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A qualitative examination of a new combined cognitive-behavioral and neuromuscular training intervention for juvenile fibromyalgia

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Abstract

Objectives—Adolescents with juvenile fibromyalgia (JFM) are typically sedentary despite recommendations for physical exercise, a key component of pain management. Interventions such as cognitive behavioral therapy (CBT) are beneficial but do not improve exercise participation. The objective of this study was to obtain preliminary information about the feasibility, safety, and acceptability of a new intervention - Fibromyalgia Integrative Training for Teens (FIT Teens), which combines CBT with specialized neuromuscular exercise training modified from evidence-based injury prevention protocols.

Methods—Participants were 17 adolescent females (ages 12–18) with JFM. Of these, 11 completed the 8-week (16-session) FIT Teens program in a small-group format with 3–4 patients

per group. Patients provided detailed qualitative feedback via individual semi-structured interviews after treatment. Interview content was coded using thematic analysis. Interventionist feedback about treatment implementation was also obtained.

Results—The intervention was found to be feasible, well-tolerated, and safe for JFM patients. Barriers to enrollment (50% of those approached) included difficulties with transportation or time conflicts. Treatment completers enjoyed the group format and reported increased self-efficacy, strength, and motivation to exercise. Participants also reported decreased pain and increased energy levels. Feedback from participants and interventionists was incorporated into a final treatment manual to be used in a future trial.

Discussion—Results of this study provided initial support for the new FIT Teens program. An integrative strategy of combining pain coping skills via CBT enhanced with tailored exercise specifically designed to improve confidence in movement and improving activity participation holds promise in the management of JFM.

Keywords

juvenile fibromyalgia; pediatric chronic pain; cognitive-behavioral therapy; physical exercise

Introduction

Juvenile Fibromyalgia (JFM) is a chronic musculoskeletal pain condition that occurs in 2–6% of children, primarily adolescent girls [1–5], and is associated with significant physical and emotional impairment [6–11]. Cognitive-behavioral therapy (CBT) has been found to be effective in reducing functional disability and depressive symptoms in JFM [12]; however, CBT alone has relatively modest effects on pain reduction [12]. One possible reason is because CBT treatment by itself does not result in greater engagement in more vigorous types of activity or exercise [13]. In particular, for musculoskeletal conditions such as JFM, engagement in regular physical exercise is recommended for pain management [14], and this not well addressed in traditionally delivered CBT. Several studies have shown the benefits of both aerobic and strengthening exercise programs in reducing pain [15–19]. Yet, in order for exercise to be effective in the long term, patients need to incorporate exercise into their daily routine even after formal training programs have ended [15]. Adequate maintenance of daily physical activity is a primary challenge for patients with fibromyalgia because the majority, including adolescents with JFM [20–22], are sedentary and adherence to exercise regimens in fibromyalgia patients is generally found to be quite poor [23, 24].

Barriers to maintenance of exercise in patients with fibromyalgia may be related to pain, activity avoidance and features of the disease itself that make patients more prone to experiencing increased pain with exercise. It has been found that adolescents with chronic pain tend to reduce physical activity following days with higher pain intensity [25] and that adolescents with JFM show decreased strength and altered biomechanics [26]. Studies in adults have indicated that patients with fibromyalgia have dysfunctional pain inhibition whereby they do not show the typical endogenous hypoalgesia following exercise [27–29]. Thus the combination of JFM pain, pain-related activity-avoidance and poor body

mechanics likely makes exercise difficult and uncomfortable [30–32] and may ultimately resulting in a downward spiral of pain and disability [33, 34].

A recent study documented altered biomechanics, decreased strength and deficits in functional performance, along with marked self-reported fear of movement in adolescents with JFM compared to their healthy peers [35]. The movement patterns identified in these patients using sophisticated biomechanical tests including 3-dimensional motion analysis are similar to movement deficits that place individuals at risk for injury [36, 37]. Therefore, traditional aerobic or resistance training programs may be difficult to sustain for patients with JFM because of poor movement confidence and a lack of fundamental movement competence. It has become clear that tailored exercise programs are needed for fibromyalgia patients [28] but thus far, finding the most appropriate type of exercise that is both tolerable and sustainable for these patients has been a challenge for the field. Using what is known from injury prevention research from the field of exercise science in conjunction with the knowledge we have gained about improving psychological coping skills from our evidence-based CBT program, we have devised a new and innovative treatment - the Fibromyalgia Integrative Training for Teens (FIT Teens) program. This intensive 8-week program is focused on enhancing CBT with the integration of specialized neuromuscular exercise training [38, 39]. FIT Teens was designed to instill confidence in patients with JFM to safely engage in physical activity and motivate them to incorporate regular exercise which could be an important step towards improved fibromyalgia pain control.

Integrative neuromuscular exercise training focuses on the development of core strength, conditioning, and fundamental movement skills [38, 40]. This approach has been well studied in adolescent athletes and found to improve core stability and strength [38, 41–44]. However, to our knowledge neuromuscular training has not yet been employed with adolescents with JFM, nor has it been applied in combination with CBT. The neuromuscular training component of the FIT Teens program was tailored for adolescents with JFM through a careful iterative process including consultation with experts in rheumatology, sports medicine/exercise science, and behavioral medicine. Exercise progressions were specifically modified to gradually increase the level of challenge and minimize muscle actions that would induce delayed-onset muscle soreness that might mimic JFM symptoms. The CBT components of the program were based on our established CBT treatment [12] modified to include application to in-vivo exercise training (e.g., activity pacing, breathing relaxation techniques, distraction, dealing with negative thoughts/anticipation of pain) which were closely integrated with the exercise component.

The primary objectives of this pilot, qualitative study were to 1) obtain information about the feasibility, safety, and tolerability of the 8-week (16 session) group-based FIT Teens intervention for adolescents with JFM and 2) gather detailed feedback from participants about their impressions of the acceptability, format, and content of the program. We hypothesized that the program would be feasible in terms of patients' willingness to participate, and safe/tolerable – because the CBT component is already well-tested and the newly added exercise component is progressive and specially designed to minimize pain. We further anticipated that the JFM patients would enjoy the group-format of training with other similar-age JFM patients, and find the content beneficial.

Materials and Methods

Participants

Patients were eligible if they were 12–18 years old and diagnosed with JFM by a pediatric rheumatologist or pain physician. Consistent with our prior studies, we used the Yunus and Masi (1985) criteria for JFM classification which require widespread pain, associated symptoms (fatigue, sleep disturbance etc.), and at least 5 painful tender points upon palpation [5]. Additional inclusion criteria were: moderate to high level of disability (Functional Disability Inventory score ≥ 12 [45]); and moderate pain intensity (≥ 4 on a 0–10 cm visual analog scale of average pain). Exclusion criteria were: diagnosis of a comorbid rheumatic disease (e.g., juvenile arthritis, systemic lupus erythematosus), untreated major psychiatric diagnosis (e.g., major depression, bipolar disorder, and psychosis), use of opioid medication, documented developmental delay, or any other medical condition determined by their physician to be a contraindication for exercise (e.g., severe orthostatic hypotension, vertigo, recent surgery or untreated seizure disorder), or ongoing participation in CBT for pain.

Recruitment

Potential participants meeting screening criteria were identified by a trained research assistant from pediatric rheumatology and pain clinics at a large children's hospital. Medical eligibility was confirmed by a physician who introduced the study to patients and their caregivers. If interested, a research assistant provided a thorough overview of the study, answered any questions, and obtained written informed consent and assent. This study was approved by the Institutional Review Board of the children's hospital.

Intervention

The format of the initial FIT Teens program piloted in this study was 16 in-person sessions (twice per week) in a small-group format, 60 minutes for each session (~30 minutes each devoted to CBT and neuromuscular training). The intervention took place at a Children's Hospital in the Sports Medicine Biodynamics and Human Performance Laboratory (similar to a gym setting) with the CBT component conducted in an adjoining conference room. Sessions were led jointly by a psychology post-doctoral fellow with specialized training in pediatric pain and a master's level exercise physiologist who was experienced (5+ years) in the delivery of neuromuscular training as part of injury prevention research protocols. They were supervised by a senior licensed psychologist (SKZ) and a doctoral level Sports Medicine researcher (GDM) via weekly team meetings.

The CBT components of the program were based on our published clinical trial [12] and consisted of training pain coping skills including education about the gate-control theory of pain, relaxation skills, distraction, activity pacing, problem solving, and modifying negative and catastrophic thoughts about pain. The content was modified to apply coping skills in vivo while participants learned neuromuscular exercises for a more integrated approach. The specialized resistive training protocol used in neuromuscular training progressed through four levels focusing on a different muscle action; Level 1: Holding Exercises, Level 2: Creating Movement Exercises, Level 3: Resisting Movement Exercises, and Level 4:

Functional Movement Exercises (see Table 1. for a description of each level of progression along with an illustrative example; complete protocol published in Thomas et al. [46]). The progression of exercises was collectively designed in order to reduce muscle pain and delayed-onset muscle soreness by moving from most basic isometric “hold” exercises to concentric “muscle shortening” exercises to eccentric “muscle lengthening” exercises to the full range of motion for “functional movement”. By gradually building upon the foundation of movement by focusing on each type of muscle action, the protocol allows participants to master each level before advancing. The final level is designed to pull together each level into functional movements that are relevant for activities of daily life. New exercises were introduced every 2 weeks with ongoing constructive feedback regarding proper form and technique before being incorporated into the full functional movement exercises in Level 4. The program was also tailored to minimize pain *during* exercise by specifically tailoring the program to each person based on their baseline levels of fitness and confidence. For example, for patients unable to perform a squat, minimizing the range of motion and providing external support were some of the modifications made which participants practiced until they were able to achieve a squat position. In contrast to traditional resistance training programs, this protocol did not include any external resistance exercises. Rather, exercises were designed to mimic movements that occur in normal daily activities and individualized for difficulty based upon participants’ baseline ability. Further, the exercise trainer ensured neutral joint positioning, particularly for any JFM patients with co-occurring joint hypermobility (as documented by a Beighton score ≥ 5) for whom joint protection should be kept in mind. Education was provided to all patients normalizing temporary muscle soreness when beginning a new exercise regimen and differentiating muscle soreness from a JFM pain flare.

At the end of each session, participants were provided home practice instructions for coping skills and physical exercises along with daily diaries to monitor progress. Participants were requested to complete a daily paper-pencil diary once at the end of each day with ratings of daily pain intensity and fatigue (both rated on a 0–10 scale), and practice of coping skills and physical exercise. Diaries were reviewed by the trainers at the following session to discuss progress and problem-solve barriers to independent home practice. Missed sessions were re-scheduled to ensure that all participants received the full course of the intervention.

Post-Intervention Interview

After the final session, adolescents met individually with a trained research staff member who was not part of the treatment team to complete a 30–45 minute semi-structured interview. The majority of interviews were conducted in-person, and one interview was conducted over the phone due to scheduling difficulties. All interviews were digitally audio-recorded, assigned an identification number to anonymize content, and transcribed for coding. Interview questions (Appendix 1) were developed a priori to examine the feasibility, tolerability, safety, content, and format of the new FIT Teens program. The interview included uniform open-ended questions, which offered flexibility for participants to provide additional relevant information and for the interviewer to ask clarifying questions.

Feedback from Interventionists

In addition to qualitative information from participants, the exercise physiologist and psychotherapist provided feedback regarding implementation of the study protocol throughout the FIT Teens program during weekly supervision meetings. They also maintained session logs documenting safety and tolerability (reports of pain during specific exercises, soreness after exercises, any JFM pain flares). Interventionists' feedback was reviewed throughout the program to clarify the need for subsequent protocol refinements.

Data Analysis

Regarding the domain of *feasibility*, the number of patients approached, the number who agreed to participate and those that declined (and reasons for declining) was recorded. The number of patients who dropped out and reasons for drop out were also documented. To assess for *safety*, the trainers recorded adverse events (e.g., any falls, injuries, excessive pain or any symptom requiring medical consultation caused by the training exercises) at each session. Temporary muscle soreness in the muscles being "worked" during exercise was an expected reaction as most patients with JFM have some level of deconditioning - and therefore not defined as an adverse reaction. Trainers tracked participants' ability and comfort completing exercises during each session as one indicator of *tolerability*. Trainers kept a log of participants' completion, modification, and level of difficulty of exercises completed by each patient and any adverse events at each session.

Qualitative Interview Analysis—Informed by Grounded Theory [47], thematic analysis [48], a rigorous, systematic and iterative method, was used to classify the verbatim responses from patients. Each transcript was reviewed independently by two trained coders (from a team including a clinical psychologist, a psychology resident, and two clinical research coordinators) and a line-by-line content analysis was used to extract data that detailed the *feasibility, safety, tolerability, format, and content* of the FIT Teens program. Themes were identified, defined, and refined through review of the interviews. Regular coding meetings were held to discuss the identified themes. When discrepancies occurred or content appeared to overlap more than one domain, the coders clarified the meaning of emerging themes by reviewing transcripts for contextual supporting information to inform a consensus interpretation of the text, and data were assigned to the one domain which best represented the content. Finally, domains were identified based on commonalities among themes reported by participants.

Study Interventionist feedback—The trainer and therapist made notes/comments about the implementation of the protocol at each session which were used by the team to make iterative changes after each group ended.

Results

Of the 34 eligible patients approached to participate, 17 declined (7 due to distance from the hospital, 8 for time/transportation constraints, and 2 for pursuing other treatments), and 17 enrolled over the course of one year. Six participants dropped out: one individual reported suicidal ideation that was not revealed at the initial evaluation and was referred for

psychiatric care, one started employment that interfered with program completion, and four others had difficulty making regular appointments and transportation arrangements. A total of 11 participants (all female, 12–18 years, $M = 16.00$ years, $SD = 2.15$) completed the FIT Teens program in its entirety during three 8-week groups and completed the post-intervention interview. One interview was lost due to recorder malfunction; therefore, 10 complete interviews were available for coding and analysis.

Mean disability score on the Functional Disability Inventory for the group was in the moderate range ($M = 24.09$, $SD = 11.42$) and the mean pain rating for the past week (0–10 scale) was 5.87 ($SD = 1.96$). Patients obtained their usual medication management through our pain and rheumatology clinics. Typical medications used in these clinics include one or more of the following: non-steroidal anti-inflammatory drugs (NSAIDs) or anticonvulsants (i.e., gabapentin) for pain, tricyclic antidepressants (i.e., amitriptyline) or muscle relaxants (i.e., cyclobenzaprine) for sleep, and serotonin and/or norepinephrine reuptake inhibitors, if needed, for mood symptoms.

Regarding safety, no adverse events were recorded during the intervention. A few participants reported occasional JFM pain flares during the intervention time span, but they reported that they were able to distinguish between pain/soreness after exercise and their usual JFM pain fluctuations that they believed were not due to the introduction of new exercises. In terms of tolerability, while modifications were made on an individual basis according to ability (e.g., starting with a half squat without using the full range of motion if needed), all participants were able to perform a form of each exercise. Patient reports of pain or inability to perform a new exercise was used by the exercise trainer as a cue to modify the exercise to a lower level of challenge until the patient was able to do the exercise with minimal discomfort.

The content of the interviews was categorized into the following a priori domains: 1) Feasibility, 2) Tolerability/Acceptability, 3) Safety, 4) Content, and 5) Format. Within each domain, common themes were identified and defined (see ***bold italics***), and key quotes that encapsulated each theme were identified. Two additional domains that emerged beyond the a priori categories were: 1) Perceived Efficacy and 2) Continued Physical Activity Participation. Primary findings are summarized below by content domain, with representative quotes from each theme provided in Tables 2–7.

Domain 1: Feasibility—Overall, participants reported that the coping skills and the physical exercises were easy to learn and perform within the sessions (Table 2). Most participants also provided specific examples of how they were ***able to regularly practice*** the skills they learned. Additionally, all participants described the ***usability of skills*** outside of sessions. Several participants discussed aspects of the program that enhanced its utility and their ***ability to adhere*** to the regimen. In particular, the specialized exercise program and being able to learn new exercises along with other teens with JFM was stated as a positive and motivating aspect of the program. Regarding ***barriers to feasibility***, participants also identified potential barriers to maintaining the treatment regimen, including difficulty exercising during pain flares, fatigue, or demands on their time after school.

Domain 2: Tolerability/Acceptability—Participants expressed no difficulties with the coping skills component of treatment. With respect to the integrated neuromuscular training, most participants observed that although the exercises were challenging and they could feel their muscles “working”, *exercises were physically tolerable* (Table 3). Nearly all participants reported that the *pace and progression* of learning exercises was a positive feature, and the majority reported that the interventionists appropriately modified the exercises as needed to meet individual levels of ability. Teens consistently identified *some exercises as being the most difficult*, particularly those including squats, hamstring curls, lying prone while extending arms and legs (“Superman”), and hip hinge on one leg. However, participants reported that if needed, the exercise physiologist made *modifications* to these exercises and they were able to perform them correctly. Several participants reported liking the squats and hamstring curls by the end of the program.

Domain 3: Safety—Participants generally reported that it was helpful to learn new exercises with modifications as needed in a supportive environment (Table 4). About half of the participants reported that it was useful to learn how to exercise with *good form*. Some participants also described that the intervention provided appropriate supervision and reassurance to ensure that participants felt comfortable with the level at which their physical abilities were challenged (*supportive environment*). Half of participants reported no pain flares, or a *reduction in pain flares* during the program; the other half reported experiencing typical JFM pain fluctuations that were described as unrelated to the exercises. Some participants reported *soreness/aches or fatigue* after the exercise sessions; one participant stated that this was likely due to an increase in overall physical activity from her baseline level of (in)activity.

The majority of participants also described learning to differentiate between their typical *fibromyalgia pain versus exercise-induced muscle soreness* which was more temporary.

Domain 4: Content—Overall, participants gave favorable reviews of exercises and coping skills learned during the intervention (Table 5). All participants gave examples of *exercises that they particularly liked*, highlighting 12 specific exercises out of the total 32. All participants also gave examples of *coping skills* that they liked, specifically mentioning all 7 coping skills.

Participants identified specific exercises and coping skills that they did not like and described the reasons for their dislike (*least favorite exercises and coping skills*). Generally, participants described disliking specific neuromuscular exercises due to difficulty performing the exercise or feeling that the targeted muscles were not “working”. Less preferred coping skills were those that required more time to complete or those that they practiced less frequently (e.g., progressive muscle relaxation).

Most participants also demonstrated understanding of how the coping skills and physical exercise portions of the intervention were complementary (*combined treatment*).

Domain 5: Format—Participants were unanimously positive about the *group format*, mainly due to the supportive and encouraging group environment and the opportunity to

meet other patients with JFM (Table 6). The majority of participants also enjoyed the *structure of the program*, progressively learning new exercises every two weeks before ultimately creating the full functional movement, and monitoring their own progress. With respect to *challenges of the group format*, two participants felt that it was sometimes difficult to get one-on-one attention when the trainer turned away to focus on other group members, and one participant would have preferred not to discuss coping skills in a group setting.

Additional Domains

Domain 6: Perceived Efficacy—Overall, participants reported feeling more confident and noticing a number of positive changes at the end of the FIT Teens program (Table 7). Nearly all participants reported increased *confidence and self-efficacy* as a result of the program, having a sense of pride in their accomplishment, and being happier. The majority also reported noticing a progressive increase in their *strength, stamina, and physical functioning*. Most participants also reported noticing a *reduction in physical symptoms* as a result of the program, particularly a reduction in pain. Over half of the participants also reported *improvement in sleep*, or feeling rested or having more energy during the day. Specifically, five reported reducing or eliminating naps from their routine. Two participants reported continued difficulty with sleep (e.g., falling asleep).

Domain 7: Continued Physical Activity Participation—During the program, all participants noted that they had increased their overall daily *physical activity*, incorporated planned physical activities into their daily schedules (Table 7), and experienced increased motivation to go out or be with their friends even if they had pain.

Feedback from Trainers

The psychotherapist and exercise physiologist provided feedback throughout the FIT Teens program in order to consider the need for subsequent protocol refinements. The timing of the sessions (3:00–4:00 pm) was reported to be a barrier for some patients, as they were unwilling to miss school to attend the program. Additionally, the interventionists noted that the length of sessions (60 minutes) was too short—there was not enough time to review homework in addition to learning and practicing new material (CBT and exercises). The exercise physiologist made note of modifications made to specific exercises for patients who reported pain/discomfort performing the exercise, and modifications for those patients who had co-occurring joint hypermobility (commonly seen in JFM patients). No safety issues were reported or adverse effects other than the expected temporary muscle soreness after initiating new exercises. The interventionists also felt that the participants needed more instruction on how each exercise was connected to daily activities such as walking up and down stairs, sitting in class or standing for a long period of time. The psychotherapist noted that many participants brought up sleep as a problem area, and there were no specific instructions on sleep hygiene in the CBT protocol. Finally, several participants had difficulty with the translatability of skills to real life, in particular remembering to do homework and increasing physical activity. This feedback was taken into consideration and changes were made (the details of which are offered in the Discussion) iteratively after each group in order to refine the intervention.

Discussion

The results of the current pilot investigation provided initial support for the feasibility and acceptability of an integrative CBT and neuromuscular training program for adolescents with JFM. The primary goal of this investigation was to obtain direct feedback from participants regarding implementation barriers to the behavioral and exercise-based skills taught during the sessions, their comfort with the format and content of the training program, and whether they found it helpful in the management of their symptoms associated with JFM. Information gleaned from individual, semi-structured interviews, along with the feedback from study staff confirmed that this innovative combined intervention was overall very well-received, safe, and potentially efficacious for adolescents with JFM.

Particular strengths of the FIT Teens intervention noted by participants were: 1) the group format – which made participants feel supported and validated in their experiences, 2) the integration of both psychological and physical interventions within the same program, 3) the progressive increase in challenge of the neuromuscular exercises and the education in proper form to exercise safely, 4) the trainers' ability to modify the exercises to participants' baseline abilities, and 5) the increased confidence and sense of strength. The trainers also noted that the group format allowed much greater patient engagement and participation and increased participants' ability to learn from and motivate one another. For example, during the course of treatment patients could assist one another (e.g., working in pairs). Also, a natural tendency to cheer and support the other members or make suggestions about how to improve technique emerged within the group members which would not occur in a one-on-one training environment. Early evidence for the efficacy of the program was suggested by participants' comments about decreases in pain flares, increased energy, reducing/eliminating naps, and participating in more activities. Interestingly, despite the research showing that isometric exercise can lead to increased pain sensitivity (at least in the short term)[29], this did not appear to hinder patient's progression through the exercise training. Perhaps the tailoring of the program which allowed for modifications of each exercise to improve tolerability with gradual increase in the level of challenge coupled with the emphasis on use of positive coping strategies and group support were jointly effective in ensuring that initial muscle soreness did not deter patients from engaging in the exercises.

In addition to the positive feedback obtained from participants about the program, this pilot study helped identify potential challenges to feasibility in implementing an intensive behavioral intervention requiring significant time commitment and effort from participants and families. About half of the eligible participants were unable to participate in the intervention and a few dropped out, citing distance from the hospital or difficulty in coming for appointments two times per week. Therefore, only the more motivated families and/or those with adequate time are likely to participate. In this study, participants were reimbursed a modest amount for gas expenses and there was no cost to the patients or their insurance companies for the sessions. Therefore, financial barriers were not a concern in this study but may arise in clinical care. These are realistic challenges in implementing any self-management training program that requires multiple in-person visits. To reduce attrition after starting the treatment, we made adjustments to the inclusion criteria to assess for complex psychiatric needs beyond the scope of the treatment (e.g. suicidal ideation) so that

such patients can be referred to more appropriate care. Also, we moved the sessions to after school hours which were preferable to families. Although efforts are being made to make some self-management interventions (e.g., CBT) more accessible in web-based format [49, 50], the neuromuscular training requires close supervision of patients who have poor movement skills to ensure proper form and safety. Also, the integration of CBT with exercise requires in-vivo exposure for maximal effectiveness. We are therefore conducting initial rigorous testing of the FIT Teens intervention as a “proof-of-concept” to develop the manualized protocol which can then be delivered in community settings where physical therapists and trainers are more readily available and can be easily trained in the protocol.

In response to the feedback from patients and interventionists, several modifications to the protocol were iteratively made. Also, the psychological screening procedures were further refined, including specific assessment of recent or ongoing suicidal ideation which would require intervention outside the scope of this program. After the first group (and implemented in the second group), the duration of each session was increased from 60 to 90 minutes to allow sufficient time to cover the material and discuss home practice, a later start time after school (4:00pm or later) was offered, specific content on sleep hygiene was added, and the protocol was expanded to include written instructions at the end of sessions to address participants’ difficulty remembering homework. For the third group, the exercise physiologist began illustrating the utility of each exercise through pictures demonstrating how each exercise relates to daily physical tasks and including explicit guidelines for gradually increasing moderate-vigorous physical activity at home (i.e., brisk walking, playing a sport, swimming) to emphasize the importance of increased physical activity outside of session. Although participants reported increased participation in physical activity, specific activity goals were added (starting with 5 min of moderate activity of their choice, once a week) and progressively increased to 30 minutes of moderate-vigorous activity at least twice a week by the end of treatment to match the recommended exercise guidelines for patients with fibromyalgia [14].

In conclusion, this study obtained extensive patient-centered information related to the feasibility, acceptability, safety, and content of a new integrative treatment program for adolescents with JFM. The refined FIT Teens protocol incorporates feedback from the teens themselves as well as the trainers and research staff to arrive at a final protocol that is now ready to be tested in a randomized clinical trial. This combined program offers a promising new approach beyond currently available CBT-only programs [12] and exercise-only programs [16]. Although there is evidence from clinical treatment programs that multidisciplinary care is a useful treatment for pediatric chronic pain [51], the innovative FIT Teens program has the advantage of being carefully developed from an evidence-based CBT protocol integrated with a highly novel and specialized approach to the delivery of exercise training (neuromuscular training) that has never been tried in chronic pain populations.

Future goals are to compare the efficacy of FIT Teens to traditional exercise programs such as graded aerobic exercise and to our established CBT intervention in rigorously designed studies to determine whether FIT Teens leads to superior outcomes. Future studies on the specific mechanisms of pain responses to different types of exercise in JFM patients is

needed and results could be used to inform more finely tailored programs. If found to be successful, the FIT Teens program will make available an evidence-based treatment manual for CBT and physical exercise (requiring minimal equipment) to be translated into regular clinical care for patients with JFM. The ultimate goal is to develop an integrated evidence-based treatment that can be disseminated widely for the treatment of adolescents and result in long-term pain control and a healthy lifestyle that reduces the likelihood of activity limitations and decreased quality of life due to JFM.

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Figure 1.
Participant Flow Chart

Table 1

Example of exercise progression along with instructions to perform the exercise

Level	Type of Movement	Example Exercise	Description of Exercise
1	"Hold Exercises" (Isometric)	BOSU Double Leg Deep Hold w/ TRX Upper Body Assistance	The patient starts by standing on the BOSU with the round side up and holding onto the TRX handles. Then, the patient bends their hips and knees until their knees are bent to approximately 90°, using the TRX handles as support. The patient holds this position for the prescribed time.
2	"Creating Movement Exercises" (Concentric)	BOSU Double Leg Squat <u>UP</u> - with TRX Assistance <u>DOWN</u>	The patient starts by standing on the BOSU with the round side up and holding onto the TRX handles. Then, the patient bends their hips and knees until their knees are bent to approximately 90°, using the TRX handles as support on the way down . The patients will slowly (3 count) raise themselves back to the starting position, using as LITTLE support from the TRX handles as possible (arms are relaxed).
3	"Resisting Movement Exercises" (Eccentric)	BOSU Double Leg Squat <u>DOWN</u> - with TRX Assistance <u>UP</u>	The patient starts by standing on the BOSU with the round side up and holding onto the TRX handles. Then, the patient slowly (count of 3) bends their hips and knees until their knees are bent to approximately 90°, using the TRX handles as LITTLE as possible for support on the way down. With support from the TRX handles, the patient will raise back to the starting position.
4	Functional Movement Exercises	BOSU Squats w/ TRX Upper Body Assistance	The patient starts by standing on the BOSU with the round side up. Then, the patient bends their hips and knees until their knees are bent to approximately 90°. The patient then returns to the starting position and repeats. Using the TRX for a LITTLE assistance as possible through the entire range of motion.

Table 2**Representative Quotes from Domain 1: Feasibility****Theme: Practice**

- I try to [practice relaxation] most nights.
- It [practicing exercises] will fit into [my life].
- It [exercises] doesn't take that long and I think once I figure out a schedule to do that with the activities then I think I'll do that [practice exercises] a lot.
- The deep breathing one I use about once every three to four days, and the mini-relaxation I will use...once every two days... I use that one more than the deep breathing one, because I had the stickers at school and everything, I am more reminded to do that.

Theme: Usability of Skills

- The mini-relaxation... is really quick, you can use it anytime. It's going to be helpful when I'm in class.
- They [coping skills] actually got me through some of the exercises some days.
- When I was getting... tired...or...frustrated, when I was learning new exercises and I wasn't quite doing them right...I would... stop and relax [do a mini-relaxation] and get a drink of water and then go try it again.
- I [used activity pacing] didn't push myself too far and I was still able to stay with my friends and do what they were doing.
- The mini-relaxations I will do during the day...if I get tensed up doing something, I will stop and do a mini-relaxation.
- Calming statements and I would be like...you can do this...you will feel better once you are done... I don't feel better physically, but I feel better mentally, because I know I was active that day.
- Mini-relaxation I would do all the time when I felt a little tense...muscle relaxation I would usually do in the morning or at night before I went to bed.
- Pleasant imagery I usually did before bed or if I was having a lot of pain...calming statements...I did mostly when I felt...anxious or when I couldn't sleep.

Theme: Program Adherence

- Not just being forced to do traditional physical therapy... with this being catered towards people with fibromyalgia.
- I was thinking that if she can do it then I can do it too.
- I need some sort of a plan. So this was helpful how it is always scheduled same day, same time.
- I get the concept but I forget the positioning exactly. So then they [exercise physiologist and psychologist] would right away be like ok here. It was never like, "Why would you forget something like that?"...they were really helpful.
- At the end of it she gave us this program [handouts] so we can keep on going...I think I'll do really well with them.
- We got the BOSU [balance trainer device] and ... a packet of exercises [to take home].

Theme: Barriers to Feasibility

- If I'm already hurting I probably won't do them as much.
- Flare-ups, because sometimes it is just easier to get into this mindset that...I am just going take it easy today. When sometimes getting up and moving makes it better, but while it is going on it is hard to remember that.
- I'll be too tired [to practice exercises].
- It was just like finding time [to do the exercises at home].

Table 3**Representative Quotes from Domain 2: Tolerability/Acceptability****Theme: Exercise Tolerability**

- It was kind of difficult but I could actually do it.
- It was like an actual workout so I did feel a little sore, but my muscles were working and it was a good sore.
- I started getting really good at it and it was better.
- The crunches were getting easier and the squats.
- I felt like I could feel my muscles working more with the Bosu.

Theme: Pace and Progression

- They [exercises] were paced really well ...the next one [exercise]...would be hard at first and then I'd get better.
- It was the right amount... everything was. It was...that point where...my body is starting to struggle...it was like a good struggle.
- [The exercise physiologist] would work with you personally to make sure you were comfortable with where you were...make sure the exercise wasn't too easy or too hard.
- New exercises [were] easy at the moment but as we were doing them they got harder... Other times they started out hard...your body wasn't used to them and then with practice it got easier.
- Definitely the right amount of time [spent on each exercise level]. You know what you are doing and how to hold positions before you move on to the next level.

Theme: Difficult Exercises

- Superman was always really hard for me.
- The hamstrings [specifically in Level 4]. I would just be so tired after doing them. The other ones I could like recover more easily.
- The hip hinge with single leg RDL [Romanian Dead Lift]...I definitely had trouble with my balance.
- The plank [was the most difficult in level 1]...my arms just started trembling and I felt like I was just going to collapse.

Theme: Modifications

- The chest press was hard on my elbows at first...they would pop but we modified that and it helped.
- The reverse hyperextension with the Swiss ball. I had to get modifications for that one because it hurt my lower back...raising opposite leg and arm was much better...a lot better.
- ...instead of hurting my back I folded my arms [modified exercise] so it was better.

Table 4**Representative Quotes from Domain 3: Safety****Theme: Good Form**

- I thought I was doing it right, but she showed me how to do it and it was helpful 'cause it felt different.
- I learned how to do them right and better.
- They also gave me ideas of how to do things [exercises] on my own...so I found out a new way to do that [modified crunches] and I love it.
- To know that I was doing it right felt really good.

Theme: Supportive Environment

- [The exercise physiologist's] reassurance was really helpful.
- I liked the way the trainer introduced the exercise...she was always giving us good support, challenging us a little.
- [The exercise physiologist] encouraged doing them [exercises]...she didn't push you too hard where you would get frustrated but...definitely wanted you to work more...if you did six she would be like try two more and then you will be done.
- [At home] I know what I needed to do. I used the modifications and I had a little [trainer's name] in my head, just encouraging me.

Theme: Reduction in Pain Flares

- My back has been really better throughout this program.
- I haven't been using that [pain medications] during this program at all.
- [Did you have any pain flares?] No, actually I didn't.

Theme: Soreness/Aches/Fatigue

- The beginning ones would hurt more because we just started the exercises and we had to get used to them.
- Every session I was a little sore afterwards.
- My body was like sore and I was exhausted by the time I get home.
- When it got a little more challenging I would be sore [for]...maybe two days.
- The squats hurt my legs.
- When I hurt it is mostly in my back and I just didn't like [assisted back extensions on the Swiss- ball].

Theme: Fibromyalgia Pain versus Exercise-Induced Muscle Soreness

- Fibro pain is sharper and it will last longer. [Exercise-induced muscle soreness] was more like my legs would be tired.
- Fibromyalgia pain for me is usually all over or there is usually some swelling...almost like arthritic pain...[Muscle-induced soreness] was less joint pain more muscle pain...I would feel the specific muscles not just like an all-over arm pain.
- Muscle induced soreness [was a] good soreness... [JFM pain was] like aches.
- Fibromyalgia pain...you can tell it's not muscle...it's shooting pains...feels like a hot knife repeatedly doing the same thing...the muscle soreness...it might hurt while you are working it out but afterwards it feel better.
- Fibromyalgia pain is more...nagging...the soreness I can tell it isn't all over it's just in specific areas.
- Muscle soreness just feels tight and fibromyalgia is really achy.
- [Exercise induced soreness] was less joint pain more muscle pain...I would feel the specific muscles not just like an all-over... pain.

Table 5**Representative Quotes from Domain 4: Content****Theme: Exercises**

- I always liked ones with the TRX [stability trainer] like the rows or chest presses.
- I felt like I could feel [planks] working.
- I liked level four because you were adding everything you learned all together.
- I liked the crunches...I liked the pelvic bridges...I ended up liking the squats, surprisingly.
- I liked the hamstring curls and the chest press...I knew how to do them and I felt it.
- My favorites were the TRX functional rotation... activities that used the TRX's and the BOSU ball.

Theme: Coping Skills

- Pleasant activities, imagery, mini-relaxation [were my favorites... and] were easiest to incorporate into my daily routine.
- I liked the pacing and calming statements.
- [Mini-relaxation] is quick and you can do it anytime.
- [My favorite was] the pleasant imagery, the mini-relaxations.
- Mini-relaxation, pleasant imagery, muscle relaxation [were the most useful coping skills].
- [I use] mini-relaxation pretty much on a daily basis.
- Mini-relaxations...in between sets...would be really helpful.

Theme: Least Favorite Exercises

- [The toe touch swimmers] were pretty hard...all of the swimmers in each level I think I didn't like them.
- The super man had to be modified for me [because of arm raises]...it wasn't difficult it was another one...I don't feel like I am doing this right... it was a very awkward exercise.
- The floor touches then the toe touch swimmers...I didn't really feel anything working.

Theme: Least Favorite Coping Skills

- I don't really use the calming statements that much.
- I kind of understood [problem solving] it I just didn't really ever have a real reason to use it.
- The imagery... was hard to figure out how to use that in the right setting.
- I mean I never used them [coping skills and exercises] together but I could see why people would use them together.
- [Least favorite] the long muscle relaxation. It just took too long.

Theme: Combined Treatment

- [FIT Teens] almost doesn't make sense if they are separate...sometimes doing the more mental thing helps me more than going out and walking a mile...it gives you different ways to go at it.
- I totally understand how they go together...the mini-relaxations worked really well with exercising.
- I also do the relaxation and the exercise [to help with pain flares].
- It was kind of like the physical aspect and then the emotional so together they really helped me.

Table 6**Representative Quotes from Domain 5: Format**

Theme: Group Format

- I really liked being with the other girls... I never knew they were going through the same things or... the same problems... knowing someone else feels the same way you do really helped.
- We were able to see how they were doing [the exercises] and encourage each other.
- The support was the biggest thing.
- Getting to know other people with fibromyalgia around my age was nice.
- I liked learning the exercises in a group format...I liked knowing that I wasn't the only one confused or I wasn't the only one that wasn't that excited about learning this really complicated exercise.
- [I] needed that re-assurance for myself...I saw that the other girls were fine with [exercises] I was like ok you are worrying over nothing.
- [I] wouldn't want to be doing it on my own... because you wanna have other people in the group cause you know that there's other people out there that are just like you and you also learn from their experience.

Theme: Structure of the Program

- It felt like [in level 4]... you got to put all the stuff you'd been working on together.
- I really liked how every week you would take...time for exercise and...time...to talk to everyone...it had an outline for you.
- They [exercises] were different every two weeks...then at the end you got to put them all together and see how much better you had gotten.
- Having to fill out a sheet that I did the relaxation... those techniques I just wasn't motivated to do... now I was doing the plan that...I was supposed to be doing...

Theme: Challenges of Group Format

- If you are trying to watch four people you won't catch everything.
 - I would...lose motivation when they would turn the other way.
 - I did not like [coping skills group] at all...when I sit down and talk to people about stuff I am going through...it's really hard.
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Table 7**Additional Domains****Representative Quotes from Domain 6: Perceived Efficacy****Theme: Confidence and Self-Efficacy**

- I realized that I was able to do a lot more than I thought I'd be able to that first week.
- This group made me more confident.
- I am glad that I went through it...now I can look back...at how far I have come...today that stuff, wasn't hard.
- It just gives you this sense of pride, like if I can overcome that, what else can I overcome?
- I learned you have to be active in order to keep your pain managed, I think it opened my eyes to that...you have a better energy and you're happier because you're getting out and doing stuff.
- I didn't think I could do all the things I can do now at all.
- It made me more comfortable with dealing with them when I had them [pain and JFM symptoms].
- I was actually doing the plan that I knew I was supposed to be doing...I was actually having a life that I could have been having.
- I have a lot more trust in my body.

Theme: Strength and Stamina

- I could just feel my strength building.
- All of the other ones [exercises], I got better at. I could hold [them] for longer and do more.
- A couple days after I'd still be really sore but the next week I would feel stronger.
- Some of them I just disliked doing, but I feel like they definitely made me stronger...each week I got more and more strong and confident in doing them [exercises].

Theme: Physical Functioning

- I have a little bit more stamina too.
- [This program] helped me not just lay around when I was hurting. It helped me get up and do something even when I am hurting.
- Usually I'd be stuck inside the house and I didn't feel like going out and doing stuff...I'm hanging out with more friends...exercising and taking walks.
- [Going up] stairs are easier... [and] doing chores like vacuuming.
- It did improve my activity, like my physical activity a lot, but I want to do more. I want to be more physical and everything.

Theme: Reduction in Physical Symptoms

- This has definitely improved my baseline...my baseline [pain] was a lot higher and lower in activity.
- Exercises helped me a lot...help me feel less tight and less pain.

Theme: Sleep

- Before the study I couldn't go a whole day without taking a nap and now I go almost every day.
- I would have to take naps, like long naps [2 hours] but I haven't been taking as many naps and if I do they are shorter maybe 15 to 45 minutes.
- I sleep better, probably because I don't take naps during the day. I am very tired at night.
- I fall asleep faster and I don't stay up as long.
- I have so much energy...I just really forgot what it feels like to feel ok.
- I honestly never thought I would say that I don't sleep throughout the day anymore.
- Before this I didn't have energy to do anything...the exercises gave me a lot of energy.

Representative Quotes from Domain 7: Continued Physical Activity Participation

- I'm going to plan on making a schedule and one day...walk for 25 minutes and the other day doing tennis.

- Yeah [I plan to continue these activities] and I am hoping to start practicing soccer on the weekends with my coach.
 - We joined the YMCA during this... I want to actually do yoga with a yoga instructor and um I want to try Pilates. I am going to do aquatics at the [sports center].
 - I'm definitely more likely to ride that bike, or go on a walk or to the Y.
 - I am going to try and continue all of them [the activities]. I liked dancing... I may start walking at night and I'd like to do a jog
 - I actually do yoga like maybe twice a week.
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