with a given weight until perceived exhaustion.⁹ The 1RM can then be calculated using this number of repetitions. The exercises included in the strength training protocol will be leg press, resisted knee extension, resisted knee flexion, biceps curls, grip strength exercises, heel raises, and core exercises.⁹ Additionally, more explosive exercises such as rapid heel raises and high-velocity knee extension will be added to the program at weeks six and ten respectively.⁹ Week two through five will consist of the above exercises at 40% of the individual's 1RM for 1-2 sets of 15-20 reps depending on the level of fatigue. The exercise parameters for weeks six through nine will be 60% of 1RM for 1-2 sets of 10-12 reps while weeks ten through fourteen will be at 80% of 1RM for 1-2 sets of 5-8 reps. The above progression is a modified version of the program implemented by Larsson et al.⁹ The sleep hygiene educational intervention will be based on the study by Orlandi et al.¹⁴ Some of the educational tips included in this intervention were related to timing of sleep, activities around bedtime, nutrition tips, and sleep environment.¹⁴ There will be certain weeks that the program deviates from the typical schedule that is detailed above. In weeks four, eight, and twelve of the program, one of the aerobic/yoga days will be replaced with staggered individual meetings of the participants with a physical therapist where any individual questions or concerns can be addressed that the participant may not feel comfortable sharing in a group session. The therapists will ask the participants for feedback at these meetings as well so that any beneficial changes can be made. Week 15 of the program will also differ from the normal schedule as there will be only one aerobic exercise/yoga day. The other two days of week 15 will be used for participants to complete the 6-minute walk test, the SEES, the FIQ, and the PSQI.

Final individual meetings will occur during week 15 as well where the PT provides the objective results of participant change and engages in motivational interviewing to help the participant leave the program with self-set goals and action steps. Final program feedback will also be requested at the final individual meetings to allow for improvements to the health promotion program. Supplies will be given to each participant to promote behavior changes at home. Each participant will receive a yoga mat, a laminated card with sleep hygiene tips, and a diary to log their exercise, sleep amount and quality, and yoga/meditation practice. Additionally, participants are assigned homework to walk for at least 30 minutes at least one day outside of the program, to practice yoga/meditation at least one session outside the program, and to log all activity related to the behaviors discussed above. The inclusion of homework in the program allows the participants to practice incorporating healthy behaviors into their lives while receiving social support and feedback from the program facilitators.

Fibromyalgia Health Promotion Program Evaluation

In evaluating this health promotion program, the CDC framework will be utilized which includes stakeholder engagement, program description, evaluation design, gathering evidence, justifying conclusions, and using evaluation findings and sharing lessons learned.¹⁹ The primary stakeholders that this health promotion program seeks to engage are women with fibromyalgia and their medical providers who are the primary referral sources for the program. The engagement of stakeholders will be evaluated based on whether there is enough demand to fill the program with a maximum of 15 participants as well as the receptiveness of the medical providers to referring their patients who met the inclusion criteria. A lack of responsiveness and interest by either

the patients with fibromyalgia or their medical providers would indicate a lack of engagement of the most important stakeholders. Stakeholders will continue to be engaged throughout the program and at its conclusion. The participants will be engaged through the methods described above while the medical providers will receive the overall results of the health promotion program to provide objective evidence of its efficacy. Another important aspect of program evaluation is revising, expanding, or contracting a program depending on the outcomes of the intervention and the feedback received.¹⁹ As detailed above in the program methods section, there are periodic individual meetings between the program facilitators and the patients to provide feedback on the program. This allows for the program to be adjusted quickly if a trend is seen in the critiques of the program. Additionally, the program will be evaluated based on the outcomes achieved and the perception of the value that each intervention provides. For example, if it is seen that the PSQI scores did not improve significantly and that the patients did not find value in the sleep hygiene education, the design for future reiterations of the program may remove the sleep hygiene education and replace it with greater volume of the other interventions already included or an additional intervention such as dietary counseling may be added.

While subjective evaluation of the program from participants will be adequately considered, the primary evaluation tool for the program will be the program goals stated above. These goals were constructed to demonstrate meaningful change and a failure to reach these goals indicates a need for program modification. The program goals also help to mitigate bias from the program facilitators in the interpretation of the evaluation findings as they are specific, measurable, and time-based. Lastly, the program efficacy

can be evaluated by looking to the literature for studies with similar interventions and outcome measures to those used in this program. This may be particularly helpful in understanding the dose-response relationship of an intervention or whether value is added from using the health belief model and social cognitive theory principles in the program. To improve the feasibility of this multi-modal program, the amount of time per session spent on exercise and yoga/meditation was decreased compared to what was found in the literature. Therefore, a comparison of effect size in the literature compared to this program may provide evidence for changes in the volume of each intervention if needed. A major difference between this health promotion program and the interventions for fibromyalgia patients found in the literature is that this program is based on principles of the health belief model and social cognitive theory. A comparison of the effect sizes seen from the interventions may show whether this added benefit in addition to the exercise, yoga, or sleep interventions. In summary, this health promotion program for patients with fibromyalgia will engage stakeholders and have a process for feedback and modification that is ongoing. Given that this is the first known program of this specific design, it is expected that alterations will be required to optimize the program and that several iterations of the program may be needed to reach the program goals stated above.

Conclusion

Fibromyalgia is a debilitating chronic disease that primarily affects women and is often accompanied by psychosocial comorbidities.^{1,2} The primary recommendations for treatment of fibromyalgia are lifestyle modifications to address exercise capacity, stress, and sleep deficiencies but compliance with these modifications can be decreased due

to low self-efficacy and fear of movement.² Based on the unique needs and challenges of patients with fibromyalgia, a multi-modal program that is rooted in behavior change principles from the health belief model and social cognitive theory is ideal for reducing the symptom burden experienced by patients with fibromyalgia and improving self-efficacy. The proposed health promotion program for patients with fibromyalgia includes aerobic and resistance exercise intervention, yoga/mindfulness training, sleep hygiene education, and group discussion as the literature has shown improvements in this population from the inclusion of these interventions.^{4,9,11,12,14} To my knowledge, this is the first program that is designed to incorporate these combined interventions in a 15-week program that utilizes behavior change principles from the health belief model and social cognitive theory. The program also includes periodic, individualized counseling to address individual concerns and to provide program feedback. The hope is that the comprehensive nature of this program will augment the already impressive results from the individual interventions seen in the literature. The program facilitators are committed to the optimization of this program through communication with stakeholders, program evaluation, and reiteration of the program to maximize its feasibility, efficiency, and effectiveness. Funding and/or support for this program via monetary support, facility/equipment provision, or referral will help to provide an excellent local resource for women with fibromyalgia and serve as a pilot program that may be implemented to help this population on a broader scale.

Bibliography

1. O'Dwyer T, Maguire S, Mockler D, Durcan L, Wilson F. Behaviour change interventions targeting physical activity in adults with fibromyalgia: a systematic review. *Rheumatol Int.* 2019;39(5):805-817. doi:10.1007/s00296-019-04270-3
2. Clauw DJ. Fibromyalgia: a clinical review. *JAMA.* 2014;311(15):1547-1555. doi:10.1001/jama.2014.3266

3. Fitzcharles MA, Ste-Marie PA, Rampakakis E, Sampalis JS, Shir Y. Disability in Fibromyalgia Associates with Symptom Severity and Occupation Characteristics. *J Rheumatol*. 2016;43(5):931-936. doi:10.3899/jrheum.151041
4. Bidonde J, Busch AJ, Schachter CL, et al. Aerobic exercise training for adults with fibromyalgia. *Cochrane Database Syst Rev*. 2017;6:CD012700. doi:10.1002/14651858.CD012700
5. Nielson WR, Jensen MP. Relationship between changes in coping and treatment outcome in patients with Fibromyalgia Syndrome. *Pain*. 2004;109(3):233-241. doi:10.1016/j.pain.2004.01.002
6. Jones CL, Jensen JD, Scherr CL, Brown NR, Christy K, Weaver J. The Health Belief Model as an explanatory framework in communication research: exploring parallel, serial, and moderated mediation. *Health Commun*. 2015;30(6):566-576. doi:10.1080/10410236.2013.873363
7. Petosa RL, Suminski R, Hertz B. Predicting vigorous physical activity using social cognitive theory. *Am J Health Behav*. 2003;27(4):301-310. doi:10.5993/ajhb.27.4.2
8. Resnick B, Jenkins LS. Testing the reliability and validity of the Self-Efficacy for Exercise scale. *Nurs Res*. 2000;49(3):154-159. doi:10.1097/00006199-200005000-00007
9. Larsson A, Palstam A, Löfgren M, et al. Resistance exercise improves muscle strength, health status and pain intensity in fibromyalgia--a randomized controlled trial. *Arthritis Res Ther*. 2015;17:161. doi:10.1186/s13075-015-0679-1
10. Kaleth AS, Slaven JE, Ang DC. Determining the Minimal Clinically Important Difference for 6-Minute Walk Distance in Fibromyalgia. *Am J Phys Med Rehabil*. 2016;95(10):738-745. doi:10.1097/PHM.0000000000000485
11. Van Gordon W, Shonin E, Dunn TJ, Garcia-Campayo J, Griffiths MD. Meditation awareness training for the treatment of fibromyalgia syndrome: A randomized controlled trial. *Br J Health Psychol*. 2017;22(1):186-206. doi:10.1111/bjhp.12224
12. Carson JW, Carson KM, Jones KD, Bennett RM, Wright CL, Mist SD. A pilot randomized controlled trial of the Yoga of Awareness program in the management of fibromyalgia. *Pain*. 2010;151(2):530-539. doi:10.1016/j.pain.2010.08.020
13. Bennett RM, Friend R, Jones KD, Ward R, Han BK, Ross RL. The Revised Fibromyalgia Impact Questionnaire (FIQR): validation and psychometric properties. *Arthritis Res Ther*. 2009;11(4):R120. doi:10.1186/ar2783
14. Orlandi AC, Ventura C, Gallinaro AL, Costa RA, Lage LV. Improvement in pain, fatigue, and subjective sleep quality through sleep hygiene tips in patients with fibromyalgia. *Rev Bras Reumatol*. 2012;52(5):666-678.
15. Smith MT, Wegener ST. Measures of sleep: The Insomnia Severity Index, Medical Outcomes Study (MOS) Sleep Scale, Pittsburgh Sleep Diary (PSD), and Pittsburgh Sleep Quality Index (PSQI). *Arthritis & Rheumatism*. 2003;49(S5):S184-S196. doi:10.1002/art.11409
16. Bennett RM, Bushmakin AG, Cappelleri JC, Zlateva G, Sadosky AB. Minimal clinically important difference in the fibromyalgia impact questionnaire. *J Rheumatol*. 2009;36(6):1304-1311. doi:10.3899/jrheum.081090
17. Ghadieh AS, Saab B. Evidence for exercise training in the management of hypertension in adults. *Can Fam Physician*. 2015;61(3):233-239.
18. The Borg Scale of Perceived Exertion | The Nutrition Source | Harvard T.H. Chan

School of Public Health. <https://www.hsph.harvard.edu/nutritionsource/borg-scale/>. Accessed November 28, 2019.

19. CDC. Introduction to Program Evaluation for Public Health Programs:A Self-Study Guide. 2011.