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Effectiveness of two video-based multicomponent treatments for fibromyalgia: The added value of cognitive restructuring and mindfulness in a three-arm randomised controlled trial

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ABSTRACT

Background/objectives: The aim of this study was to examine the effectiveness of two video-based multicomponent programs (FIBROWALK) and the Multicomponent Physiotherapy Program (MPP) for patients with fibromyalgia (FM) compared to treatment-as-usual (TAU) only. We posit that FIBROWALK, due to inclusion of specific psychological ingredients (cognitive restructuring and mindfulness), can produce additional clinical benefits when compared to TAU or MPP alone.

Methods: A total of 330 patients with FM were recruited and randomly allocated (1:1:1) to TAU only, TAU + FIBROWALK, or TAU + MPP. FIBROWALK and MPP consisted of weekly videos on pain neuroscience education, therapeutic exercise and self-management patient education, but only the FIBROWALK intervention provided cognitive restructuring and mindfulness. Both programs were structurally equivalent. Between-group differences in functional impairment, pain, kinesiophobia, anxious-depressive symptoms and physical functioning were evaluated at post-treatment following Intention-To-Treat and complete-case approaches.

Results: Compared to TAU only, individuals in the FIBROWALK arm showed larger improvements in all clinical outcomes; similarly, participants in the MPP program also showed greater improvements in functional impairment, perceived pain, kinesiophobia, depressive symptoms compared to TAU only. The FIBROWALK intervention showed superior effects in improving pain, anxiety and depressive symptoms and physical functioning compared to MPP.

Conclusions: This RCT supports the short-term effectiveness of the video-based multicomponent programs FIBROWALK and MPP for FM and provides evidence that cognitive-behavioural and mindfulness-based techniques can be clinically useful in the context of physiotherapeutic multicomponent treatment programs.

Trial registration number: NCT04571528.

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1. Introduction

Fibromyalgia (FM) is a complex and highly prevalent disease (2–4% in the general population) characterized by widespread musculoskeletal pain, and often accompanied by symptoms of fatigue, sleep disturbance, cognitive problems, and psychological distress, which is usually diagnosed in women between the ages of 20 and 50 years (Häuser et al., 2015). People with FM typically present with comorbid psychiatric disorders, particularly major depressive disorder (63% of FM patients with lifetime depression) but also bipolar disorder, panic disorder, or post-traumatic stress disorder (Kleykamp et al., 2021; Lichtenstein, Tiosano, & Amital, 2018). These comorbidities, in turn, can aggravate the negative influence of pain on health-related quality of life (Galvez-Sánchez, Duschek, & Reyes Del Paso, 2019).

FM represents a great challenge for national health services because of the lack of curative treatment options. The efficacy of pharmacological approaches alone is generally limited, and more generalized clinical effects have been found for non-pharmacological interventions (Perrot & Russell, 2014). In response to the increased evidence of efficacy of non-pharmacological modalities, the 2016 revised European League of Association of Rheumatology recommendations point to the need to increase the implementation of non-pharmacological interventions gradually and sequentially in the treatment of FM (Macfarlane et al., 2017; Okifuji & Hare, 2010).

In this regard, education is a fundamental ingredient of many treatment programs for managing FM symptoms and is typically used as a first-line therapeutic option (Cunningham & Kashikar-Zuck, 2013). Increased knowledge about pain mechanisms and the FM diagnosis itself through education has been associated with positive effects in self-management skills and health outcomes in FM subjects (Camerini, Camerini, & Schulz, 2013; Musekamp et al., 2019). Patients who are well-informed regarding their disease, prognosis and symptom-management strategies are better prepared to cope with the disease and thereby reduce its consequences (De Miquel et al., 2010). Furthermore, when comparing different types of pain education, there are clear differences between classical biomedical education (i.e., contents related to pathophysiology and biomechanics) and Pain Neuroscience Education (PNE) (i.e., contents related to pain neurobiology and pain processing). PNE is based on the reconceptualization of pain-related cognitive factors, within a biopsychosocial model, emphasizing that any evidence of danger or safety can increase or decrease the patient's pain experience (Moseley & Butler, 2015). A recent systematic review has supported the efficacy of PNE in people with chronic musculoskeletal pain in terms of improvements in pain catastrophizing, pain-related disability, inactivity, and avoidance behaviours (Louw, Puentedura, Zimney, & Schmidt, 2016). Due to the mounting evidence of the beneficial effects of PNE in people with FM, it is progressively becoming a standard treatment modality for this population (Amer-Cuenca et al., 2020; Moseley, 2003).

It is also important to note that PNE might be more effective when combined with other techniques such as therapeutic exercise or cognitive behavioural therapy (CBT; Moseley et al., 2017). There is solid evidence that therapeutic exercise can result in significant improvments in core FM symptoms such as pain, depressive symptomatology, sleep, fatigue, global well-being, and health-related quality of life (Kundakci et al., 2021; Sosa-Reina et al., 2017). Frequently recommended exercises for FM include low-impact aerobic exercises, stretching, balance training, posture correction, and gentle strengthening exercises adapted to a patient's current physical state (e.g., Serrat, Almirall, et al., 2020).

Psychotherapeutic approaches have also been used for treating FM. A systematic review and meta-analysis found that psychological therapies for FM were associated with improvements in depression symptoms, catastrophizing, sleep disturbance, functional status, and short- and long-term pain reduction (Glombiewski et al., 2010). These outcomes were determined to be comparable to traditional FM treatment modalities, including pharmacological treatments. CBT demonstrated the greatest effect sizes in this meta-analysis. A separate systematic review determined that CBT is the most common psychological intervention used for treating FM, both standalone and within multidisciplinary programs (Albajes & Moix, 2021). The efficacy of CBT has been demonstrated in many studies, resulting in treatment improvements in many core FM symptoms, including pain, fatigue, depression, psychological well-being, and physical functioning (Albajes & Moix, 2021; Bernardy, Klose, Welsch, & Häuser, 2018; Glombiewski et al., 2010; Kundakci et al., 2021; Macfarlane et al., 2017; Sosa-Reina et al., 2017). The American Psychological Association division 12 (Society of Clinical Psychology division of the APA) rated CBT interventions for FM as having strong research support (https://div12.org/diagnosis/fibromyalgia/).

In addition to CBT-based approaches, mindfulness training has been shown to be effective in people with FM (Haugmark, Hagen, Smedslund, & Zangi, 2019; Pérez-Aranda, Andrés-Rodríguez, et al., 2019). For instance, Mindfulness-Based Stress Reduction has demonstrated treatment improvements in functional impairment, anxiety and depressive symptoms in FM subjects (Pérez-Aranda, Feliu-Soler, et al., 2019). Mechanisms of this intervention seem to be related to a decreased pain catastrophizing and increased self-efficacy, pain acceptance and psychological flexibility (Pardos-Gascón, Narambuena, Leal-Costa, & van-der Hofstadt-Román, 2021; Pérez-Aranda, Feliu-Soler, et al., 2019; Turner et al., 2016). Though these treatments are traditionally provided face-to-face, these psychological approaches have shown positive results in online formats in individuals with FM (Bernardy, Klose, Welsch, & Häuser, 2019; Davis & Zautra, 2013).

In light of the above, PNE, therapeutic exercises, CBT-based techniques, and mindfulness training are the four non-pharmacological therapy approaches that have the most published evidence for FM management (Aman, Jason Yong, Kaye, & Urman, 2018). While the first two approaches are more in the area of physiotherapy, the others tend to belong to the field of psychotherapy. There is burgeoning interest in the scientific literature in integrating these therapies and evaluating the specific contribution of each one within chronic pain treatment programs (Conversano & Di Giuseppe, 2021; Merlo, 2019). In this regard, an interdisciplinary treatment approach, using multicomponent empirically validated therapeutic techniques within a biopsychosocial perspective, is considered the best treatment model for FM (De Miquel et al., 2010; Häuser, Bernardy, Arnold, Offenbächer, & Schiltenwolf, 2009; Macfarlane et al., 2017; Rivera et al., 2006). Multicomponent treatment approaches are recommended by most of national and international FM treatment guidelines (Rivera et al., 2006; Thieme, Mathys, & Turk, 2017). Although there is evidence that multidisciplinary approaches that integrate physiotherapy and psychology components can be superior to physiotherapy alone for subjects with general chronic pain conditions, this has not yet been fully evaluated in subjects with FM (Kamper et al., 2015; Wilson & Cramp, 2018).

FIBROWALK is a multicomponent treatment program, involving 2-h weekly sessions over 12 weeks, that was specifically designed for, and tested with, individuals with FM (Serrat et al., 2020a, 2021b). It involves five components, including PNE (sessions 1–10), therapeutic exercise (sessions 2–9), self-management patient education (sessions 2–9; 11–12), CBT techniques (cognitive restructuring; sessions 8–9; 11–12), and mindfulness training (sessions 2–9; 11–12) in a group-based format. Traditionally, physiotherapists have been responsible for PNE, therapeutic exercise, and self-management patient education and psychologists have been responsible for teaching CBT and mindfulness techniques. A previous randomised controlled trial (RCT) has shown that the FIBROWALK program (vs. usual care) was effective (with medium-to-large effect sizes) for significantly improving functional impairment, pain, kinesiophobia, physical function, fatigue, anxiety, and depressive symptoms in a sample of patients with FM (Serrat, Sanabria-Mazo, et al., 2021).

Recently, a video-based version, including all FIBROWALK components, was adapted into a home-based format and tested in a pilot RCT

during the first Spanish COVID-19 lockdown (Serrat, Coll-Omaña, et al., 2021). The goal of this online version was to provide clinical support to patients with FM who were unable to attend face-to-face treatment. The online FIBROWALK program was found to be effective (with small-to-moderate effect sizes) for improving patient-reported functional impairment and other relevant FM symptoms (Serrat, Coll-Omaña, et al., 2021; Serrat, Sanabria-Mazo, et al., 2021). It is well known that efficacious online interventions have several advantages over face-to-face interventions, including cost, convenience, and availability for those patients with limited mobility and transportation options (Andersson, 2018; Andersson & Titov, 2014).

Determining the effects of specific physiotherapy and psychotherapeutic modalities can provide new clues for refining and improving treatment efficacy. Therefore, the primary aim of this RCT was to evaluate the effectiveness of two video-based multicomponent treatment programs for FM, one that integrated physiotherapy and psychotherapeutic modalities (i.e., FIBROWALK) and one that only used physiotherapy techniques (i.e., Multicomponent Physiotherapy Program; MPP), and to compare them to treatment-as-usual (TAU) only. Treatment effectiveness of the two programs was determined by improvements in patient-reported functional impairment (primary outcome), pain, anxious-depressive symptoms, kinesiophobia, and physical function. Our hypotheses were as follows: It was expected that both FIBROWALK and MPP arms, which were equivalent in terms of treatment dosage, would show greater improvements in primary and secondary outcomes when compared to TAU alone (hypothesis 1). Furthermore, it was expected that FIBROWALK would result in better improvement in anxiety and depressive symptoms compared to MPP because CBT and mindfulness techniques have been shown to have significant effects on these variables (Etzelmueller et al., 2020; Spijkerman, Pots, & Bohlmeijer, 2016) (hypothesis 2). In addition to assessing statistical significance, the number-needed to treat (NNT) index was computed to allow findings from this study to be more meaningful to clinicians. We expected a lower NNT in both active treatment arms when compared to TAU alone (hypothesis 3) as well as a lower NNT for FIBROWALK when compared to MPP (hypothesis 4). As far as we know, this was the first study to assess the unique contribution of cognitive restructuring and mindfulness training in a multicomponent treatment program for the management of FM.

2. Methods

2.1. Design

A three-arm randomised controlled trial (RCT) was carried out, with assessments at pre- and post-treatment. This RCT was approved by the Ethics Committee of Clinical Investigation (PR(AG)249/2020), posted and registered in Clinicaltrials.gov (NCT04571528) and was conducted in accordance with the guidelines issued by the Consolidated Standards of Reporting Trials (CONSORT; Moher et al., 2012).

2.2. Sample size

The required sample size was estimated to be n = 51 participants per study arm, considering a moderate effect size (Cohen's $d = 0.50$) for the between-group differences at post-treatment for the primary outcome (i.e., Revised Fibromyalgia Impact Questionnaire total score) with an $\alpha = .05$ and power 1-b = 0.80. Expecting an attrition of at least 20%, the required sample size was nearly doubled so that small differences could be detected between the active treatment arms.

2.3. Participants

A total of 337 patients with FM participated in the study from September 2020 to January 2021. All participants were consecutively recruited from the Vall d'Hebron University Hospital - Central Sensitivity Syndromes Specialised Unit and were assessed by a rheumatologist and a physical therapist to ensure they met the selection criteria. The inclusion criteria were as follows: (a) 18–75 years of age; (b) fulfilment the FM classification criteria according to 2010/2011 American College of Rheumatology (Wolfe et al., 2010), i.e., widespread pain index (WPI) ≥7 and symptom severity (SS) scale score ≥5 or WPI 3–6 and SS scale score ≥9, symptoms have been present at a similar level for at least 3 months, and the patient does not have a disorder that would otherwise explain the pain; (c) being able to understand Spanish; and (d) written informed consent. Individuals participating in concurrent or past RCTs (during the previous year) or suffering any comorbidity such as severe mental disorders (i.e., psychosis) or neurodegenerative diseases (i.e., Alzheimer) that would have limited the ability of the patient to participate in the RCT were excluded.

2.4. Procedure

The study was carried out in the context of routine clinical practice at the Vall d'Hebron University Hospital - Central Sensitivity Syndromes Specialised Unit. That is, all participants were provided by their rheumatologist with an overview of the study aims when they visited the hospital. COVID safety measures were followed. Participants were told that they would receive a potentially effective treatment in addition to the usual one that the Unit usually provides. Those interested in participating signed informed consent and were told that their data would be used in this study. Participants were informed about their right to withdraw from the research at any time, with the assurance that they could continue to receive usual care. They were asked to complete an online questionnaire, gathering sociodemographic and clinical information, and all study outcome measures. The online measures were completed both at pre- and at post-treatment.

Participants who voluntarily agreed to participate in the study were assigned to an alphanumeric code list and were randomised (1:1:1 ratio) using SPSS v25 to receive either TAU only, TAU + video-based FIBROWALK or TAU + video-based MPP. Numbered sealed envelopes which included information sheets related to participant allocation were used within the randomization process. The envelopes were distributed by a nurse from the Vall d'Hebron University Hospital - Central Sensitivity Syndromes Specialised Unit. Neither the participants nor the therapist responsible for the treatments were blinded to the participants' allocated intervention. However, the nursing staff who coordinated the online assessments were blinded to the participants' treatment allocation.

2.5. Treatment interventions

Both FIBROWALK and MPP were delivered as add-ons to TAU. Subjects participated in no additional treatments during the study. TAU care in the Vall d'Hebron University Hospital - Central Sensitivity Syndromes Specialised Unit included: (a) prescribed medications for FM (i.e., amitriptyline, duloxetine, pregabalin and/or tramadol at low doses) adapted to each patient's needs and (b) written advice on PNE and aerobic exercise adapted to the physical capacities of the patients. Subjects in the TAU group were offered the opportunity to participate in the FIBROWALK program upon study completion.

The video-based FIBROWALK program consisted of weekly 60-min videos that were presented over the course of 12 weeks. Subjects participated in the virtual training from home. Each video was comprised of different components of the program. The FIBROWALK intervention included PNE, therapeutic physical exercise, Self-management Patient Education, CBT techniques (mainly cognitive restructuring), and mindfulness training. PNE was based on the book "Explain Pain" (Moseley & Butler, 2017) and was the essential constituent that directed the approach taken by all the procedures involved in FIBROWALK. Therapeutic physical exercise interventions were designed from the recommendations of the American College of Sports Medicine

and were taught from the same procedures described elsewhere (Serrat, Sanabria-Mazo, et al., 2020). The Self-management Patient Education was comprised of different educational components aimed at teaching patients how psychosocial stressors can impact pain perception and ways of managing symptoms and improving health and well-being. Specifically, patients were taught strategies for increasing activity, improving sleep quality, increasing autonomy, coping better with stress and other FM symptoms, enhancing treatment adherence, preventing relapses/aggravations, and developing a greater ability to live a meaningful life despite pain. CBT techniques, mainly cognitive restructuring, were introduced for improving mood, reducing anxiety, enhancing adaptive emotional regulation responses, reducing catastrophic thinking about pain, and promoting positive behaviour changes towards a healthier lifestyle. Patients were taught how to identify automatic negative thoughts and to challenge them with more rational responses, including recognizing and removing cognitive biases and correcting false beliefs and assumptions. Mindfulness training included meditation practices based on Mindfulness-Based Stress Reduction (Kabat-Zinn, 2013). This training was aimed at changing the relationship with one's thoughts (to accept thoughts nonjudgmentally without trying to change their content) in order to foster alternative and healthier ways of relating and responding to personal life challenges, including chronic pain. For a more detailed description of the FIBROWALK contents, see the supplementary tables (Supplementary Tables S1 and S3).

Participants allocated to the video-based MPP training received all aspects of the FIBROWALK arm except for cognitive restructuring and mindfulness training. The length of time spent on each component of the MPP training (including PNE, therapeutic physical exercise therapy, and self-management patient education) was slightly longer compared to those in the FIBROWALK in order to match the overall treatment doses of 1 h per week for 12 weeks between the two active arms. See Supplementary Tables S2 and S3 for more details.

To verify that participants adhered to FIBROWALK and MPP interventions, participants were asked to complete a brief online questionnaire (5–10 items) every week. This questionnaire asked for verification of follow-through with homework exercises (e.g., meditation practices, guided relaxation exercises, therapeutic exercise recommendations) and for one's understanding of very basic concepts explained in the videos (e.g., "Please, provide a short example of a catastrophic thought"). These weekly questionnaires were used for the early detection of potential adherence issues (e.g., not watching the videos, not doing the homework) as well as to prevent potential dropouts. The first author (MS) supervised all participants and provided remote guidance. She is both a physical therapist (>17 years of experience) and a health psychologist (>8 years of experience). In addition, she has also been trained in CBT and mindfulness. Every week, the therapist (MS) contacted (via SMS and/or telephone calls) those participants who did not answer the questionnaire or reported issues with participation (e.g., not being able to do the homework, watch the videos, answer the questionnaire, etc.) and helped them develop solutions for enhancing adherence. If necessary, individuals who were unable to view or answer the questionnaire in a specific week could request an extension of the date. There was no therapeutic interaction with the participants, but participants were invited to contact the therapist by email if they experienced any problems. Approximately 24 h of clinician time was spent on the guidance of both interventions (i.e., FIBROWALK and MPP).

2.6. Study measures

A sociodemographic and clinical ad-hoc questionnaire was used. It collected information about age, gender, educational level, employment situation, living arrangement (alone/accompanied), civil status, height and current weight (for calculating body mass index), illness self-perceived start/duration, incapacity certificate (indicating level of incapacity if affirmative), and diagnosis of chronic fatigue syndrome by a rheumatologist (yes/no).

2.6.1. Primary outcome

The *Fibromyalgia Impact Questionnaire Revised* (FIQR; Bennett et al., 2009) was used to assess the functional impairment experienced by participants during the previous week. The FIQR includes a total of 21 items, scored on a 0–10 numerical scale, which are distributed into three dimensions: physical dysfunction (ranging from 0 to 30), overall impact (ranging from 0 to 20), and intensity of symptoms (ranging from 0 to 50) with a total possible score of 100. Higher scores indicate greater functional impairment. The Spanish version of the FIQR has demonstrated satisfactory internal consistency (Luciano, Aguado, Serrano-Blanco, Calandre, & Rodriguez-Lopez, 2013; Cronbach's $\alpha = 0.91$); in our sample, the internal consistency of the FIQR was found to be excellent ($\alpha = 0.94$).

2.6.2. Secondary outcomes

The *Visual Analog Scale* (VAS) for pain (i.e., intensity of perceived pain during last week, from 0 = "no pain", to 10 = "unbearable pain") from the FIQR was used to assess pain intensity (Bennett et al., 2009).

The *Tampa Scale for Kinesiophobia* (TSK; Miller, Kori, & Todd, 1991) was used to assess fear of movement. This scale comprises 11 items which are scored with a 4-point Likert scale (total score ranging from 11 to 44). Higher scores are indicative of greater pain and fear of movement. The Spanish version of the TSK has demonstrated satisfactory internal consistency ($\alpha = 0.79$; Gómez-Pérez, López-Martínez, & Ruiz-Párraga, 2011). The α for the TSK was 0.89 in our sample.

The *Hospital Anxiety and Depression Scale* (HADS; Zigmond & Snaith, 1983). It includes two main dimensions (anxiety and depression), with 7 items each, which are scored with a 4-point Likert scale. The scores of the HADS subscales range from 0 to 21 with higher scores reflecting higher symptom severity. The Spanish version of the HADS has demonstrated satisfactory internal consistency for anxiety ($\alpha = 0.83$) and depression ($\alpha = 0.87$) subscales (Luciano, Barrada, Aguado, Osma, & García-Campayo, 2014). In this work, the α was 0.84 and 0.86 for HADS-A and HADS-D, respectively.

The *Physical Function subscale from the 36-Item Short Form Survey* (SF-36; Ware & Sherbourne, 1992) assessed perceived level of physical functioning. This subscale includes 10 items, each scored with a 3-point Likert scale. Total scores are transformed to obtain scores that can range from 0 to 100, with higher scores indicate better physical functioning. The Spanish version of the physical function SF-36 subscale has shown satisfactory internal consistency ($\alpha = 0.94$; Alonso, Prieto, & Antó, 1995). The α in our sample was .84.

2.7. Statistical analysis

All study outcomes were analyzed with descriptive statistics and expressed as means and standard deviations (SD) for quantitative variables, and percentages (%) and frequencies (f) for categorical variables. The Levene test was used to evaluate the equality of variances of continuous variables, and Kolmogorov-Smirnov was used to verify sample normality and distribution.

Baseline between-group differences were calculated for both continuous and categorical variables. MANOVA was used to assess baseline differences in continuous variables, whereas the χ^2 test was applied for categorical variables.

An analysis of covariance (ANCOVA), considering baseline values as a covariate, was conducted to analyse between-group differences at post-treatment in all study outcomes. The ANCOVA has shown greater power to discern changes than analyses of variance (ANOVA) in randomised study designs (Van Breukelen, 2006).

Taking an Intention-To-Treat (ITT) approach as reference, all outcomes were analyzed using Multiple Imputation (Jakobsen, Gluud, Wetterslev, & Winkel, 2017). Five imputations of all outcome variables were computed, from which pooled post-treatment means and standard deviations were calculated. The pooling of ANCOVA statistics is not available in SPSS. Therefore, the tables report inferential statistics (F, p,

Cohen's *d*) for the most "pessimistic" analytic scenario, i.e., the imputation iteration that yielded the highest *p*-value, to prevent an inflation of false positives (Type I error). In addition, a sensitivity analysis was conducted with the complete-case sample. The effect size (Cohen's *d*) for each pairwise comparison, using the pooled baseline SD to analyse the differences in the baseline-post intervention mean values and correct these values for the estimated population, was also computed for the complete-case sample (Morris, 2008). For the imputed dataset, the *d* was calculated by subtracting the means and dividing the results by the pooled standard deviation. Effect sizes were considered small ($d = .20$), medium ($d = 0.50$), and large ($d = 0.80$) according to classical cut-offs (Cohen, 1988).

A $\geq$ 20% reduction in the total FIQR score at post-treatment compared to pre-treatment was considered a clinically relevant treatment response (Bennett et al., 2009). This classification in responders vs non-responders was used to compute the Number Needed to Treat (NNT) of each intervention arm. The NNT is an index aimed at make results from RCTs more meaningful to clinicians. It refers to the estimated number of individuals who need to be treated with a novel proposed treatment (i.e., FIBROWALK or MPP) instead of the usual care for one additional patient to benefit (i.e., vs. TAU or MPP). An NNT between 2 and 5 is indicative of a clinically effective treatment in pharmaceutical research (Cook & Sackett, 1995). Furthermore, in order to identify baseline characteristics potentially associated with being a "responder" in each evaluated treatments, baseline differences among sociodemographic and clinical variables between "responders" and "non-responders" were evaluated with a Student's t-test (for quantitative variables) and χ2-test (for categorical variables). All statistical analyses were computed with the SPSS v25.

3. Results

3.1. Participant's flow and treatment adherence

As shown in Fig. 1, a total of 387 patients with FM were assessed for eligibility. Fifty-seven did not meet the eligibility criteria, and therefore, a total of 330 patients were finally included and randomised [TAU (n = 110), TAU + FIBROWALK (n = 110) and TAU + MPP (n = 110)]. The participants' mean age was approximately 53 years old (SD = 9.11; range: 20–77). The mean body mass index (BMI) of 27.27 kg/cm2 (SD = 5.56) indicated that the subject group was overweight. The mean FM duration was 15.6 years (SD = 9.12). Approximately 24% of the participants were employed, 57% married/in a stable relationship, 83% lived with someone, 60% reported having secondary education level or higher, 70% reported some degree of disability, and 86% had a comorbid chronic fatigue syndrome diagnosis (Table 1). Retention rate was high in the three intervention arms (around 10% dropped out of treatment in each arm). No differences were found in the retention rate at post-treatment (FIBROWALK: 90.9%; MPP: 89.1%; TAU: 90.9%; $\chi^2(2) = 0.277$, $p = .87$). All participants in the FIBROWALK and MPP arms attended all 12 sessions of the programs, watched the videos, and completed the weekly questionnaires.

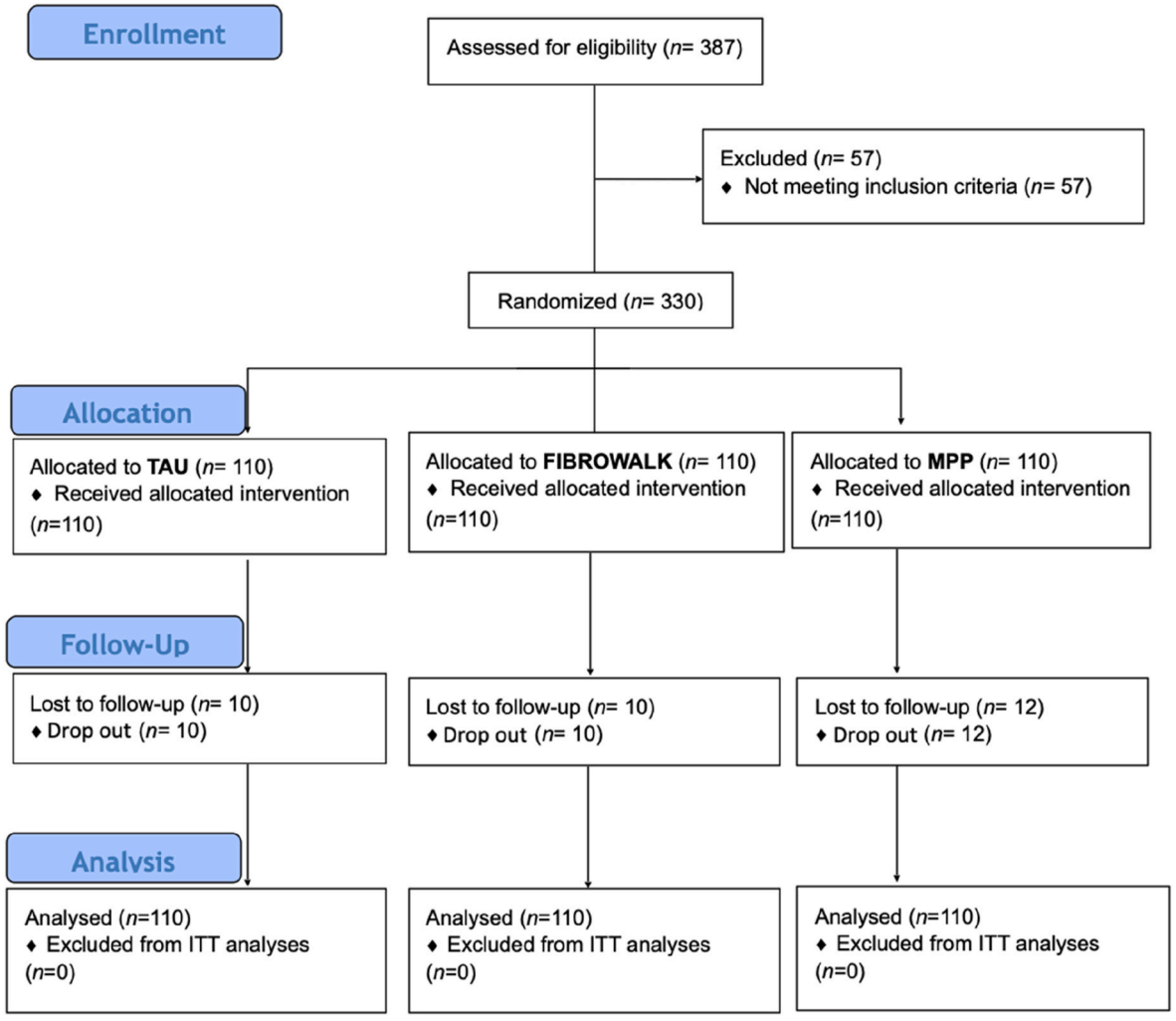

Fig. 1. CONSORT Flow diagram of participants throughout the randomised controlled trial.

3.2. Baseline differences between study arms

There were no statistically significant differences between treatment arms in demographic or baseline clinical characteristics (see Table 1).

3.3. Between-group differences in the primary and secondary outcomes

3.3.1. Primary outcome

Individuals allocated to both active treatment arms showed greater reductions in FIQR scores when compared to those allocated to TAU only ($p < .001$; FIBROWALK, $d = 0.80$; MPP, $d = .53$). No differences in FIQR scores were found between the FIBROWALK and the MPP groups ($p = .163$; $d = 0.26$). Mean differences and SDs between pre- and post-treatment for each study arm are detailed in Table 2 (ITT approach). Similar results were found in the complete-case sample (Table 3).

3.4. Secondary outcomes

Patients allocated to FIBROWALK showed greater reductions in perceived pain intensity, kinesiophobia, anxiety and depressive symptoms and increased physical functioning compared to the TAU only group (all $p < .001$), with medium-to-large effect sizes ($d = 0.51–1.48$). Similarly, significant treatment effects ($p < .05$) in favor of the MPP arm were found when compared to TAU in perceived pain intensity ($d = .39$), kinesiophobia ($d = 1.13$), and depressive symptoms ($d = 0.37$) (all $p < .05$). No differences between MPP and TAU were found in the other outcomes. When comparing FIBROWALK and MPP arms, statistically significant effects in favor of the former were found in pain intensity, depression, and physical functioning (all $p < .05$), with small-to-medium effect sizes ($d = 0.24$-0.49).

Similar results were found when looking at the complete-case dataset, except for the differences between FIBROWALK and MPP arms in anxiety and depressive symptoms. As shown in Table 3, FIBROWALK was significantly more effective than MPP for reducing anxiety symptoms ($p = .036$, $d = 0.50$). In the case of depressive symptoms, the differences were marginally significant in favor of FIBROWALK ($p = .053$, $d = 0.22$).

3.5. Baseline differences between "Responders" and "Non-Responders" to treatment

In the FIBROWALK arm, individuals classified as responders indicated less anxiety ($p = .02$), depressive symptoms ($p = .02$) and better physical functioning ($p = .03$) prior to treatment compared to non-responders. MPP responders were older ($p = .05$), men (100% men vs. 94% of women; $p = .05$), reported less pain ($p < .001$), had less functional impairment ($p = .03$), and better physical functioning ($p = .01$) than "non-responders." All details are shown in Table 4.

3.6. Number Needed to Treat (NNT)

Forty-two subjects (42%) in the FIBROWALK arm and 33 subjects in the MPP arm (34%) showed a clinically significant improvement in their FIQR total score at post-treatment (i.e., ≥20%) so were considered responders, whereas only four subjects (4%) from the TAU only arm achieved the status of responder. The absolute risk reduction in the FIBROWALK arm in comparison with TAU only was 38% (95% CI = 27.59–48.41%), with an NNT = 3 (95% CI = 2.1 to 3.6). The absolute risk reduction obtained in the MPP versus TAU only was 29.67% (95% CI = 19.56–39.79%), with an NNT = 4. The absolute risk reduction obtained in the FIBROWALK versus the MPP arm was 8.33% (95% CI = −5.13 to 21.78%) with an NNT = 13. As in this latter case, the 95%CI for the absolute risk reduction extended from a negative number (FIBROWALK may not benefit) to a positive number (FIBROWALK may benefit), the NNT result had no interpretable meaning.

Table 1
Demographic and baseline clinical characteristics by treatment groups.

	TAU (n = 110)	TAU + FIBROWALK (n = 110)	TAU + MPP (n = 110)	F/χ^2 (df)	*p*
Age (years), M ± SD	53.48 ± 8.93	52.78 ± 8.64	52.54 ± 9.78	.318 (2)	.73
Women, *n* (%)	103 (96.7)	109 (99.1)	107 (97.3)	5.27 (2)	.07
Civil Status, n (%)				9.61 (6)	.14
Single	24 (21.8)	22 (20.0)	13 (12.7)		
Married	52 (47.3)	62 (56.4)	73 (66.4)		
Divorced	27 (24.5)	21 (19.1)	16 (14.5)		
Widow	7 (6.4)	5 (4.5)	7 (6.4)		
Not living Alone, n (%)	84 (76.4)	93 (84.5)	97 (88.2)	5.72 (2)	.06
Educational Level, n (%)				14.86 (10)	.14
Without Studies	3 (2.7)	2 (1.8)	0 (0.0)		
Primary Education not completed	9 (8.2)	10 (9.2)	6 (5.5)		
Primary Education	40 (36.4)	28 (25.5)	25 (22.7)		
Secondary Education	31 (28.2)	47 (42.7)	54 (49.1)		
Higher Education	24 (21.8)	20 (18.2)	23 (20.9)		
Other	3 (2.7)	3 (2.7)	2 (1.8)		
Employment Situation, n (%)				14.71 (14)	.40
Housekeeper	13 (11.8)	10 (9.1)	9 (8.2)		
Active	22 (20.0)	26 (23.6)	30 (27.3)		
On leave	22 (20.0)	25 (22.7)	24 (21.8)		
Unemployed with allowance	6 (5.5)	13 (11.8)	5 (4.5)		
Unemployed without allowance	10 (9.1)	7 (6.4)	4 (3.6)		
Retired	15 (13.6)	10 (9.1)	10 (9.1)		
Temporary work disability	12 (10.9)	8 (7.3)	10 (9.1)		
Other	10 (9.1)	11 (10.0)	18 (16.4)		
Incapacity certificate, n (%)				4.382 (4)	.36
No	31 (28.2)	24 (21.8)	35 (31.8)		
Between 33% and 66%	65 (59.1)	73 (66.4)	58 (52.7)		
More than 66%	14 (12.7)	13 (11.8)	17 (15.5)		
BMI, M ± SD	27.62 ± 5.41	27.31 ± 6.17	26.89 ± 5.06	.477 (2)	.62
ISPS, M ± SD	15.79 ± 9.12	16.21 ± 9.24	14.80 ± 8.72	.692 (2)	.50
With CFS, *n* (%)	94 (85.5)	100 (90.9)	88 (80.0)	5.27 (2)	.07
FIQR, M ± SD		74.72 ± 14.71		.043	.96

(*continued on next page*)

Table 1 (*continued*)

	TAU (n = 110)	TAU + FIBROWALK (n = 110)	TAU + MPP (n = 110)	F/χ^2 (df)	*p*
	74.57 ± 15.63		75.16 ± 16.00		
Pain (VAS), M ± SD	7.99 ± 1.44	8.02 ± 1.28	8.11 ± 1.57	.204	.82
TSK, M ± SD	30.56 ± 7.99	30.16 ± 7.98	31.67 ± 7.46	1.100	.33
HADS Anxiety, M ± SD	13.70 ± 4.31	12.93 ± 4.42	13.69 ± 4.12	1.314	.27
HADS Depression, M ± SD	12.69 ± 4.31	12.06 ± 4.38	12.01 ± 4.83	.838	.43
SF36-PF, M ± SD	32.59 ± 17.36	35.14 ± 20.15	34.81 ± 20.42	.565	.57

Note: TAU = Treatment-as-usual; MPP = Multicomponent Physiotherapeutic Program; BMI: Body Mass Index; CFS: Chronic Fatigue Syndrome; FIQR: Revised Fibromyalgia Impact Questionnaire; HADS: Hospital Anxiety and Depression Scale; ISPS: Illness Self-Perceived Start; SF-PF: Physical Functioning component of the 36-Item Short Form Survey; TSK: Tampa Scale for Kinesiophobia.

4. Discussion

Both the video-based FIBROWALK and MPP multicomponent treatments were found to be more efficacious than TAU only, with small-to-large clinical effects. The superiority of these two programs over TAU only was corroborated by the low NNT values. Furthermore, FIBROWALK produced additional clinical benefits when compared to MPP. Our findings provide additional evidence of the effectiveness of video-based FIBROWALK, which was initially obtained in a pilot study during the first lockdown due to COVID-19 pandemic in Spain (Serrat, Coll-Omaña et al., 2021) and confirmed existing evidence of the efficacy of PNE combined with therapeutic exercise in people with FM (Barrenengoa-Cuadra et al., 2021; Ceballos-Laita et al., 2020; Louw, Puentedura, et al., 2016).

Interestingly, although both FIBROWALK and MPP were effective in improving the primary outcome of perceived functional impairment, only FIBROWALK showed statistically significant effects on *all* the study outcomes. Though the MPP program was also effective in reducing perceived pain intensity, kinesiophobia, and depressive symptoms it did not result in improved anxiety symptoms and perceived level of physical function compared to TAU only. Furthermore, though the effect sizes were small-to-medium, FIBROWALK achieved statistically larger improvements in the secondary outcomes of pain intensity, anxiety (only in the complete-case dataset) and depressive symptoms and physical function compared to MPP. These findings suggest a broader and stronger therapeutic effect by combining psychological ingredients with physiotherapy interventions based on PNE and therapeutic exercise. These results are in line with other studies evaluating the effects of physiotherapy plus psychological interventions compared with physiotherapy alone in other chronic pain samples (Wilson & Cramp, 2018). These findings are remarkably important, as they support the inclusion of evidence-based psychotherapeutic approaches in ongoing multicomponent physiotherapy programs for people with FM.

The efficacy of the two treatments, in part, rely on the shared components of PNE and therapeutic exercise. Many studies have separately supported the efficacy of both PNE and therapeutic exercise (e.g., adapted aerobic and muscle strengthening exercises) in reducing pain, affective symptoms, kinesiophobia, and perceived disability and in improving global well-being and health-related quality of life in people with musculoskeletal pain (Sosa-Reina et al., 2017; Watson et al., 2019). It is known that PNE and therapeutic exercise can be even more effective when combined (Louw, Zimney, Puentedura, & Diener, 2016; Malfliet

Table 2
Descriptive statistics and between-group analyses for primary and secondary outcomes from an ITT approach (with multiple imputation of missing data).

	TAU (n = 110) Mean (SD)	TAU + FIBROWALK (n = 110) Mean (SD)	TAU + MPP (n = 110) Mean (SD)	TAU vs TAU + FIBROWALK				TAU vs TAU + MPP			TAU + FIBROWALK vs TAU + MPP		
				F	p	d	(95% CI)	d	p	(95% CI)	d	p	(95% CI)
FIQR													
Baseline	74.57 ± 15.63	74.72 ± 14.71	75.16 ± 16.00										
Post-Treatment	74.92 ± 14.58	60.68 ± 20.56	65.84 ± 19.34	27.58	**<.001**	.80	**<.001** (8.83–17.74)	.53	**<.001**	(4.59–13.28)	.26	.163	(-8.03 to .88)
Pain (VAS)													
Baseline	7.99 ± 1.44	8.02 ± 1.28	8.11 ± 1.57										
Post-Treatment	8.12 ± 1.50	6.73 ± 2.12	7.43 ± 2.01	20.97	**<.001**	.76	**<.001** (.85–1.86)	.39	**.002**	(.22–1.23)	.34	**.017**	(-1.09 to −.08)
TSK													
Baseline	30.56 ± 7.99	30.16 ± 7.98	31.67 ± 7.46										
Post-Treatment	32.11 ± 6.44	22.52 ± 6.55	24.40 ± 7.24	90.08	**<.001**	1.48	**<.001** (7.47–11.05)	1.13	**<.001**	(6.26–9.84)	.27	.654	(-2.67 to .86)
HADS Anxiety													
Baseline	13.70 ± 4.31	12.93 ± 4.42	13.69 ± 4.12										
Post-Treatment	13.66 ± 4.37	11.35 ± 4.74	13.11 ± 4.59	7.75	**.001**	.51	**<.001** (.66–2.63)	.12	1.000	(-.62 to 1.35)	.38	.128	(-1.87 to .16)
HADS Depression													
Baseline	12.69 ± 4.31	12.06 ± 4.38	12.01 ± 4.83										
Post-Treatment	13.12 ± 4.53	10.15 ± 4.93	11.36 ± 5.05	13.38	**<.001**	.63	**<.001** (1.22–3.35)	.37	**.037**	(.053–2.28)	.24	**.045**	(-2.23 to −.02)
SF-PF													
Baseline	32.59 ± 17.36	35.14 ± 20.15	34.81 ± 20.42										
Post-Treatment	30.47 ± 14.09	45.14 ± 20.80	35.22 ± 20.02	22.68	**<.001**	.83	**<.001** (-16.44 to −7.49)	.27	.389	(-7.29 to 1.65)	.49	**<.001**	(4.68–13.61)

Note: Statistically significant effects are shown in bold ($p \leq 0.05$). Pooled post-treatment means and standard deviations are shown. Bonferroni-adjusted post hoc tests were conducted for pairwise comparisons. The table reports inferential statistics (*F*, *p*, Cohen's *d*) for the imputation iteration that yielded the highest p-value, to prevent an inflation of false positives (Type I error). 95%CI for the between-groups difference adjusted means at post are shown. TAU = Treatment-as-usual; MPP = Multicomponent Physiotherapeutic Program; FIQR: Revised Fibromyalgia Impact Questionnaire; TSK: Tampa Scale for Kinesiophobia; HADS; Hospital Anxiety and Depression Scale; ISPS: Illness Self-Perceived Start; SF-PF: Physical Functioning component of the 36-Item Short Form Survey.

Table 3
Descriptive statistics and between-group analyses for primary and secondary outcomes (only with completers).

	TAU (n = 100) Mean (SD)		TAU + FIBROWALK (n = 100) Mean (SD)	TAU + MPP (n = 98) Mean (SD)				TAU vs TAU + FIBROWALK			TAU vs TAU + MPP			TAU + FIBROWALK vs TAU + MPP		
					F	P	d	p	(95% CI)	d	p	(95% CI)	d	p	(95% CI)
FIQR															
Baseline	74.12 ± 15.92		74.26 ± 14.91	74.77 ± 16.64											
Post-Treatment	74.49 ± 13.93		60.66 ± 20.93	65.28 ± 19.80	27.84	<.001	−.92	**<.001**	(9.33–18.55)	−.62	**<.001**	(5.09–14.36)	.26	.088	(-.42 to 8.85)
Pain (VAS)															
Baseline	7.97 ± 1.45		7.99 ± 1.27	8.08 ± 1.62											
Post-Treatment	8.08 ± 1.43		6.73 ± 2.16	7.39 ± 2.08	19.38	<.001	1.01	**<.001**	(-1.90 to −.84)	.54	**.002**	(-1.31 to −.25)	.40	**.025**	(-1.12 to −.05)
TSK															
Baseline	30.43 ± 7.99		29.73 ± 8.02	31.67 ± 7.19											
Post-Treatment	31.96 ± 6.31		22.43 ± 6.64	22.29 ± 7.35	85.17	<.001	−1.14	**<.001**	(7.30–11.04)	−1.39	**<.001**	(6.44–10.20)	.21	.829	(-1.03 to 2.74)
HADS Anxiety															
Baseline	13.43 ± 4.26		12.80 ± 4.53	13.51 ± 4.16											
Post-Treatment	13.47 ± 4.33		11.27 ± 4.85	12.93 ± 4.60	7.87	<.001	−.33	**<.001**	(.65–2.75)	−.33	.521	(-.46 to 1.65)	.50	**.036**	(.05–2.16)
HADS Depression															
Baseline	12.74 ± 4.41		12.07 ± 4.54	11.87 ± 4.67											
Post-Treatment	13.05 ± 4.55		10.23 ± 5.01	11.20 ± 5.103	11.78	<.001	−.50	**<.001**	(1.16–3.44)	−.26	**.045**	(.02–2.31)	.22	.053	(-.01 to 2.28)
SF-PF															
Baseline	32.80 ± 17.35		35.15 ± 20.46	35 ± 21.26											
Post-Treatment	30.70 ± 13.74		44.75 ± 21.09	35.92 ± 20.39	22.00	<.001	.61	**<.001**	(7.87–17.20)	.61	.156	(-.89 to 8.49)	.42	**<.001**	(4.05–13.42)

Note: Statistically significant effects are shown in bold ($p \leqq 0.05$). Unadjusted means are shown. Bonferroni-adjusted post hoc tests were conducted for pairwise comparisons. When the Benjamini–Hochberg correction was applied to correct for multiple comparisons, all significant effects remained significant. 95%CI for the between-groups difference adjusted means at post are shown. TAU = Treatment-as-usual; MPP = Multicomponent Physiotherapy Program; FIQR: Revised Fibromyalgia Impact Questionnaire; HADS: Hospital Anxiety and Depression Scale; ISPS: Illness Self-Perceived Start; SF-PF: Physical Functioning component of the 36-Item Short Form Survey; TSK: Tampa Scale for Kinesiophobia.

et al., 2017). Furthermore, FIBROWALK and MPP shared other self-management and patient education components, which were found in a recent systematic review in FM to be effective in improving pain intensity, fatigue, sleep quality, depression, anxiety, functional ability, cognitive impairment, and quality of life (Gómez-de-Regil, 2021).

While superior improvements in anxiety and depressive symptoms were expected outcomes for the FIBROWALK arm, participants allocated to this intervention also showed greater pain ameliorations and physical functioning when compared to those allocated to MPP. Similar results have also been found in other studies assessing the effects of CBT or mindfulness-based interventions in subjects with FM (Bennett & Nelson, 2006; Kundakci et al., 2021; Williams et al., 2002). Moreover, larger improvements in physical function after multidisciplinary interventions, including both psychotherapeutic and physiotherapeutic components compared to physiotherapy interventions alone were also reported in a systematic review and meta-analysis including different chronic pain samples (Wilson & Cramp, 2018). In this regard, it is known that patients suffering from chronic pain tend to exhibit maladaptive beliefs regarding physical exercise (Harding & Williams, 1995), which can lead to a sedentary lifestyle and non-compliance with physical therapy recommendations (Dysvik, Vinsnes, & Eikeland, 2004). Avoidance of physical activity is often a barrier to recovery and can contribute to reduced physical function, deconditioning, and increased pain. The psychological components included in FIBROWALK were aimed at helping patients overcome such barriers by modifying maladaptive pain beliefs and cognitive biases and fostering adaptive emotional regulation in order to reduce pain catastrophizing, increase psychological flexibility, and promote positive behavioural changes. Addressing these barriers to function are essential steps for escaping from the vicious circle of fear and avoidance of physical activity in musculoskeletal pain (Vlaeyen, Crombez, & Linton, 2016; Wright & Gatchel, 2002). Similarly, mindfulness can play an important role in breaking this vicious circle by reducing negative rumination, increasing pain acceptance, and improving one's ability to stay focused on the present moment with a non-judgemental attitude (Curtin & Norris, 2017; McCracken & Keogh, 2009; Pérez-Aranda, Feliu-Soler, et al., 2019). Both cognitive restructuring and mindfulness, combined with PNE, can contribute to reduce fear of pain and fear of movement (Jay et al., 2016). In this way, CBT, Mindfulness, therapeutic exercise and PNE might present a synergistic effect (Heller et al., 2021) in which all components have a greater effect when combined than the sum of their separate effects. Furthermore, given the known bidirectional relationship between pain-related distress and physical function (e.g., Stegenga et al., 2012; Talaei-Khoei et al., 2018; Wegener et al., 2011), the additional CBT and mindfulness approaches for reducing pain-related distress in FIBROWALK may have contributed to the stronger therapeutic effects compared to MPP and TAU only.

When looking specifically at the impact on kinesiophobia, both active groups showed similar improvements (large effect sizes) compared to TAU. In this regard, adding CBT and mindfulness training did not increase the effects of the MPP on this variable, which probably reached a therapeutic ceiling. Previous research has suggested that changes in cognitive biases and behavioural factors in chronic pain conditions might not occur exclusively by means of psychological approaches but also by providing subjects with comprehensive information about the biopsychosocial essence of chronic pain as is done in PNE (Burns, Van Dyke, Newman, Morais, & Thorn, 2020). PNE is aimed at reconceptualizing pain in order to break the cycle of fear of movement and avoidance. Previous studies have reported that PNE is high effectivity in reducing kinesiophobia in FM and other musculoskeletal pain conditions (Louw, Diener, Butler, & Puentedura, 2011; Luque-Suarez, Martinez-Calderon, & Falla, 2019; Siddall et al., 2022; Watson et al., 2019).

Although both FIBROWALK and MPP were clearly superior to TAU alone, it is important to highlight that only 42% and 34% of the participants, respectively, showed a clinically significant improvement (i.e.,

Table 4
Baseline differences between responders (FIQR≧20%) and non-responders from the FIBROWALK and MPP.

	FIBROWALK (n = 100)				MPP (n = 98)			
	Non-Responders (n = 58)	Responders (n = 42)	t/x2	p	Non-Responders (n = 65)	Responders (n = 33)	t/x2	p
Age (years), M ± SD	52.59 ± 7.84	54.40 ± 9.28	−1.031	.306	51.42 ± 9.81	55.12 ± 7.78	−2.035	**.045**
Women, n (%)	58 (100.0)	41 (97.6)	1.395	.238	65 (100)	31 (93.9)	4.021	**.045**
Civil Status, n (%)			2.326	.508			.109	.991
Single	14 (24.1)	8 (19.0)			8 (12.3)	4 (12.1)		
Married	28 (48.3)	26 (61.9)			43 (66.2)	22 (66.7)		
Divorced	12 (20.7)	7 (16.7)			9 (13.8)	5 (15.2)		
Widow	4 (6.9)	1 (2.4)			5 (7.7)	2 (6.1)		
Not living Alone, n (%)	50 (86.2)	34 (81.0)	.500	.479	60 (92.3)	27 (81.8)	2.417	.120
Educational Level, n (%)			6.977	.222			1.996	.736
Without Stydies	2 (3.4)	0 (0.0)						
Primary Education not completed	8 (13.8)	1 (2.4)			4 (6.2)	1 (3.0)		
Primary Education	13 (22.4)	14 (33.3)			14 (21.5)	8 (24.2)		
Secondary Education	25 (43.1)	19 (45.2)			34 (52.3)	15 (45.5)		
Higher Education	9 (15.5)	8 (19.0)			12 (18.5)	9 (27.3)		
Other	1 (1.7)	0 (0.0)			1 (1.5)	0(0.0)		
Employment Situation, n (%)			4.279	.747			6.002	.539
Housekeeper	4 (6.9)	3 (7.1)			5 (7.7)	3 (9.1)		
Active	13 (22.4)	9 (21.4)			18 (27.7)	10 (30.3)		
On leave	16 (27.6)	8 (19.0)			18 (27.7)	5 (15.2)		
Unemployed with allowance	8 (13.8)	5 (11.9)			4 (6.2)	1 (3.0)		
Unemployed without allowance	4 (6.9)	3 (7.1)			1 (1.5)	1 (3.0)		
Retired	3 (5.2)	7 (16.7)			3 (4.6)	5 (15.2)		
Temporary work disability	4 (6.9)	2 (4.8)			7 (10.8)	2 (6.1)		
Other	6 (10.3)	5 (11.9)			9 (13.8)	6 (18.2)		
Incapacity certificate, n (%)			6.665	.155			1.220	.748
No	12 (20.7)	8 (19.0)			19 (29.2)	12 (36.4)		
Between 33% and 66%	40 (69.0)	23 (54.8)			32 (49.2)	15 (45.5)		
More than 66%	5 (8.6)	5 (11.9)			9 (13.8)	5 (15.2)		
BMI, M ± SD	27.28 ± 5.86	27.77 ± 6.88	−.371	.711	26.84 ± 5.38	27.11 ± 4.97	−.248	.805
ISPS, years, M ± SD	16.62 ± 10.14	15.48 ± 8.09	.627	.532	14.83 ± 8.41	14.27 ± 9.09	.294	.769
With CFS, n (%)	55 (94.8)	37 (88.1)	1.500	.221	53 (81.5)	25 (75.8)	.450	.502
FIQR, M ± SD	75.59 ± 15.34	72.43 ± 14.28	1.056	.294	77.46 ± 15.48	69.47 ± 17.79	2.193	**.032**
Pain (VAS), M ± SD	8.09 ± 1.27	7.86 ± 1.26	.891	.375	8.46 ± 1.44	7.33 ± 1.73	3.429	**.001**
TSK, M ± SD	30.07 ± 7.55	20.26 ± 8.70	.484	.630	31.92 ± 6.89	31.18 ± 7.84	.460	.647
HADS Anxiety, M ± SD	13.71 ± 4.01	11.55 ± 4.95	2.328	**.023**	14.26 ± 3.79	12.03 ± 4.52	2.436	**.018**
HADS Depression, M ± SD	12.98 ± 4.05	10.81 ± 4.91	2.349	**.021**	12.42 ± 5.00	10.79 ± 3.76	1.646	.103
SF36-PF, M ± SD	31.29 ± 18.79	40.47 ± 21.66	−2.210	**.030**	31.15 ± 21.02	42.58 ± 19.93	−2.632	**.011**

Note: Statistically significant effects appear in bold (p ≦ 0.05). MPP = Multicomponent Physiotherapeutic Program; BMI: Body Mass Index; CFS: Chronic Fatigue Syndrome; FIQR: Revised Fibromyalgia Impact Questionnaire; TSK: Tampa Scale for Kinesiophobia; HADS: Hospital Anxiety and Depression Scale; ISPS: Illness Self-Perceived Start; SF-PF: Physical Functioning component of the 36-Item Short Form Survey.

20% between pre- and post-treatment) in the primary outcome measure of perceived functional impairment, as determined by FIQR scores. Though FIBROWALK in the present study yielded a higher rate of responders (43%) than the initial pilot RCT (30%), which was conducted during the Spanish lockdown (Serrat, Coll-Omaña, et al., 2021), there is room for considerable improvement. Moreover, greater clinical effects in FIQR scores (Cohen's *d* of 0.83 vs 1.13; NNT = 3 vs 2) and a larger proportion of treatment "responders" were found in the face-to-face FIBROWALK format (Serrat, Sanabria-Mazo, et al., 2021) compared to the video-based version in the present study (42% vs 51.85%). It is also important to note that, although online approaches may be less effective than equivalent face-to-face options, these video-based programs are highly scalable and have the potential to provide treatment availability for FM patients who are unable to attend face-to-face sessions. Furthermore, these telemedicine programs may help reduce healthcare costs and decongest health system services which are experiencing huge workload burdens as a result of the current COVID-19 pandemic (Moman et al., 2019).

Although comparisons in effectiveness between the virtual and face-to-face formats of FIBROWALK should be evaluated in future RCTs, many factors may contribute to these apparent differences, including the feeling of belonging to a group and having regular contact with a therapist, which both have potentially therapeutic benefits. Furthermore, we cannot rule out that our results would have been better in a patient sample with less severe symptoms. In this regard, compared to non-responders in the present study, the responders reported lower pre-treatment symptom severity. In general, the patients in our sample reported a relatively high degree of pre-treatment functional impairment,

low degree of perceived physical function, high perceived pain intensity and a moderate degree of depressive and anxiety symptomatology. Future studies should evaluate if additional treatment time or tailored adaptations of FIBROWALK (e.g., adding individual therapy or extra CBT virtual sessions for those individuals scoring high in anxiety and/or depression) may work better for those patients with a higher risk of non-responsiveness. In this regard, evidence-based care has started to move toward process-based therapies to target core mediators and moderators based on testable theories, to identify what treatments are most effective, for whom, why and under what set of circumstances (Hofmann & Hayes, 2019; McCracken, 2020). This change of perspective from "one size fits all" to more individualised treatment may better suit the high level of complexity that chronic pain conditions, and particularly FM, present.

Finally, FIBROWALK and MPP showed a relatively low attrition rate (around 10%). This low rate of dropouts supports the feasibility of these virtual interventions. A range between 4% and 54% of attrition has been found with other online interventions in patients with chronic pain (Buhrman, Gordh, & Andersson, 2016). The attrition rate in FIBROWALK was also lower than in the pilot RCT conducted during the COVID-19 outbreak (38.7%; Serrat, Coll-Omaña, et al., 2021) and even lower than the reported in the face-to-face version of the program (9% vs 24%) (Serrat, Sanabria-Mazo, et al., 2021). This finding may suggest a superior ability of the virtual format of the FIBROWALK for engaging participants who were not able to attend a 12-week face-to-face intervention. The increased adherence and low attrition rate of participants in the present study could have been due to the high flexibility of the video-based format, participation through the hospital system from which they were receiving TAU care, the emphasis at the beginning of the study about the importance of actively participating in the intervention, and therapist support during the program. Results from the present study suggest that the virtual interventions of FIBROWALK and MPP can be effective therapeutic alternatives to classical face-to-face treatments in times of pandemics and beyond when it comes to specific logistic barriers, such as timing, difficulties in access to treatment in remote areas, or other perceived barriers, such as individual's fatigue or family conciliation issues.

This RCT had several strengths, such as the inclusion of two innovative video-based active treatments that were structurally equivalent, the relatively large sample size and the reduced number of dropouts. However, there were several limitations. First, comparisons between the two intervention groups (FIBROWALK vs MPP) may have been underpowered. Second, this study was carried out in daily clinical practice in a specialised tertiary care hospital. Therefore, stricter eligibility criteria could not be applied. Subjects with certified disability were included in our sample. The sample was composed of people with FM with high impact on daily functioning and relatively long duration of the disease. Future studies could explore the role of multicomponent interventions in other settings (e.g. primary care) including less severe patients. Third, no long-term follow-ups were done, due the fact that the present study was carried out within usual clinical practice. Future studies should include long-term follow-ups for assessing the stability of the observed clinical effects. Fourth, it cannot be confirmed that all subjects viewed all the videos and performed all the homework, even though they reported compliance in a weekly questionnaire format. Fifth, all outcome data were patient-reported. No objective functional data were measured. Though it is common to use patient-reported data to evaluate FM symptom domains (Outcome Measures in Rheumatology Clinical Trials; Mease et al., 2009), future studies should include complementary objective measures. Future studies should also include weekly patient-reported state measures to examine the evolution of participants throughout the study instead of only at the end of the intervention (e.g., Navarrete, García-Salvador, Cebolla, & Baños, 2022). Sixth, future studies should evaluate potential sampling bias, which are inherent to any study, including online interventions. Participants with a perceived low digital competency may have been self-excluded themselves when initially being told about the virtual nature of the intervention, which may have undermined the generalizability of our findings. Finally, this trial was conducted under de COVID-19 pandemic context and after termination of national lockdowns. Given the well-known negative effects of these circumstances on mental health and treatment adherence (e.g., López-Medina et al., 2021), further studies conducted beyond current pandemic context should be done to evaluate the generalizability of our findings.

5. Conclusions

This study showed that two video-based multicomponent treatments including PNE, therapeutic exercise and self-management patient education, were clinically effective in improving functional disability, pain and kinesiophobia compared to TAU only for people with FM. Furthermore, FIBROWALK, which combined all therapeutic components of MPP with cognitive restructuring and mindfulness training, was more effective in reducing anxiety, depressive symptoms and in improving physical function than MPP or TAU only. The results of this RCT support the clinical effectiveness of both video-based treatments over usual care in FM and provide more scientific evidence regarding the increased benefits of combining physical therapy and psychological techniques in the management of this highly prevalent and limiting disease.

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CRediT authorship contribution statement

Mayte Serrat: Conceptualization, Methodology, Resources, Software, Data curation, Validation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition. **Klara Albajes:** Conceptualization, Methodology, Resources, Software, Data curation, Validation, Formal analysis, Writing – original draft, Writing – review & editing, Supervision. **Jaime Navarrete:** Formal analysis, Writing – review & editing. **Miriam Almirall:** Writing – review & editing, Supervision. **Enrique Lluch Girbés:** Writing – review & editing. **Randy Neblett:** Writing – review & editing. **Juan V. Luciano:** Conceptualization, Writing – review & editing, Supervision. **Jenny Moix:** Writing – review & editing, Supervision. **Albert Feliu-Soler:** Conceptualization, Methodology, Resources, Software, Data curation, Validation, Formal analysis, Writing – original draft, Writing – review & editing, Supervision, Project administration, Funding acquisition.

Declaration of competing interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brat.2022.104188.

References

Albajes, K., & Moix, J. (2021). Psychological interventions in fibromyalgia: An updated systematic review. *Mediterranean Journal of Clinical Psychology, 9*(1). https://doi.org/10.6092/2282-1619/mjcp-2759

Alonso, J., Prieto, L., & Antó, J. M. (1995). La versión española del SF-36 health survey (Cuestionario de Salud SF-36): Un instrumento para la medida de los resultados clínicos [the Spanish version of the SF-36 health survey (the SF-36 health questionnaire): An instrument for measuring clinical results]. *Medicina Clínica, 104*(20), 771–776. PMID: 7783470.

Aman, M. M., Jason Yong, R., Kaye, A. D., & Urman, R. D. (2018). Evidence-based non-pharmacological therapies for fibromyalgia. *Current Pain and Headache Reports, 22*(5), 1–5.

Amer-Cuenca, J. J., Pecos-Martín, D., Martínez-Merinero, P., Lluch Girbés, E., Nijs, J., Meeus, M., et al. (2020). How much is needed? Comparison of the effectiveness of different pain education dosages in patients with fibromyalgia. *Pain Medicine, 21*(4), 782–793. https://doi.org/10.1093/pm/pnz069

Andersson, G. (2018). Internet interventions: Past, present and future. *Internet interventions, 12*, 181–188.

Andersson, G., & Titov, N. (2014). Advantages and limitations of Internet-based interventions for common mental disorders. *World Psychiatry, 13*(1), 4–11.

Barrenengoa-Cuadra, M. J., Muñoa-Capron-Manieux, M., Fernández-Luco, M., Angón-Puras, L.Á., Romón-Gómez, A. J., Azkuenaga, M., et al., FIMIDOC Working Group researchers. (2021). Effectiveness of a structured group intervention based on pain neuroscience education for patients with fibromyalgia in primary care: A multicentre randomized open-label controlled trial. *European Journal of Pain, 25*(5), 1137–1149. https://doi.org/10.1002/ejp.1738

Bennett, R. M., Friend, R., Jones, K. D., Ward, R., Han, B. K., & Ross, R. L. (2009). The revised fibromyalgia impact questionnaire (FIQR): Validation and psychometric properties. *Arthritis Research and Therapy, 11*(4), R120. https://doi.org/10.1186/ar2783

Bennett, R., & Nelson, D. (2006). Cognitive behavioral therapy for fibromyalgia. *Nature Clinical Practice Rheumatology, 2*(8), 416–424. https://doi.org/10.1038/ncprheum0245

Bernardy, K., Klose, P., Welsch, P., & Häuser, W. (2018). Efficacy, acceptability and safety of cognitive behavioural therapies in fibromyalgia syndrome - a systematic review and meta-analysis of randomized controlled trials. *European Journal of Pain, 22*(2), 242–260. https://doi.org/10.1002/ejp.1121

Bernardy, K., Klose, P., Welsch, P., & Häuser, W. (2019). Efficacy, acceptability and safety of internet-delivered psychological therapies for fibromyalgia syndrome: A systematic review and meta-analysis of randomized controlled trials. *European Journal of Pain, 23*(1), 3–14. https://doi.org/10.1002/ejp.1284

Buhrman, M., Gordh, T., & Andersson, G. (2016). Internet interventions for chronic pain including headache: A systematic review. *Internet interventions, 4*, 17–34. https://doi.org/10.1016/j.invent.2015.12.001

Burns, J. W., Van Dyke, B. P., Newman, A. K., Morais, C. A., & Thorn, B. E. (2020). Cognitive behavioral therapy (CBT) and pain education for people with chronic pain: Tests of treatment mechanisms. *Journal of Consulting and Clinical Psychology, 88*(11), 1008–1018. https://doi.org/10.1037/ccp0000612

Camerini, L., Camerini, A. L., & Schulz, P. J. (2013). Do participation and personalization matter? A model-driven evaluation of an internet-based patient education intervention for fibromyalgia patients. *Patient Education and Counseling, 92*(2), 229–234. https://doi.org/10.1016/j.pec.2013.04.007

Ceballos-Laita, L., Mingo-Gómez, M. T., Navas-Cámara, F., Estébanez-de-Miguel, E., Caudevilla-Polo, S., Verde-Rello, Z., et al. (2020). Therapeutic exercise and pain neurophysiology education in female patients with fibromyalgia syndrome: A feasibility study. *Journal of Clinical Medicine, 9*(11), 3564. https://doi.org/10.3390/jcm9113564

Cohen, J. (1988). *Statistical power analysis for the behavioral sciences (No. 300.72 C6)*. New York, NY: Routledge Academic.

Conversano, C., & Di Giuseppe, M. (2021). Psychological factors as determinants of chronic conditions: Clinical and psychodynamic advances. *Frontiers in Psychology, 12*, Article 635708. https://doi.org/10.3389/fpsyg.2021.635708

Cook, R. J., & Sackett, D. L. (1995). The number needed to treat: A clinically useful measure of treatment effect. *BMJ, 310*(6977), 452–454. https://doi.org/10.1136/bmj.310.6977.452

Cunningham, N. R., & Kashikar-Zuck, S. (2013). Nonpharmacological treatment of pain in rheumatic diseases and other musculoskeletal pain conditions. *Current Rheumatology Reports, 15*(2), 306. https://doi.org/10.1007/s11926-012-0306-y

Curtin, K. B., & Norris, D. (2017). The relationship between chronic musculoskeletal pain, anxiety and mindfulness: Adjustments to the Fear-Avoidance Model of Chronic Pain. *Scandinavian journal of pain, 17*, 156–166. https://doi.org/10.1016/j.sjpain.2017.08.006

Davis, M. C., & Zautra, A. J. (2013). An online mindfulness intervention targeting socioemotional regulation in fibromyalgia: Results of a randomized controlled trial. *Annals of Behavioral Medicine : A Publication of the Society of Behavioral Medicine, 46*(3), 273–284. https://doi.org/10.1007/s12160-013-9513-7

De Miquel, C. A., Campayo, J., Flórez, M. T., Arguelles, J. M., Tarrio, E. B., Montoya, M. G., et al. (2010). Interdisciplinary consensus document for the treatment of fibromyalgia. *Actas Espanolas de Psiquiatria, 38*(2), 108–120.

Dysvik, E., Vinsnes, A. G., & Eikeland, O. J. (2004). The effectiveness of a multidisciplinary pain management programme managing chronic pain. *International Journal of Nursing Practice, 10*(5), 224–234. https://doi.org/10.1111/j.1440-172X.2004.00485.x

Etzelmueller, A., Vis, C., Karyotaki, E., Baumeister, H., Titov, N., Berking, M., et al. (2020). Effects of internet-based cognitive behavioral therapy in routine care for adults in treatment for depression and anxiety: Systematic review and meta-analysis. *Journal of Medical Internet Research, 22*(8), Article e18100. https://doi.org/10.2196/18100

Galvez-Sánchez, C. M., Duschek, S., & Reyes Del Paso, G. A. (2019). Psychological impact of fibromyalgia: Current perspectives. *Psychology Research and Behavior Management, 12*, 117–127. https://doi.org/10.2147/PRBM.S178240

Glombiewski, J. A., Sawyer, A. T., Gutermann, J., Koenig, K., Rief, W., & Hofmann, S. G. (2010). Psychological treatments for fibromyalgia: A meta-analysis. *Pain, 151*(2), 280–295. https://doi.org/10.1016/j.pain.2010.06.011

Gómez-de-Regil, L. (2021). Psychoeducation for patients with fibromyalgia: A systematic review. *Healthcare (Basel, Switzerland), 9*(6), 737. https://doi.org/10.3390/healthcare9060737

Gómez-Pérez, L., López-Martínez, A. E., & Ruiz-Párraga, G. T. (2011). Psychometric properties of the Spanish version of the Tampa scale for kinesiophobia (TSK). *The Journal of Pain, 12*(4), 425–435. https://doi.org/10.1016/j.jpain.2010.08.004

Harding, V., & Williams, A. C. (1995). Extending physiotherapy skills using a psychological approach: Cognitive-behavioural management of chronic pain. *Physiotherapy, 81*, 681–688. https://doi.org/10.1016/S0031-9406(05)66622-9

Haugmark, T., Hagen, K. B., Smedslund, G., & Zangi, H. A. (2019). Mindfulness- and acceptance-based interventions for patients with fibromyalgia - a systematic review and meta-analyses. *PLoS One, 14*(9), Article e0221897. https://doi.org/10.1371/journal.pone.0221897

Häuser, W., Ablin, J., Fitzcharles, M. A., Littlejohn, G., Luciano, J. V., Usui, C., et al. (2015). Fibromyalgia. *Nature Reviews Disease Primers, 1*(1), 1–16. https://doi.org/10.1038/nrdp.2015.22

Häuser, W., Bernardy, K., Arnold, B., Offenbächer, M., & Schiltenwolf, M. (2009). Efficacy of multicomponent treatment in fibromyalgia syndrome: A meta-analysis of randomized controlled clinical trials. *Arthritis & Rheumatism, 61*(2), 216–224. https://doi.org/10.1002/art.24276

Heller, H. L., Borges, A. R., Franco, L. O. A., De Oliveira Aucelio, J. P., Vargas, M. I. A., Lorga, R. N., et al. (2021). Role of cognitive behavioral therapy in fibromyalgia: A systematic review. *Open Journal of Rheumatology and Autoimmune Diseases, 11*, 169–187. https://doi.org/10.4236/ojra.2021.114018

Hofmann, S. G., & Hayes, S. C. (2019). The future of intervention science: Process-based therapy. *Clinical Psychological Science : A Journal of the Association for Psychological Science, 7*(1), 37–50. https://doi.org/10.1177/2167702618772296

Jakobsen, J. C., Gluud, C., Wetterslev, J., & Winkel, P. (2017). When and how should multiple imputation be used for handling missing data in randomised clinical trials–a practical guide with flowcharts. *BMC Medical Research Methodology, 17*(1), 1–10.

Jay, K., Brandt, M., Jakobsen, M. D., Sundstrup, E., Berthelsen, K. G., Schraefel, M., et al. (2016). Ten weeks of physical-cognitive-mindfulness training reduces fear-avoidance beliefs about work-related activity: Randomized controlled trial. *Medicine, 95*(34), e3945. https://doi.org/10.1097/MD.0000000000003945

Kabat-Zinn, J. (2013). *Full catastrophe living, revised edition: How to cope with stress, pain and illness using mindfulness meditation* (Paperback UK).

Kamper, S. J., Apeldoorn, A. T., Chiarotto, A., Smeets, R. J., Ostelo, R. W., Guzman, J., et al. (2015). Multidisciplinary biopsychosocial rehabilitation for chronic low back pain: Cochrane systematic review and meta-analysis. *BMJ, 350*, h444. https://doi.org/10.1136/bmj.h444

Kleykamp, B. A., Ferguson, M. C., McNicol, E., Bixho, I., Arnold, L. M., Edwards, R. R., et al. (2021). The prevalence of psychiatric and chronic pain comorbidities in fibromyalgia: An ACTION systematic review. *Seminars in Arthritis and Rheumatism, 51*(1), 166–174. https://doi.org/10.1016/j.semarthrit.2020.10.006

Kundakci, B., Kaur, J., Goh, S. L., Hall, M., Doherty, M., Zhang, W., et al. (2021). Efficacy of nonpharmacological interventions for individual features of fibromyalgia: A systematic review and meta-analysis of randomised controlled trials. *Pain*. https://doi.org/10.1097/j.pain.0000000000002500, 10.1097/j.pain.0000000000002500. Advance online publication.

Lichtenstein, A., Tiosano, S., & Amital, H. (2018). The complexities of fibromyalgia and its comorbidities. *Current Opinion in Rheumatology, 30*(1), 94–100. https://doi.org/10.1097/BOR.0000000000000464

López-Medina, C., Ladehesa-Pineda, L., Gómez-García, I., Puche-Larrubia, M.Á., Sequí-Sabater, J. M., Armenteros-Ortiz, P., et al. (2021). Treatment adherence during the COVID-19 pandemic and the impact of confinement on disease activity and emotional status: A survey in 644 rheumatic patients. *Joint Bone Spine, 88*(2), Article 105085. https://doi.org/10.1016/j.jbspin.2020.105085

Louw, A., Diener, I., Butler, D. S., & Puentedura, E. J. (2011). The effect of neuroscience education on pain, disability, anxiety, and stress in chronic musculoskeletal pain. *Archives of Physical Medicine and Rehabilitation, 92*(12), 2041–2056. https://doi.org/10.1016/j.apmr.2011.07.198

Louw, A., Puentedura, E. J., Zimney, K., & Schmidt, S. (2016). Know pain, know gain? A perspective on pain neuroscience education in physical therapy. *Journal of Orthopaedic & Sports Physical Therapy, 46*(3), 131–134. https://doi.org/10.2519/jospt.2016.0602

Louw, A., Zimney, K., Puentedura, E. J., & Diener, I. (2016). The efficacy of pain neuroscience education on musculoskeletal pain: A systematic review of the

literature. *Physiotherapy: Theory and Practice, 32*(5), 332–355. https://doi.org/10.1080/09593985.2016.1194646

Luciano, J. V., Aguado, J., Serrano-Blanco, A., Calandre, E. P., & Rodriguez-Lopez, C. M. (2013). Dimensionality, reliability, and validity of the revised fibromyalgia impact questionnaire in two Spanish samples. *Arthritis Care & Research, 65*(10), 1682–1689. https://doi.org/10.1002/acr.22034

Luciano, J. V., Barrada, J. R., Aguado, J., Osma, J., & García-Campayo, J. (2014). Bifactor analysis and construct validity of the HADS: A cross-sectional and longitudinal study in fibromyalgia patients. *Psychological Assessment, 26*(2), 395–406. https://doi.org/10.1037/a0035284

Luque-Suarez, A., Martinez-Calderon, J., & Falla, D. (2019). Role of kinesiophobia on pain, disability and quality of life in people suffering from chronic musculoskeletal pain: A systematic review. *British Journal of Sports Medicine, 53*(9), 554–559. https://doi.org/10.1136/bjsports-2017-098673

Macfarlane, G. J., Kronisch, C., Dean, L. E., Atzeni, F., Häuser, W., Fluß, E., et al. (2017). EULAR revised recommendations for the management of fibromyalgia. *Annals of the Rheumatic Diseases, 76*(2), 318–328. https://doi.org/10.1136/annrheumdis-2016-209724

Malfliet, A., Van Oosterwijck, J., Meeus, M., Cagnie, B., Danneels, L., Dolphens, M., Buyl, R., & Nijs, J. (2017). Kinesiophobia and maladaptive coping strategies prevent improvements in pain catastrophizing following pain neuroscience education in fibromyalgia/chronic fatigue syndrome: An explorative study. *Physiotherapy: Theory and Practice, 33*(8), 653–660. https://doi.org/10.1080/09593985.2017.1331481

McCracken, L. M. (2020). Necessary components of psychological treatment for chronic pain: More packages for groups or process-based therapy for individuals? *European Journal of Pain, 24*(6), 1001–1002. https://doi.org/10.1002/ejp.1568

McCracken, L. M., & Keogh, E. (2009). Acceptance, mindfulness, and values-based action may counteract fear and avoidance of emotions in chronic pain: An analysis of anxiety sensitivity. *The Journal of Pain, 10*(4), 408–415. https://doi.org/10.1016/j.jpain.2008.09.015

Mease, P., Arnold, L. M., Choy, E. H., Clauw, D. J., Crofford, L. J., Glass, J. M., et al., OMERACT Fibromyalgia Working Group. (2009). Fibromyalgia syndrome module at OMERACT 9: Domain construct. *Journal of Rheumatology, 36*(10), 2318–2329. https://doi.org/10.3899/jrheum.090367

Merlo, E. M. (2019). Opinion Article: The role of psychological features in chronic diseases, advancements and perspectives. *Mediterranean Journal of Clinical Psychology, 7*(3). https://doi.org/10.6092/2282-1619/2019.7.2341

Miller, R. P., Kori, S. H., & Todd, D. D. (1991). The Tampa scale: A measure of kinisophobia. *The Clinical Journal of Pain, 7*(1), 51. https://journals.lww.com/clinicalpain/Citation/1991/03000/The_Tampa_Scale__a_Measure_of_Kinisophobia.53.aspx.

Moher, D., Hopewell, S., Schulz, K. F., Montori, V., Gøtzsche, P. C., Devereaux, P. J., et al. (2012). CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. *International Journal of Surgery, 10*(1), 28–55. https://doi.org/10.1016/j.ijsu.2011.10.001

Moman, R. N., Dvorkin, J., Pollard, E. M., Wanderman, R., Murad, M. H., Warner, D. O., et al. (2019). A systematic review and meta-analysis of unguided electronic and mobile health technologies for chronic pain-is it time to start prescribing electronic health applications? *Pain medicine (Malden, Mass, 20*(11), 2238–2255. https://doi.org/10.1093/pm/pnz164

Morris, S. B. (2008). Estimating effect sizes from pretest-posttest-control group designs. *Organizational Research Methods, 11*(2), 364–386. https://doi.org/10.1177/1094428106291059

Moseley, L. (2003). Unraveling the barriers to reconceptualization of the problem in chronic pain: The actual and perceived ability of patients and health professionals to understand the neurophysiology. *The Journal of Pain, 4*(4), 184–189. https://doi.org/10.1016/s1526-5900(03)00488-7

Moseley, G. L., & Butler, D. S. (2015). Fifteen years of explaining pain: The past, present, and future. *The Journal of Pain, 16*(9), 807–813. https://doi.org/10.1016/j.jpain.2015.05.005

Moseley, G. L., & Butler, D. S. (2017). *Explain pain supercharged*. NOI. https://www.painsupportjersey.com/media/1084/explain-pain-supercharged-advert.pdf.

Musekamp, G., Gerlich, C., Ehlebracht-Kï Nig, I., Dorn, M., Hï Fter, A., Tomiak, C., et al. (2019). Evaluation of a self-management patient education programme for fibromyalgia-results of a cluster-RCT in inpatient rehabilitation. *Health Education Research, 34*(2), 209–222. https://doi.org/10.1093/her/cyy055

Navarrete, J., García-Salvador, M.Á., Cebolla, A., & Baños, R. (2022). Impact of mindfulness training on Spanish police officers' mental and emotional health: A non-randomized pilot study. *Mindfulness, 13*(3), 695–711.

Okifuji, A., & Hare, B. D. (2010). Management of musculoskeletal pain. In M. H. Ebert, & R. D. Kerns (Eds.), *Behav psychopharmacol pain manag, 286*. Cambridge University Press.

Pardos-Gascón, E. M., Narambuena, L., Leal-Costa, C., & van-der Hofstadt-Román, C. J. (2021). Differential efficacy between cognitive-behavioral therapy and mindfulness-based therapies for chronic pain: Systematic review. *International Journal of Clinical and Health Psychology : IJCHP, 21*(1), Article 100197. https://doi.org/10.1016/j.ijchp.2020.08.001

Pérez-Aranda, A., Andrés-Rodríguez, L., Feliu-Soler, A., Núñez, C., Stephan-Otto, C., Pastor-Mira, M. A., et al. (2019). Clustering a large Spanish sample of patients with fibromyalgia using the fibromyalgia impact questionnaire-revised: Differences in clinical outcomes, economic costs, inflammatory markers, and gray matter volumes. *Pain, 160*(4), 908–921. https://doi.org/10.1097/j.pain.0000000000001468

Pérez-Aranda, A., Feliu-Soler, A., Montero-Marín, J., García-Campayo, J., Andrés-Rodríguez, L., Borràs, X., et al. (2019). A randomized controlled efficacy trial of mindfulness-based stress reduction compared with an active control group and usual care for fibromyalgia: The EUDAIMON study. *Pain, 160*(11), 2508–2523. https://doi.org/10.1097/j.pain.0000000000001655

Perrot, S., & Russell, I. J. (2014). More ubiquitous effects from non-pharmacologic than from pharmacologic treatments for fibromyalgia syndrome: A meta-analysis examining six core symptoms. *European Journal of Pain, 18*(8), 1067–1080. https://doi.org/10.1002/ejp.564

Rivera, J., Alegre, C., Ballina, F. J., Carbonell, J., Carmona, L., Castel, B., et al. (2006). Documento de consenso de la Sociedad Española de Reumatología sobre la fibromialgia. *Reumatología Clínica, 2*(Suppl 1). S55–S66. 10.1016.

Serrat, M., Almirall, M., Musté, M., Sanabria-Mazo, J. P., Feliu-Soler, A., Méndez-Ulrich, J. L., et al. (2020). Effectiveness of a multicomponent treatment for fibromyalgia based on pain neuroscience education, exercise therapy, psychological support, and nature exposure (NAT-FM): A pragmatic randomized controlled trial. *Journal of Clinical Medicine, 9*(10), 3348. https://doi.org/10.3390/jcm9103348

Serrat, M., Coll-Omaña, M., Albajes, K., Solé, S., Almirall, M., Luciano, J. V., et al. (2021). Efficacy of the FIBROWALK multicomponent program moved to a virtual setting for patients with fibromyalgia during the COVID-19 pandemic: A proof-of-Concept RCT performed alongside the state of alarm in Spain. *International Journal of Environmental Research and Public Health, 18*(19), Article 10300. https://doi.org/10.3390/ijerph181910300

Serrat, M., Sanabria-Mazo, J. P., Almirall, M., Musté, M., Feliu-Soler, A., Méndez-Ulrich, J. L., et al. (2021). Effectiveness of a multicomponent treatment based on pain neuroscience education, therapeutic exercise, cognitive behavioral therapy, and mindfulness in patients with fibromyalgia (FIBROWALK study): A randomized controlled trial. *Physical Therapy, 101*(12), pzab200. https://doi.org/10.1093/ptj/pzab200

Serrat, M., Sanabria-Mazo, J. P., García-Troiteiro, E., Fontcuberta, A., Mateo-Canedo, C., Almirall, M., et al. (2020). Efficacy of a multicomponent intervention for fibromyalgia based on pain neuroscience education, exercise therapy, psychological support, and nature exposure (NAT-FM): Study protocol of a randomized controlled trial. *International Journal of Environmental Research and Public Health, 17*(2), 634. https://doi.org/10.3390/ijerph17020634

Siddall, B., Ram, A., Jones, M. D., Booth, J., Perriman, D., & Summers, S. J. (2022). Short-term impact of combining pain neuroscience education with exercise for chronic musculoskeletal pain: A systematic review and meta-analysis. *Pain, 163*(1), e20–e30. https://doi.org/10.1097/j.pain.0000000000002308

Sosa-Reina, M. D., Nunez-Nagy, S., Gallego-Izquierdo, T., Pecos-Martín, D., Monserrat, J., & Álvarez-Mon, M. (2017). Effectiveness of therapeutic exercise in fibromyalgia syndrome: A systematic review and meta-analysis of randomized clinical trials. *BioMed Research International.* , Article 2356346. https://doi.org/10.1155/2017/2356346

Spijkerman, M. P., Pots, W. T., & Bohlmeijer, E. T. (2016). Effectiveness of online mindfulness-based interventions in improving mental health: A review and meta-analysis of randomised controlled trials. *Clinical Psychology Review, 45*, 102–114. https://doi.org/10.1016/j.cpr.2016.03.009

Stegenga, B. T., Nazareth, I., Torres-González, F., Xavier, M., Svab, I., Geerlings, M. I., et al. (2012). Depression, anxiety and physical function: Exploring the strength of causality. *Journal of Epidemiology & Community Health, 66*(7), e25. https://doi.org/10.1136/jech.2010.128371

Talaei-Khoei, M., Fischerauer, S. F., Jha, R., Ring, D., Chen, N., & Vranceanu, A. M. (2018). Bidirectional mediation of depression and pain intensity on their associations with upper extremity physical function. *Journal of Behavioral Medicine, 41*(3), 309–317. https://doi.org/10.1007/s10865-017-9891-6

Thieme, K., Mathys, M., & Turk, D. C. (2017). Evidenced-based guidelines on the treatment of fibromyalgia patients: Are they consistent and if not, why not? Have effective psychological treatments been overlooked? *The Journal of Pain, 18*(7), 747–756. https://doi.org/10.1016/j.jpain.2016.12.006

Turner, J. A., Anderson, M. L., Balderson, B. H., Cook, A. J., Sherman, K. J., & Cherkin, D. C. (2016). Mindfulness-based stress reduction and cognitive behavioral therapy for chronic low back pain: Similar effects on mindfulness, catastrophizing, self-efficacy, and acceptance in a randomized controlled trial. *Pain, 157*(11), 2434–2444. https://doi.org/10.1097/j.pain.0000000000000635

Van Breukelen, G. J. (2006). ANCOVA versus change from baseline: More power in randomized studies, more bias in nonrandomized studies [corrected]. *Journal of Clinical Epidemiology, 59*(9), 920–925. https://doi.org/10.1016/j.jclinepi.2006.02.007

Vlaeyen, J., Crombez, G., & Linton, S. J. (2016). The fear-avoidance model of pain. *Pain, 157*(8), 1588–1589. https://doi.org/10.1097/j.pain.0000000000000574

Ware, J. E., Jr., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Medical Care, 30*(6), 473–483. PMID: 1593914.

Watson, J. A., Ryan, C. G., Cooper, L., Ellington, D., Whittle, R., Lavender, M., et al. (2019). Pain neuroscience education for adults with chronic musculoskeletal pain: A mixed-methods systematic review and meta-analysis. *The Journal of Pain, 20*(10), 1140. https://doi.org/10.1016/j.jpain.2019.02.011. e1–1140.e22.

Wegener, S. T., Castillo, R. C., Haythornthwaite, J., MacKenzie, E. J., Bosse, M. J., & The LEAP Study Group. (2011). Psychological distress mediates the effect of pain on function. *Pain, 152*(6), 1349–1357. https://doi.org/10.1016/j.pain.2011.02.020

Williams, D. A., Cary, M. A., Groner, K. H., Chaplin, W., Glazer, L. J., Rodriguez, A. M., et al. (2002). Improving physical functional status in patients with fibromyalgia: A brief cognitive behavioral intervention. *Journal of Rheumatology, 29*(6), 1280–1286. PMID: 12064847.

Wilson, S., & Cramp, F. (2018). Combining a psychological intervention with physiotherapy: A systematic review to determine the effect on physical function and quality of life for adults with chronic pain. *Physical Therapy Reviews, 23*(3), 214–226. https://doi.org/10.1080/10833196.2018.1483550

Wolfe, F., Clauw, D. J., Fitzcharles, M. A., Goldenberg, D. L., Katz, R. S., Mease, P., et al. (2010). The American College of Rheumatology preliminary diagnostic criteria for fibromyalgia and measurement of symptom severity. *Arthritis Care & Research, 62*(5), 600–610. https://doi.org/10.1002/acr.20140

Wright, A. R., & Gatchel, R. J. (2002). Occupational musculoskeletal pain and disability. In D. C. Turk, & R. J. Gatchel (Eds.), *Psychological approaches to pain management: A practitioner's handbook* (pp. 349–364). Guilford Press.

Zigmond, A. S., & Snaith, R. P. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica, 67*(6), 361–370. https://doi.org/10.1111/j.1600-0447.1983.tb09716