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Protocol for a phase II, multicenter, open-label, randomized controlled trial to compare the efficacy of gamification using Nintendo Switch Ring Fit Adventure game versus standard exercise in the treatment of fibromyalgia

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Abstract:

Background: *Fibromyalgia (FM) is a chronic condition related to dysfunctional central pain processing mechanisms, which affects 3-6% of the world population, leading to widespread pain, stiffness, and tenderness of the muscles, tendons, and joints, as well as restless sleep, fatigue, depression, and anxiety. Exercise is the most effective way of reducing pain and improving global well-being in people with FM, but such patients present an important limitation to exercise adherence.*

Objective: *We aim to evaluate whether a home-based gamification strategy will improve the Fibromyalgia Impact Questionnaire Revised (FIQR) scores in female patients aged 18-60 years old as an alternative to traditional exercise.*

Methods: *The proposed trial is a multicenter, phase II, open-label, parallel, randomized, superiority trial. Female patients ranging from 18 to 60 years old with a diagnosis of FM will be randomized to the intervention group, designed to play the Nintendo Switch Ring Fit Adventure game on three home-based weekly sessions, or to the control group, which will receive general educational guidance through videos and pamphlets provided by the study staff for a total of 12 weeks. The primary outcome will be the mean change in FIQR score results.*

Discussion: *The development of new strategies to increase exercise adherence can enhance the control of symptoms such as pain, depression, low quality of sleep, and physical limitation in FM patients, thereby improving their quality of life. We believe that gamification strategies such as the one used here can make physical activity more playful, accessible, and dynamic, motivating patients and increasing their physical function compared to those seeking center-based or conventional exercises.*

Keywords: *Gamification, fibromyalgia, chronic pain, randomized controlled trial, quality of life, exercise.*

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INTRODUCTION

Fibromyalgia (FM) is a chronic condition associated with widespread pain, stiffness, and tenderness of the muscles, tendons, and joints, as well as restless sleep, fatigue, depression, and anxiety (Jahan et al., 2012). According to the National Fibromyalgia Association, it

Abbreviations:
FM: Fibromyalgia
FIQR: The Fibromyalgia Impact Questionnaire Revised
BPI: The Brief Pain Inventory
BDI-II: The Beck Depression Inventory II
BDI: The Beck Depression Inventory
DSM-IV: Diagnostic and Statistical Manual of Mental Disorders-IV
FDA: Food and Drug Administration
QoL: Quality of Life

affects an estimated 3-6% of the world population, 75-90% of whom are women. The diagnosis is usually made between the ages of 20 to 50 years, and the incidence of this condition increases with age (Jahan, Nanji, Qidwai, & Qasim, 2012; Sosa-Reina et al., 2017). The severity of symptoms in patients with FM is related to dysfunctional central pain processing mechanisms, leading to exacerbated responses to normal, painful, or repetitive painful stimuli. Studies evaluating magnetic resonance imaging (MRI) scans during exercise indicate that physical activity has the potential for modulating pain perception and, thus, can have a significant effect on pain control and other symptoms, such as the quality of sleep and feeling of fatigue in these patients (Chinn et al., 2016).

A meta-analysis published in 2017 demonstrated that aerobic and strengthening exercises are the most effective way of reducing pain and improving global well-being in individuals with FM. Additionally, combined exercise strategies increased the beneficial effects on symptoms of depression in this population (Sosa-Reina et al., 2017). However, the available literature lacks detailed information on the ideal exercise program for such patients (Schmidt-Wilcke & Diers, 2017).

As FM patients present an important limitation to exercise adherence due to pain and other symptoms (Martín-Martínez, Villafaina, Collado-Mateo, Pérez-Gómez, & Gusi, 2019; Sosa-Reina et al., 2017), innovative strategies are necessary to provide alternative ways of pursuing an active routine and experience a better overall quality of life (QoL).

In that regard, gamification, the application of game design elements in non-game contexts, is increasingly being used in health interventions, such as physical activity (Sardi, Idri, & Fernández-Alemán, 2017). A previous randomized controlled trial (RCT) suggested that exergames (i.e., technology-driven physical activities) might effectively reduce pain and increase health-related QoL in women with FM (Collado-Mateo, Dominguez-Muñoz, Adsuar, Garcia-Gordillo, & Gusi, 2017). However, this study was conducted using an exergame specially developed for a hospital-based protocol, limiting the intervention's adherence and feasibility, as well as its generalizability.

Therefore, this study proposes a novel home-based gamification strategy using Nintendo Switch "Ring Fit Adventure" game (https://www.nintendo.com/products/detail/ring-fit-adventure-switch/) as a playful and dynamic alternative to traditional exercise in FM patients. The primary outcome will be to compare the mean change in the Revised Fibromyalgia Impact Questionnaire (FIQR) scores between groups. Specific details about Nintendo Switch "Ring Fit Adventure" game such as number of exercise sessions per week, duration of the sessions and the degree of effort of each session could be addressed in a phase III trial if the phase II shows benefit in the outcomes.

MATERIALS AND METHODS

Trial Design

This is a multicenter, phase II, open-label, parallel, randomized, superiority trial designed to compare the efficacy of gamification using Nintendo Switch ¨Ring Fit Adventure¨ game versus standard exercise in the treatment of female patients ranging from 18 to 60 years old with FM.

Study Setting

The trial constitutes a multicenter study. Data will be collected from three teaching hospitals in the United States of America (Mayo Clinic, Massachusetts General Hospital, and Johns Hopkins Hospital), which are referral centers for FM treatment, providing high-quality patient assistance.

Randomization

Block randomization stratified by center will be performed prior to the eligibility assessment of participants, with random block sizes of 4 or 6 patients.

The randomization list of participants will be obtained using randomized sequential numbers (0 or 1) generated by a computer (website http://www.randomization.com), which will determine the components of the Nintendo group and the control group. The list will be uploaded to the Research Electronic Data Capture (REDCap) software

(https://www.project-redcap.org), an electronic data capture tool that does not release the randomization group until the subject has been recruited and the baseline measurements have been completed, thereby ensuring allocation concealment. Subsequently, the staff will be able to generate the group allocation of each participant sequentially.

Blinding

This is an open-label trial. Although, independent outcome assessors and statisticians will be blinded when assessing the results of the FIQR score for each subject. Given its open-label attribute, emergency unblinding is not applicable.

Inclusion and Exclusion Criteria

The inclusion criteria are female patients ranging from 18 to 60 years old with a diagnosis of FM established according to the American College of Rheumatology criteria (2010 ACR criteria) (Wolfe et al., 2010) and patients (or a legally acceptable representative) who have personally agreed to and signed an informed consent form comprising all the pertinent aspects of the trial.

The exclusion criteria are chronic conditions that might hinder or impair, to a certain degree, the practice of unsupervised exercise, such as, but not limited to, chronic heart failure (New York Heart Association III/IV functional classification), moderate to severe pulmonary diseases, such as chronic obstructive pulmonary disease, uncontrolled asthma, restrictive pulmonary disease, and oxygen-dependent interstitial lung disease, neuromuscular disorders, such as orthopedic conditions of the shoulder, arm, forearm, wrist, hand, or fingers that might limit the appropriate handling of the interventional device; any mental condition such as, but not limited to, uncontrolled psychiatric disorders that prevent participants from following the study instructions; concurrent participation in any other RCT; individuals who participated in a previous trial and dropped out before completing the protocol; pregnancy and individuals who are not willing to participate.

Recruitment and Adherence

Recruitment will be based on physician referral from the included sites and will only begin after Research Ethics Committee approval, along with a thorough explanation of the trial protocol to all the staff members. Explanatory lectures will also be given to patients, detailing the trial design and the intervention in both arms, with instructions on managing the device (intervention group) or general exercise guidance (control group) and awareness of the possible risks. Participants will also be informed that there will be no financial costs or incentives for participating in the study. Subsidies will be provided for transportation and for any other costs related to the study protocol.

The following strategies to maintain adherence will be used during the trial:

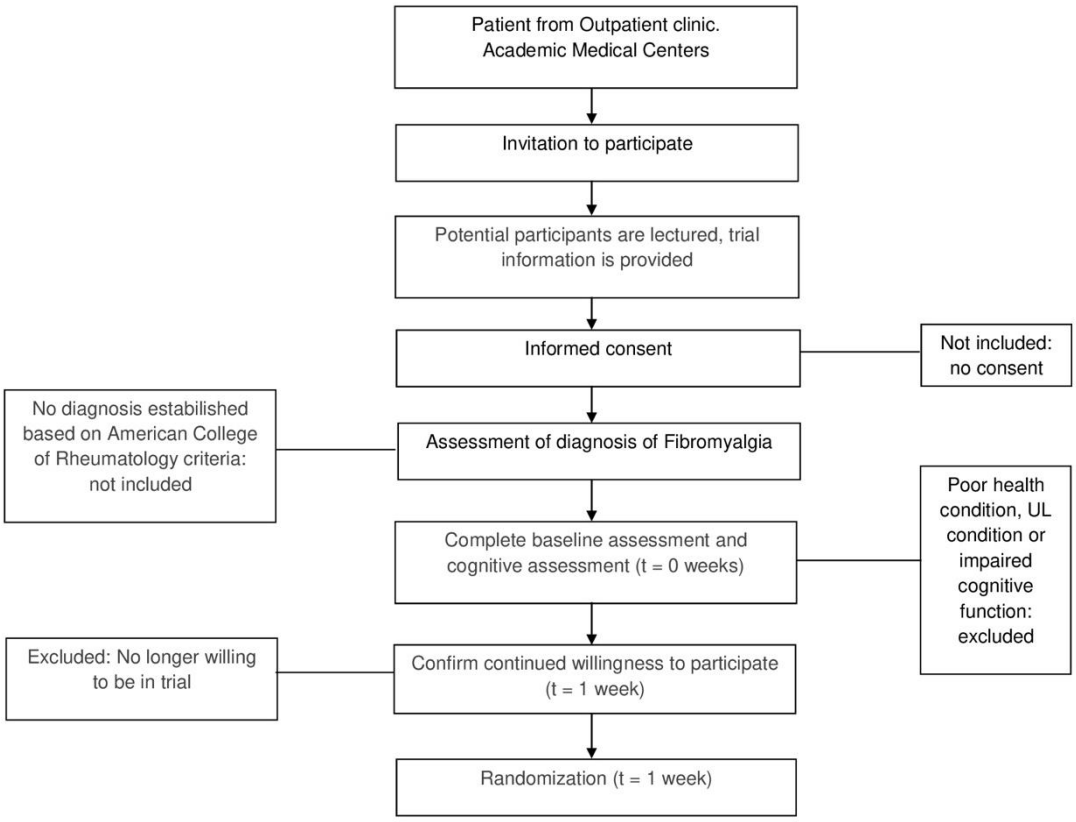
1. Every subject in both groups should complete a questionnaire assessing exercise performance sent to them by email using REDCap (**Appendix A**).
2. Each subject will automatically receive a message of encouragement sent through REDCap reminding them to exercise. In the control group, once there is a response to the message, they will receive a link that will lead to a video teaching a suggested exercise. As for the intervention group, this arm will also be advised to reply, but it will not receive any other form of exercise guidance apart from that of the game itself.
3. The research staff will check each participant's questionnaires and text messages weekly, in order to oversee possible noncompliance or any other issues.
4. Patients unable to continue in the trial due to adverse events or worsening of previous health conditions will be reported to the assessor and statistician as a dropout at the end of the study.

Study Timeline

The schedule and procedures of this protocol are presented in **Figure 1**.

Interventions

The intervention will be the Nintendo Switch "Ring Fit Adventure" game, which should be carried out by patients for at least 10 to 60 minutes, three times a week, for a total period of three months (12 weeks). The chosen game was the ring-shaped adventure game; this is a form of motion-controlled video game and an alternative to the traditional exercise strategy. (Collado-Mateo et al., 2017; Mortensen, Kristensen, Brooks, & Brooks, 2015; Staiano & Flynn, 2014) It requires two main extra accessories: "the ring-con" and "the leg strap." The research staff will provide both accessories and the Nintendo Switch console to the intervention group during the study period.



	1m	2m	3m	4m	5m	6m	7m	8m	9m	10m	11m	12m	13m	14m
Trial design	x													
Sponsorship		x												
Ethics Committee approval		x	x											
Preparing explanatory lectures			x	x										
Awareness Lecture and Mailing			x	x										
Recruitment phase				x	x	x	x							
Intervention				x	x	x	x	x	x	x	x	x		
Pooling of data									x	x	x	x	x	
Statistical Analysis													x	x
Manuscript writing													x	x
Disclosure of Results														x

Figure 1.

Before the beginning of the study, patients in the intervention group will receive guidance on the device's operation, game options, and exercise execution in three personally guided sessions to assess all details in handling the video game. Patients must attach the leg strap around the left thigh and hold the ring, a flexible structure that can be pressed to control the avatar, with both hands. They must also insert a "joy-con control" in

each accessory to execute the game. The subject controls all movements of the character, and the intensity of the exercise can be adapted to the patient's ability or fitness level.

Every exercise performed will be guided by the Ring Fit Adventure game. The game combines aerobic components, such as light runs in place, and knee pads to move the character with strengthening exercises by interacting with the ring-con accessory. Also, movements that resemble yoga and flexibility exercises are possible. The specific type of exercise can vary during the game, generating a training plan similar to that of the standard exercise.

Subjects assigned to the control group will receive general educational guidance supervised by a physician, through videos recorded by a certified exercise professional, as well as pamphlets suggesting exercise options and advising the participants as to the benefits of exercise, as recommended by the ACSM guidelines of 2013. According to this guideline, the ideal exercise frequency is three times per week, ranging from 20-60 minutes, with a 48-hour rest between workouts to ensure muscle recovery. (American College of Sports Medicine, 2018). Taking into consideration that in FM patients 20 minutes minimum could be considered excessive especially when they were previously inactive we recommend a minimum of 10 minutes per session for both groups.

Depending on any ensuing spontaneous demand from participants in the Nintendo Switch group, they will be allowed to adjust their exercise protocol to their own capabilities. Subjects in the control group will also be allowed to be able to reduce the exercise protocol's intensity if they experience any symptom exacerbation after physical activity. In this case, adjustments will be made by a professional physical trainer who will be contacted once there is reporting of symptoms in the weekly questionnaires.

Both groups will have emergency contacts in case they need assistance with exercise sessions.

Outcomes

- Primary Outcome:
  The primary outcome is the mean change in FIQR score results between baseline and after 3 months of intervention. (Williams & Arnold, 2011) The FIQR score is a self-report questionnaire that evaluates the impact of FM in 3 domains of the patient's quality of life (physical function, overall effect, and symptoms) through a numeric rating scale of 0 to 10 for a total of 30 items, weighted by their respective domains (30% weight for ¨function¨ items, 50% for ¨symptoms¨, and 20% for ¨overall impact¨). The total score varies between 0 to 100. (**Appendix B**) Since this score has not been properly validated for usage in the male population, we excluded men from our study population.
- Secondary outcomes:
  1. The Brief Pain Inventory is a self-reported rating scale containing 15 items that measure the severity of pain and the interference of pain on general function. (Keller et al., 2004; Williams & Arnold, 2011) (**Appendix C**) The success measure is identified as a more than 2-point improvement in the BPI average and severity pain score between baseline and study completion. This measure of success was selected as it is considered to be clinically significant based on previous studies. (Mease et al., 2011)
  2. The Beck Depression Inventory-II (BDI-I) is a revised version of the BDI published in 1996, created to align with the updated DSM-IV criteria for depression. It contains 21 items and identifies symptoms and attitudes associated with depression based on the patients' feelings of the preceding two weeks. (Arnau, Meagher, Norris, & Bramson, 2001; Beck, Epstein, Brown, & Steer, 1988) (**Appendix D**)
  3. Adherence: Adherence will be measured by the number of workouts completed per week assessed by the self-report questionnaire sent weekly via email to the patient.
  4. Proportion of responders: Patients will be considered responders if their final FIQR score is at least 14% lower than the baseline score. The proportions of responders in both groups will be recorded and compared.

Data Monitoring

Study data will be collected and managed using REDCap. Researchers will offer access to the database, when requested, in a de-identified manner (Harris et al., 2009).

Considering the short follow-up period and relatively small sample size of this trial, an interim analysis has not been planned, since it could impact the power, clinical significance, and overall robustness of our results.

Sample size calculation

Sample size calculation was performed based on a previous study which showed that FM patients have a

mean FIQ score of 56.6 (SD 20). Besides, considering that FIQR is a modified version of the FIQ score with a good correlation between them (a correlation coefficient of 0.83; $P < 0.005$) (Bennett, Friend, et al., 2009), we assumed both scores could be used interchangeably for this estimation.

We assumed a minimal clinically significant difference for FIQR changes to be at least 14%, since this is related to the clinical perception of improvement among FM patients (Bennett, Bushmakin, et al., 2009; Garcia-Palacios et al., 2015). Thus, to obtain a power of 80% to detect such difference with a two-sided t-test at a significance level of 0.05, and assuming equal variance between groups, a minimum of 102 participants in each group is required.

The dropout rate is expected to be approximately 20% (Bennett, Bushmakin, et al., 2009; Garcia-Palacios et al., 2015). Therefore, to account for possible losses, we increased the sample size to a total of 128 participants in each arm.

Statistical Analysis for Primary and Secondary Outcomes

Demographic variables and primary and secondary outcomes will be summarized by descriptive statistics and sorted by group treatment.

For the primary outcome, the difference in FIQR means at baseline and the end of the intervention, used as a continuous variable, will be compared between the two groups using a t-test for independent samples. Assessment of normality will not be performed since the estimated sample size is large enough to provide robust results using the proposed test. Confidence intervals for differences in means will be presented using 0.05 as the significance level.

For the secondary outcome analysis of BPI and DBI-II, the changes in the means between the groups will be compared using the same approach as described for the primary outcome. The proportion of responders according to the FIQR score, the proportion of responders, and the adherence rate in each group will be compared using Fisher's exact test.

Missing Data

Data will be analyzed by the intention to treat strategy. The maximum likelihood method will be used as the imputation method for missing data, which will be considered missing at random (MAR).

DISCUSSION

The current study protocol aims to compare the changes in FIQR scores between FM patients who follow conventional exercise recommendations and those who exercise using the "Ring Fit Adventure" Nintendo Switch Workout Game.

A home-based videogame training strategy was chosen because adherence is an essential issue for FM patients, and this may be further aggravated by depression and low motivation. We believe that by introducing alternative methods for exercising using gamification methods, may result in physical activity being more enjoyable, accessible, and dynamic. This way, patients may feel more motivated, increase their physical function, and improve their quality of life compared to those seeking a center-based or conventional exercise.

Since FM is a fairly common disease, recruitment should not be a significant issue. Other strengths of the protocol include the acceptance of the FIQR score as a good predictor of disease burden and the short period of follow-up of our trial, which renders it both feasible and affordable.

On the other hand, the current protocol does present a few limitations. The issue of adherence and the expected dropout rates are potentially increased by the particular characteristics of the study population and the nature of the intervention, which may lead to a considerable amount of missing data. Moreover, the need for electrical and internet support to ensure the completion of the intervention is expensive and may contribute to increased costs. Lastly, the open-label nature of this trial is a potential source of bias. In an attempt to minimize this limitation, we decided to keep independent outcome assessors and statisticians blinded.

By using the change in FIQR scores as a primary continuous outcome, we aimed to increase statistical power and reduce the costs by decreasing the sample size, with the potential disadvantage of losing some degree of clinical understanding and relevance.

Of note, the FDA recently approved, for the first time, a specific electronic game as a therapeutic option for human disease. (Food and Drug Administration, 2020) Hence, this protocol provides a framework for the beginning of a new market for the game and health industry. This may offer a shifting paradigm for the therapeutic approach to FM patients, which can be used by healthcare providers worldwide as a valid exercise approach for patients for whom adherence to traditional exercise schedules is a major obstacle.

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Conflict of interest

No conflict of interests.

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