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The Journal of Pain

# Effectiveness of the FIBROWALK Multicomponent Therapy in Online and Outdoor Formats for Fibromyalgia: A Randomized Controlled Trial (The On&Out Study)

--Manuscript Draft--

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| **Abstract:** | This study evaluated the effectiveness of FIBROWALK multicomponent intervention, delivered online (FIBRO-On) or outdoors (FIBRO-Out), compared to treatment as usual (TAU) in reducing fibromyalgia (FM) severity measured by FIQR, which assesses functional impairment, symptom intensity, and overall impact. A total of 225 individuals with FM were randomly assigned to 12 weeks of FIBRO-On (plus TAU), FIBRO-Out (plus TAU), or TAU alone. Assessments were conducted at baseline, mid-intervention (6 weeks), post-intervention (12 weeks), and 6-months (3 months post-intervention). Results from linear mixed-effects models indicated that FIBRO-On ( = -10.68, 95% CI = -15.13, -6.23) and FIBRO-Out ( = -9.91, 95% CI = -14.4, -5.42) were more effective than TAU in reducing FM severity at post-intervention. FIBRO-On ( = -6.02, 95% CI = -10.78, -1.27) was more effective than TAU in reducing FM severity at 6 months, whereas FIBRO-Out showed no such advantage. No significant differences were observed between FIBRO-On and FIBRO-Out for any clinical measure at any time point. Clinically meaningful improvement was observed in 36.3% of FIBRO-On and 37.2% of FIBRO-Out post-intervention and ~20% at follow-up. Reductions in psychological inflexibility and kinesiophobia after the intervention mediated the effects of FIBROWALK on FM severity at 6-month follow-up, supporting the inclusion of acceptance and commitment therapy components in future versions. Low dropout rates, minimal adverse effects, and significant improvements across clinical outcomes highlight the feasibility and effectiveness of both formats. These findings support FIBROWALK, particularly FIBRO-On, as a scalable FM intervention. Future research should optimize long-term outcomes and explore personalized treatment delivery. |

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**Highlights:**

- A three-arm RCT evaluated the effectiveness of the FIBROWALK intervention for fibromyalgia.
- Online and outdoor formats showed short-term benefits in fibromyalgia severity and secondary outcomes.
- Only the online format maintained mid-term improvements in fibromyalgia severity and pain.
- Psychological inflexibility and kinesiophobia mediated treatment effects.
- Results support scalable delivery of online FIBROWALK for fibromyalgia.

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# Effectiveness of the FIBROWALK Multicomponent Therapy in Online and Outdoor Formats for Fibromyalgia: A Randomized Controlled Trial (The On&Out Study)

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## Abstract

This study evaluated the effectiveness of FIBROWALK multicomponent intervention, delivered online (FIBRO-On) or outdoors (FIBRO-Out), compared to treatment as usual (TAU) in reducing fibromyalgia (FM) severity measured by FIQR, which assesses functional impairment, symptom intensity, and overall impact. A total of 225 individuals with FM were randomly assigned to 12 weeks of FIBRO-On (plus TAU), FIBRO-Out (plus TAU), or TAU alone. Assessments were conducted at baseline, mid-intervention (6 weeks), post-intervention (12 weeks), and 6-months (3 months post-intervention). Results from linear mixed-effects models indicated that FIBRO-On ($\beta$ = -10.68, 95% CI = -15.13, -6.23) and FIBRO-Out ($\beta$ = -9.91, 95% CI = -14.4, -5.42) were more effective than TAU in reducing FM severity at post-intervention. FIBRO-On ($\beta$ = -6.02, 95% CI = -10.78, -1.27) was more effective than TAU in reducing FM severity at 6 months, whereas FIBRO-Out showed no such advantage. No significant differences were observed between FIBRO-On and FIBRO-Out for any clinical measure at any time point. Clinically meaningful improvement was observed in 36.3% of FIBRO-On and 37.2% of FIBRO-Out post-intervention and ~20% at follow-up. Reductions in psychological inflexibility and kinesiophobia after the intervention mediated the effects of FIBROWALK on FM severity at 6-month follow-up, supporting the inclusion of acceptance and commitment therapy components in future versions. Low dropout rates, minimal adverse effects, and significant improvements across clinical outcomes highlight the feasibility and effectiveness of both formats. These findings support FIBROWALK, particularly FIBRO-On, as a scalable FM intervention. Future research should optimize long-term outcomes and explore personalized treatment delivery.

**Trial number:** NCT05377567.

**Perspective:**

This study supports the short-term effectiveness of FIBROWALK in both formats, and mid-term reduction of fibromyalgia severity and pain in the online version. Mediation analyses suggest that reductions in psychological inflexibility and kinesiophobia underlie treatment effects. Its feasibility and scalability support potential for broader clinical implementation in fibromyalgia care.

*Keywords*: Fibromyalgia, Multicomponent intervention, FIBROWALK, Online, Outdoor, RCT.

## 1. Introduction

Fibromyalgia (FM) is a syndrome characterized by chronic pain, fatigue, cognitive dysfunction, and sleep disturbances [1,2], often co-occurring with other musculoskeletal and psychiatric conditions. [3–5] Affecting approximately 2% of the general population, FM shows a higher prevalence among women aged 40 to 50 [2,6] and represents a persistent challenge for public healthcare systems worldwide. [7–9]

Currently, there is no curative treatment for FM, but there are pharmacological and non-pharmacological approaches aimed at reducing pain, alleviating psychological symptoms, and improving functioning and quality of life. [2,10] Among these, non-pharmacological strategies such as Pain Science Education (PSE), Cognitive Behavioural Therapy (CBT), mindfulness training, and exercise therapy have demonstrated significant benefits in improving FM symptoms, functionality and quality of life. These approaches often yield broader and more substantial effects compared to pharmacological approaches.[11–18]

Although multicomponent interventions are frequently recommended in clinical guidelines and a recent systematic review and meta-analysis has reported small-to-moderate improvements in pain, function, and psychological outcomes compared with usual care or

minimally active interventions,[19–21] robust studies directly comparing multicomponent programs with intensive unimodal therapies remain scarce and methodologically heterogeneous. Häuser et al. defined multicomponent programs as those that combine at least one educational or psychological intervention with one form of exercise therapy.[22] FIBROWALK, a multicomponent program that integrates PSE, therapeutic physical exercise, CBT, and mindfulness techniques, was initially developed for hospital settings specializing in central sensitivity syndromes, but it has since been adapted to online and outdoor nature-based formats. [20,21,23,24]

In recent years, online and outdoor therapeutic approaches have emerged as effective adaptations of traditional face-to-face indoor interventions for FM, a shift accelerated by the COVID-19 pandemic. Online therapies improve accessibility, reduce healthcare burdens and costs, and extend evidence-based care to those facing barriers to in-person treatment. [25–30]

This study evaluated the effectiveness of the multicomponent FIBROWALK intervention delivered in two formats: an online format (FIBRO-On) and an outdoor format (FIBRO-Out), compared to TAU. Based on prior evidence, [20,21] we hypothesized that both formats would lead to greater clinical improvements than TAU at post-treatment and 6-month follow-up (3 months post-treatment). The outdoor format was expected to yield higher patient satisfaction, greater perceived clinical improvement and better adherence to homework exercises due to greater perceived therapist support, while the online format was anticipated to result in higher session attendance and lower attrition rates due to its flexibility. Improvements in kinesiophobia, pain catastrophizing, psychological inflexibility, and pain-related knowledge, core targets of FIBROWALK, were hypothesized to mediate these effects.

The present study builds on previous [20,21] and recent [31] findings on the short-term effects of these interventions while addressing key methodological challenges common in multicomponent intervention research, such as the lack of active control groups, high drop-out

rates, and inconsistent reporting of treatment fidelity and adverse events.[22,32] For the first time, online and outdoor multicomponent approaches are directly compared in a RCT that includes a larger sample, more comprehensive treatment measures, the involvement of multiple therapists to facilitate generalizability of findings to public health settings, assessment of adverse effects, mid-term follow-up, treatment fidelity evaluation, and mediation analyses to explore the psychological mechanisms underlying sustained clinical improvements. By providing robust evidence on the effectiveness and feasibility of these interventions, this study offers valuable insights to inform decisions on whether FIBROWALK should be integrated into the public healthcare system.

## 2. Methods

### 2.1. Design

The study was designed as a 6-month, randomized controlled trial (RCT) with three treatment arms: FIBRO-On (online) + TAU, FIBRO-Out (outdoor) + TAU, and TAU alone, with the Revised Fibromyalgia Impact Questionnaire (FIQR) as the primary outcome measure. A detailed description of the study protocol can be found elsewhere. [33]

This article reports the clinical effectiveness outcomes from the On&Out project, which was designed to comprehensively evaluate the FIBROWALK interventions from multiple perspectives, including clinical effectiveness, economic impact, and immune-inflammatory effects. To ensure methodological clarity and depth, these aspects have been analyzed separately and presented in different publications. In this regard, a separate article has already examined the biomarker changes associated with the evaluated treatments. [31]

The study was approved by the Ethics Committee of Clinical Investigation of the Hospital Universitari Vall d'Hebron (HUVH; code: PR(AG)99/2022) and was performed following the Declaration of Helsinki. This RCT was registered on ClinicalTrials.gov (NCT05377567) and is reported in accordance with the CONSORT guidelines. [34]

Patients or members of the public were not involved in the design, conduct, or reporting of this study. However, patient and public involvement was planned for the dissemination of the main results to ensure that the findings were communicated in an accessible and meaningful manner.

### 2.2. Sample Size

The required sample size was estimated to be $n$ = 64 participants per group, assuming a moderate effect size (Cohen's $d$ = 0.5) for the difference between either of the active arms and the control group on the primary variable (i.e., FIQR score) at post-intervention, with an alpha set at 0.05 and 1-b power of 0.80. The Cohen's d = 0.5 effect size aligns with the average effect size observed in previous studies evaluating multicomponent interventions in FM vs. a control group. [17] Previous RCTs evaluating the FIBROWALK intervention indicated effect sizes for the primary outcome of FM severity $d$ = 0.4 [24] and $d$ = 1.83. [20] Considering a dropout rate of 20%–25% —based on previous FM and FIBROWALK studies —the final estimated sample size was adjusted to 75 individuals per arm.[21]

### 2.3. Randomization

After completing the initial assessment, participants were assigned unique alphanumeric codes and randomly allocated (1:1:1 ratio) using a computer-generated randomization list based on block randomization with randomly varying block sizes to one of three groups: TAU only, TAU + Online FIBROWALK, or TAU + Outdoor FIBROWALK. Allocation was performed by a researcher not involved in the recruitment process.

### 2.4. Participants

Inclusion criteria were participants aged 18-65 years, diagnosed with FM using the American College of Rheumatology (ACR) 2010/2011 classification criteria,[35] and fluent in Spanish. Exclusion criteria included receiving psychological treatment currently or within the last year, comorbid severe mental disorder (e.g., schizophrenia) or other terminal clinical conditions,

scheduled treatments that might interrupt study follow-up, or anticipation that the subject would be unable to participate consistently in the weekly FIBROWALK treatment sessions. The study protocol included an exclusion criterion regarding participants involved in litigation with the healthcare system to obtain a permanent leave of absence. However, some individuals awaiting a decision on such leave were nevertheless enrolled in the study, as required by the hospital administration.

### 2.5. Recruitment

The study was conducted in two consecutive periods between September 2022 and July 2023, with six study groups (two TAU, two FIBRO-Out, and two FIBRO-On) running in parallel in each period. Each group included 18–20 participants, with a total sample size of 75. Specifically, data were collected in September 2022 and February 2023 (baseline assessments), October 2022 and March 2023 (mid-intervention assessments), May 2022 and April 2023 (post-intervention assessments), and February 2023 and July 2023 (follow-up assessments).

### 2.6. Procedure

Participant recruitment was conducted at the Central Sensitivity Syndromes Specialized Unit (CSSSU) at Vall d'Hebron Hospital in Barcelona, Spain, through two methods: consecutive recruitment during consultations by CSSSU rheumatologists and screening a list of patients who had contacted the unit within the previous six months. Telephone screenings were performed by the clinicians involved in the project (MA and MS), who invited individuals meeting the study's selection criteria to participate. All patients had been previously diagnosed with FM by a medical doctor from the unit.

Participants first provided verbal consent during an initial phone screening. Those who met preliminary eligibility criteria were then invited to participate and provided written informed consent prior to the baseline assessment. They were informed of their right to withdraw from the study at any time while continuing to receive their usual treatment if desired.

Participants agreeing to participate completed an online demographic questionnaire and a baseline test battery. Both outcome assessment and data analysis were conducted blind to the condition (i.e., incorporating both blinded outcome assessment and a blinded data analyst), ensuring unbiased evaluation and interpretation. The study primarily relied on standardized, validated patient-reported outcome measures, while ad hoc items were used exclusively to assess treatment fidelity, adverse events, and self-reported physical activity.

After baseline assessments, participants were randomly assigned to the study arms by a technician who was not involved in the assessments or analyses, as described in the CONSORT reporting guidelines. [34] Participants were notified of their group allocation via email by administrative personnel. Allocation was concealed in an encrypted file stored on a password-protected computer in the clinical trials supervisor's office. As is common in non-pharmacological trials, neither participants nor therapists were blinded to treatment allocation. Following randomization, research assistants, coordinated follow-up clinical assessments at three time points: six weeks (mid-intervention), 12 weeks (post-intervention), and 6 months after the baseline assessment. All assessments were conducted online, with telephone support available if needed. Research assistants were blinded to group allocation to minimize potential bias during data collection and participant interaction. They were also available to support participants who had questions while completing the questionnaires. If a participant did not respond, they were contacted to check for difficulties or doubts.

## 2.7. Interventions

### *2.7.1. Treatment as usual (TAU)*

Although there is no gold-standard treatment for FM, the TAU for FM in the Spanish public healthcare context typically focuses on a pharmacological approach tailored to each patient's symptomatology profile and is usually combined with guidelines that promote aerobic physical exercise adapted to the individual's limitations. At the conclusion of the study, participants in

the TAU-only condition were offered the opportunity to enrol in either the FIBRO-On or FIBRO-Out program, according to their preference.

#### *2.7.2. FIBRO-On*

The FIBRO-On program, developed during the COVID-19 lockdown, has been implemented at the Central Sensitivity Syndromes Specialized Unit of the HUVH. [21,23] It replicates all components of the in-person FIBROWALK program over a 12-week period, delivering 60-minute therapeutic video and slide presentations that include pain neuroscience education (PSE), physical exercise, cognitive behavioural therapy (CBT), and mindfulness techniques (for details [36]) Each week, participants received a video link uploaded to a YouTube account, accompanied by prescribed exercises, requiring approximately 120 minutes per session (60 minutes of video plus 60 minutes of exercises at home). Participants who were unable to watch the video during a given treatment week were allowed a one-time extension of an additional 1–2 weeks to complete that specific video. For instance, if a participant missed the video in week 3, they could still watch it during week 4 or, at the latest, by week 5, alongside the videos scheduled for those weeks.

The program was delivered by MS, a physiotherapist and health psychologist with over 20 years of experience in FM treatment, who also developed the FIBROWALK program. While the weekly sessions did not involve direct therapeutic interaction, participants were informed they could contact MS via email with questions or concerns regarding the therapy content or its implementation. Therapist contact was minimal, limited to participant-initiated inquiries, and primarily related to minor technical issues (e.g., video access) rather than therapeutic support, with contact frequency not systematically recorded. Video completion and comprehension were assessed through brief post-session questionnaires (5–10 items), with correct responses used to confirm attendance.

### *2.7.3. FIBRO-Out*

Participants in the FIBRO-Out group received a content-equivalent version of the FIBRO-On program [20] delivered in an outdoor setting at "Parc del Cargol" (Location: 41.43028486467208, 2.13941336194866), alongside TAU. The intervention incorporated pain neuroscience education (PSE), therapeutic physical exercise, CBT, and mindfulness training, conducted in groups of 18–20 participants. Consistent with recommendations for RCTs evaluating non-pharmacological therapies,[37] multiple therapists delivered the intervention, including three health psychologists and three physiotherapists. This approach enhanced generalizability and minimized therapist-specific biases, ensuring the evaluation reflected the intervention's effectiveness rather than individual therapist expertise.

Each group session, spanning 12 weeks, was co-led by a psychologist and a physiotherapist. The physiotherapist conducted the first hour (PSE and physical exercise), while the psychologist led the second hour (CBT and mindfulness). All therapists had prior professional experience with physiotherapy or CBT for FM or chronic pain. Prior to the trial, therapists completed an 8-hour training session covering the core components and structure of FIBROWALK[36] (see the study protocol for a detailed description[33]).

Treatment fidelity in the FIBRO-Out arm was assessed using the FIBROWALK Fidelity Measure (FFM). Research assistants, trained under MS's supervision, participated in the same 8-hour preparation, completed the FIBRO-On program as users, and followed the FIBROWALK manual. They attended at least three sessions per therapist to evaluate adherence to the protocol, ensuring fidelity assessments adhered to established guidelines (see *Supplementary File 1*).

## 2.8. Study Measures

### *2.8.1. Sociodemographic and Clinical Data*

Participants completed a baseline questionnaire that collected sociodemographic (i.e., gender, age, body mass index, marital status, living arrangement, educational level, and employment status) and clinical data (i.e., years since FM diagnosis, degree of disability, comorbid medical/psychiatric conditions, and current medications).

The following outcome and secondary measures were administered at baseline, 6 weeks (mid-intervention), post-intervention, and 6-month follow-up (3 months post-treatment).

### *2.8.2. Primary Clinical Outcome*

The ***Revised Fibromyalgia Impact Questionnaire*** (FIQR [38]; Spanish version [39]) is designed to measure FM severity by evaluating functional impairment, symptom intensity and overall impact in individuals with FM over the past week. It consists of 21 items divided into three different dimensions: physical dysfunction (9 items), overall impact of FM (2 items), and severity of core FM symptoms (10 items). The items are rated using an 11-point numerical rating scale (from 0 to 10) to determine the level of impairment, with 10 indicating higher impairment. Total FIQR scores were calculated by summing the three domain scores: functional domain (sum of 9 items divided by 3), overall impact (2 items summed directly), and symptoms (sum of 10 items divided by 2), and the total score ranges from 0 to 100, with higher values indicating greater FM severity. The Spanish version of the FIQR has excellent internal consistency (Cronbach's $\alpha$ = 0.91–0.95 [39]).

### *2.8.3. Secondary Clinical Outcomes*

The ***Numerical Rating Scale for Pain*** (NRS-Pain [40]) is one of the most used measures to evaluate pain intensity [41]. Participants rated their pain intensity during the past week on an 11-point numerical scale ranging from 0 (*No pain*) to 10 (*Unbearable pain*). Higher scores indicate higher levels of pain intensity.

The ***Numerical Rating Scale for Fatigue*** (NRS-Fatigue [42]) is a self-reported measure of fatigue and energy during the last week on an 11-point numerical scale ranging from 0 (*lots of energy*) to 10 (*no energy*), where higher scores indicate greater fatigue.

Although the protocol[33] originally listed VAS measures, Numeric Rating Scales (0–10) were used for pain and fatigue due to their ease of online administration, greater feasibility, and strong psychometric equivalence to VAS.

The ***Hospital Anxiety and Depression Scale*** (HADS [43]; Spanish version [44]) assesses anxiety and depression symptoms in two separate subscales. Each subscale consists of 7 items, with responses recorded on a 4-point Likert scale. Total subscale scores range from 0 to 21, with higher scores indicating more severe symptoms. The Spanish version of the HADS has demonstrated adequate internal consistency for anxiety ($\alpha = 0.83$) and depression ($\alpha = 0.87$) subscales in FM. [44]

The ***Perceived Stress Scale, 4-item version*** (PSS-4 [45]; Spanish version [46]) assesses one's level of perceived stress over the last month. Responses are recorded on a 5-point Likert scale ranging from 0 (*never*) to 4 (*very often*). The total score ranges from 0 to 16, with higher scores indicating a higher level of perceived stress. The Spanish 4-item version of the PSS demonstrates acceptable internal consistency ($\alpha = 0.77$ [46])

The ***9-item version of the Central Sensitization Inventory*** (CSI [47,48]) assesses central sensitization symptoms. On CSI Part A, items are rated on a Likert scale from 0 (*never*) to 4 (*always*), where higher scores indicate a higher presence of central sensitization symptoms. CSI Part B asks patients to indicate if they have been diagnosed with a list of specific disorders related to central sensitization. The CSI-9 has adequate internal consistency ($\alpha = 0.80$ [48])

The ***Physical Function Subscale of the Short Form-36 Health Survey*** (SF-36 PF [49]; Spanish version [49]) assesses one's perceived level of functional limitations in performing activities of daily living. The SF-PF comprises 10 items, with responses on a 3-point Likert

scale ranging from 0 (*yes, limited a lot*) to 3 (*no, not limited at all*). Following recommended scoring procedures, SF-36 PF scores were transformed to a 0–100 scale with the higher score indicating better physical health. The Spanish version of the SF-PF has demonstrated excellent internal consistency ($\alpha$ = 0.94; [49]).

The ***Pittsburgh Sleep Quality Index***, ***brief version*** (PSQI [50]; Spanish brief version [51]) is a self-report instrument widely used in research and clinical practice to evaluate sleep quality. The brief version of the PSQI includes six items about sleep quality. The total scores range from 0 to 16, with higher scores indicating worse sleep quality. The Spanish version of the B-PSQI has demonstrated adequate psychometric properties ($\alpha$ = 0.79 [51]).

The ***Multidimensional Inventory of Subjective Cognitive Impairment*** (MISCI [52]; Spanish version [53]) assesses perceived cognitive dysfunction (i.e., mental clarity, memory, attention/concentration, executive functioning, and language) in individuals with FM over the past week. The MISCI comprises 10 items which are rated on a 5-point Likert scale from 1 (*not at all or never*) to 5 (*very much or always*). Lower total scores indicate higher cognitive dysfunction. The Spanish version of the MISCI has excellent internal reliability ($\alpha$ = 0.91; [53]).

#### *2.8.4. Potential Mediators*

We assessed theoretically derived mediators to investigate potential mechanisms of change targeted by FIBROWALK (i.e., CBT, therapeutic physical exercise, mindfulness training, and PSE), as described below.

The ***Tampa Scale for Kinesiophobia*** (TSK-11 [54]; Spanish version [55]) assesses fear of pain and movement. The scale comprises 11 items which are rated on a 4-point Likert scale from 1 (*strongly disagree*) to 4 (*strongly agree*). The total score ranges from 11 to 44, where higher scores indicate a greater fear of pain and movement. The Spanish version of the TSK has shown good internal consistency ($\alpha$ = 0.79 [55]).

The ***Pain Catastrophising Scale*** (PCS [56]; Spanish version [57]) measures catastrophic thoughts related to pain. It consists of 13 items grouped into three dimensions: rumination, magnification, and helplessness. Responses are rated on a 5-point Likert scale from 0 (*not at all*) to 4 (*all the time*), with total scores ranging from 0 to 52, where higher scores indicate greater levels of pain catastrophizing. The Spanish version demonstrates adequate internal consistency ($\alpha = 0.79$ [57]).

The ***Psychological Inflexibility in Pain Scale*** (PIPS [58]; Spanish version [59]) is a 12-item scale that measures psychological inflexibility in individuals who experience pain to be applied in third-wave CBT (e.g., mindfulness). The PIPS comprises two factors: avoidance and cognitive fusion with pain. Respondents are asked to rate each item on a 7-point scale ranging from 1 (*never true*) to 7 (*always true*). A higher score indicates a greater level of psychological inflexibility. The Spanish version of the PIPS has shown good internal consistency ($\alpha = 0.90$ [59]).

The ***Revised Neurophysiology of Pain Questionnaire*** (R-NPQ [60]) assesses a patient's knowledge of pain biology. It comprises 13 statements answered as *True, False,* or *I do not know*. The score of the R-NPQ is calculated as the sum of all correct items, which can range from 0 to 13. The R-NPQ has excellent internal consistency in Spanish samples ($\alpha = 0.87–0.92$ [60]).

#### *2.8.5. Other Study Measures*

The ***Patient's Global Impression of Change*** and the ***Patient's Specific Impression of Change*** (PGIC and PSIC [61]) assess one's self-perceived meaningful clinical change. This questionnaire was administered post-intervention. The PGIC focuses on general change (1 item), while the PSIC examines specific domains, including physical and social functioning, work-related activities, mood, and pain (5 items). The responses are indicated on a 7-point Likert scale that ranges from 1 (*much better*) to 7 *(much worse*).

The ***Adapted version of the Credibility/Expectancy Questionnaire*** (CEQ [62]) consists of 6 items designed to assess treatment expectancy and credibility. It is administered both pre-intervention (as an expectancy questionnaire) and post-intervention (as an opinion questionnaire). Credibility is evaluated through questions assessing the perceived logic, utility, and confidence in recommending the treatment to someone with a similar condition (e.g., *To what extent does this therapy seem logical to you?*). Expectancy measures focus on the patient's anticipation of improvement, belief in the treatment's effectiveness, and confidence in symptom reduction (e.g., *To what extent do you think this treatment will be useful in your case?*). Post-treatment opinions are assessed using the same items in the past tense. Responses are rated on a scale from 0 (*not at all*) to 10 (*very much*), and mean scores are calculated for each questionnaire, with higher scores indicating more positive credibility/expectancy or better opinions. The CEQ has demonstrated adequate internal consistency ($\alpha = 0.84–0.85$) in previous research involving a similar clinical sample. [14]

***Adverse effects*** were assessed retrospectively at post-treatment using a custom single-item question developed for this study (i.e., *Have you experienced, during the treatment you have received over the past 3 months, any unwanted symptoms that you believe may be directly or indirectly associated with this treatment?*). If the answer was affirmative, they were requested to specify (open-field question) the adverse effects they were experiencing. No prospective monitoring was conducted, which is acknowledged as a limitation.

To assess ***adherence to homework exercises*** in the FIBRO-On and FIBRO-Out programs, participants completed an ad hoc questionnaire about their personal practice log for weekly psychotherapeutic and therapeutic physical exercise homework (i.e., breathing, relaxation, mindfulness, stretching, and strength exercises). Adherence to the recommended therapeutic practices since completing the FIBROWALK intervention was retrospectively evaluated at the 6-month follow-up using the same ad hoc questionnaire. An additional item

was also administered (at post- and follow-up assessments) to assess perceived compromise with personal homework practices (i.e., *If you had to rate your level of commitment to completing the proposed therapeutic tasks/homework on a scale from 0—unable to complete almost any of the recommended tasks—to 10—able to complete nearly all of them—what score would you give yourself?*).

To assess ***treatment fidelity to the FIBROWALK protocol*** in the FIBRO-Out arm, an ad hoc measure entitled fidelity measure (FFM) was administered at the end of the treatment by research assistants, who were also clinicians trained in FIBROWALK (for a overview of the FFM, see *Supplementary File 1*). The FFM included a checklist based on predefined intervention components to assess whether the intervention had been properly delivered, in order to verify its quality according to established standards. This measure evaluated therapists' fidelity to the FIBROWALK principles, protocols, and prescribed methods, and consisted of five sections: general organization of the therapy (3 items), therapist knowledge (2 items), personal skills (4 items), therapy-related skills (7 items), and group management (3 items). Each of the 20 items was rated on a 5-point Likert scale, ranging from 0 (*not met*) to 4 (*fully met*). A total score between 0 and 20 was calculated by averaging the items in each section and then summing them, with higher scores indicating greater treatment fidelity. Several sessions were evaluated at the end of the intervention, globally at the conclusion of the full program.

### 2.9. Statistical Analyses

Analyses were conducted using SPSS v25 for all statistical tests, except for the mediation analysis, which was performed using *Lavaan* package in R.[63] The primary between-group analysis for assessing treatment effects was conducted following an intention-to-treat (ITT) approach[64], using the FIQR total score as a continuous variable. Secondary clinical measures were also analysed under this approach. In our study, the primary endpoint was reduction in FM severity (as measured by the FIQR) from baseline to post-intervention. Given the low

dropout rates across all groups and the absence of significant differences in dropout reasons (see study flowchart in Figure 1), missing data were assumed to be missing at random. Linear mixed-effects models were employed, applying restricted maximum likelihood estimation to account for the correlation between repeated measures within individuals.

The estimated coefficients (B) and 95% confidence intervals (95% CIs) for the time x group interaction were calculated at mid-treatment, post-treatment, and 6-month follow-up. Pairwise effect sizes (Cohen's *d*) were reported using the pooled baseline *SD* to adjust pre–post differences and estimate population-level effects. Effect sizes were interpreted as small (0.20), medium (0.50), and large (0.80). To adjust for multiple comparisons, the Benjamini–Hochberg correction was applied, assigning local significance levels based on ordered *p*-values. [65] We reported the original *p*-values, and explicitly indicated in the text and corresponding tables when a result was no longer significant after correction. Additionally, per-protocol analyses (PPA), including only participants who attended at least 75% of the sessions (i.e., 9 out of 12), were conducted to examine the robustness of the findings. To improve clarity in presenting the main findings of this study, and considering their complementary nature, the per-protocol analyses are reported in *Supplementary File 2* and detailed in *Supplementary Table 1* and *Supplementary Table 2.*

To evaluate the clinical significance of changes in the primary outcome (FIQR), we dichotomized participants into responders and non-responders using a cutoff criterion of ≥20% reduction in the total FIQR score from baseline to post-intervention or follow-up, based on the criterion developed with the original FIQ.[38] To date, the threshold for a minimal clinical important difference (MCID) for the FIQR questionnaire has not been determined, so this was a pragmatic decision based on previous studies with the FIQR that have used this same criterion. [14,20,21,23,24,66]

This classification was assessed both post-intervention and at follow-up. Additionally, the number needed to treat (NNT) was calculated for FIBRO-On and FIBRO-Out compared to TAU. The NNT represents the estimated number of patients who must receive the proposed treatment (e.g., FIBRO-On or FIBRO-Out) instead of the control (TAU) for one additional patient to benefit. In clinical trials, an NNT below 10 is typically considered indicative of a clinically meaningful treatment, though higher values may still be relevant in complex conditions with limited therapeutic options. [67] Corresponding 95% confidence intervals (CIs) were computed for each NNT estimate. Using the same responder/non-responder classification, baseline sociodemographic and clinical characteristics, as well as treatment expectancies and adherence variables, were compared through t-tests and $\chi^2$ tests. Since the NNT calculations and comparisons between treatment responders and non-responders are not central to the main goals of the study, these results have been moved to *Supplementary File 2*, where they can be consulted in detail.

PGIC and PSIC were analysed using the $\chi^2$ test with continuity correction, while treatment expectancies and opinions at post-intervention (CEQ) were compared using t-tests. A 5% significance level was applied in all two-tailed tests.

A mediation analysis was conducted using the *Lavaan* package in R [63], which allows for path analysis based on structural equation modelling (SEM). We examined whether changes in potential mediators from pre to post-treatment (i.e., PIPS, R-NPQ, PCS, and TSK) mediated the effects of FIBROWALK on FIQR at the 6-month follow-up. A single outcome model was specified in *Lavaan*, [63] estimating the following paths, with Maximum Likelihood (ML):

1. The effect of the treatment group (FIBROWALK vs. TAU) on each potential mediator at post-intervention.
2. The effect of each mediator on FIQR at the 6-month follow-up.

3. Baseline scores of each potential mediator were examined in relation to both post-intervention and 6-month follow-up scores.
4. The direct effect of the treatment group on FIQR at the 6-month follow-up.

Indirect effects (axb) and total effects (direct effect [c] + indirect effect [axb]) were computed, with 95% bootstrap confidence intervals (CIs) generated using 5000 bootstrap samples. Indirect effects were considered significant if the CIs did not include zero. [68] To facilitate interpretation of the relative contribution of each mediator, we also calculated the proportion of each specific indirect effect relative to the sum of the absolute values of all specific indirect effects. These proportions serve to illustrate the distribution of mediated effects across pathways and should not be interpreted as a decomposition of the total treatment effect.

## 3. Results

### 3.1. Participants Flow and Study Compliance

From the 298 screened participants, 225 met inclusion criteria and were randomized into three study arms, with 75 patients per arm (see Flowchart in Figure 1). For the 6-week, post-intervention, and 6-month follow-up, the attrition rates were (respectively): 5.3%, 10.7%, and 16% in the FIBRO-On group; 10.7%, 16%, and 20% in the FIBRO-Out group; and 2.7%, 2.7% and 1.3% in the TAU group. The chi-square test revealed significant between-group differences in rates, both at post-intervention ($\chi^2(2, N = 225) = 7.66$, $p = 0.022$) and at the 6-month follow-up ($\chi^2(2, N = 225) = 13.3$, $p = 0.001$). Notably, both FIBROWALK intervention arms exhibited higher attrition rates compared to TAU, although the differences between the two intervention formats were not statistically significant ($p > 0.05$). Only minor baseline differences were observed between participants who completed the study assessments and those who did not (see *Supplementary File 2*).

Due to the outdoor nature of the FIBRO-Out condition, some sessions had to be relocated indoors to a room within the hospital due to adverse weather. Consequently, the number of sessions conducted outdoors in the four subgroups of FIBRO-Out were as follows: 9 out of 12 sessions (75%), 10 out of 12 sessions (83.3%), 8 out of 12 sessions (66.7%), and 6 out of 12 sessions (50%).

### 3.2. Baseline Data

Table 1 shows the subjects' baseline demographics and clinical characteristics grouped by study arm. Most participants were middle-aged married women who had at least a primary or secondary education. Around half of the sample were employed at the beginning of the study. Overall, participants exhibited elevated FM severity, accompanied by a high prevalence of comorbidities. The most frequently reported conditions included anxiety, depression, chronic fatigue syndrome, and osteoarthritis. Table 2 shows the means and *SD*s for primary and secondary clinical outcomes in each study arm. To improve the readability of the article, results from the 6-week assessment are presented in Tables 2 and 3 but are not discussed in the results section.

### 3.3. Effects on the Primary Outcome

Linear mixed model results for between-group analyses are shown in Table 2. Both FIBRO-On and FIBRO-Out reduced FM severity (FIQR) compared to TAU at post-intervention (FIBRO-On: $\beta$ = -10.68, 95% CI = -15.13 to -6.23, $d$ = -1; FIBRO-Out: $\beta$ = -9.91, 95% CI = -14.4 to -5.42, $d$ = -0.92). However, only the FIBRO-On was more effective than TAU at the follow-up ($\beta$ = -6.02, 95% CI = -10.78 to -1.27, $d$ = -0.56). No significant differences were observed between the FIBRO-On and FIBRO-Out groups regarding FM severity at any time points evaluated in the study.

At post-treatment, 36.5% of FIBRO-Out participants, 37.3% of FIBRO-On participants, and 8.2% of TAU participants achieved a ≥ 20% reduction in FIQR scores,

qualifying as treatment responders. At the 6-month follow-up, the responder rates were 20% for FIBRO-Out, 23.8% for FIBRO-On, and 12.2% for TAU.

The percentage of individuals who showed clinical deterioration (i.e., a 20% increase in FIQR scores) was assessed at post-treatment and follow-up. At post-treatment, 25.4% of FIBRO-Out participants, 23.9% of FIBRO-On participants, and 49.3% of TAU participants demonstrated clinical deterioration. At the 6-month follow-up, the rates were 35% for FIBRO-Out, 23.8% for FIBRO-On, and 43.2% for TAU.

### 3.4. Effects on Secondary Outcomes

Linear mixed model results for between-group analyses for secondary outcomes are shown in Table 2. At post-intervention, there was a significant difference in pain reduction in the FIBRO-On ($\beta$ = -0.94, 95% CI = -1.54 to -0.35, $d$ = -0.68) and FIBRO-Out ($\beta$ = -1.12, 95% CI = -1.72 to -0.52, $d$ = -0.81) groups compared to TAU. Additionally, FIBRO-On and FIBRO-Out showed more fatigue reduction than TAU (FIBRO-On: $\beta$ = -0.98, 95% CI = -1.86 to -0.10, $d$ = -0.50; FIBRO-Out: $\beta$ = -1.10, 95% CI = -1.99 to -0.21, $d$ = -0.56). FIBRO-On and FIBRO-Out also demonstrated a significant anxiety reduction compared to TAU ($\beta$ = -1.31, 95% CI = -2.39 to -0.23, $d$ = -0.51; and ($\beta$ = -1.09, 95% CI = -2.19 to 0, $d$ = -0.50, respectively). For the depression outcome, both FIBRO-On ($\beta$ = -2.00, 95% CI = -3.12 to -0.89, $d$ = -0.77) and FIBRO-Out ($\beta$ = -1.63, 95% CI = -2.75 to -0.51, $d$ = -0.62) were more effective than TAU. FIBRO-On also demonstrated a significant improvement over TAU in central sensitization symptoms ($\beta$ = -2.53, 95% CI = -4.24 to -0.83, $d$ = -0.22). In terms of improvements in quality of sleep, FIBRO-On and FIBRO-Out were superior to TAU (FIBRO-On: $\beta$ = -1.38, 95% CI = -2.37 to -0.39, $d$ = -0.64; FIBRO-Out: $\beta$ = -1.00, 95% CI = -2.98 to -0.03, $d$ = -0.47; p-value after Benjamini–Hochberg correction = 0.07). Improvements in perceived cognitive dysfunction were also observed in FIBRO-On ($\beta$ = 4.41, 95% CI = 2.28 to 6.53, $d$ = 0.87) and FIBRO-Out ($\beta$ = 3.10, 95% CI = 0.96 to 5.24, $d$ = 0.61), compared to TAU.

At 6 months follow-up, the effectiveness of FIBRO-On compared to TAU in pain intensity reduction remained significant ($\beta$ = -0.69, 95% CI = -1.32 to -0.06, $d$ = -0.50). No other significant effects emerged when comparing FIBRO-On or FIBRO-Out to TAU (all $p$ > 0.05).

No significant differences were observed between FIBRO-On and FIBRO-Out for any secondary outcomes. Furthermore, there were no significant differences between the three study arms in stress and physical function at any assessment point.

### 3.5. Effects on Potential Mediators

At post-intervention, both FIBRO-On and FIBRO-Out continued to show superior effects to TAU in reducing kinesiophobia (FIBRO-On: $\beta$ = -6.31, 95% CI = -8.31 to -4.31, $d$ = -1.31; FIBRO-Out: $\beta$ = -5.02, 95% CI = -7.04 to -3.01, $d$ = -1.04), reducing catastrophizing (FIBRO-On: $\beta$ = -6.58, 95% CI = -10.33 to -2.84, $d$ = -0.73; FIBRO-Out: $\beta$ = -5.97, 95% CI = -9.75 to -2.20, $d$ = -0.66), reducing psychological inflexibility (FIBRO-Out: $\beta$ = -9.74, 95% CI = -14.65 to -4.83, $d$ = -0.85; and FIBRO-On: $\beta$ = -9.36, 95% CI = -14.23 to -4.50, $d$ = -0.82), and increasing pain knowledge (FIBRO-On: $\beta$ = 2.85, 95% CI = 2.05 to 3.66, $d$ = 1.50; FIBRO-Out: $\beta$ = 3.69, 95% CI = 2.89 to 4.50, $d$ = 1.94). Regarding pain knowledge, there was a significant difference between the FIBRO-On and FIBRO-Out groups ($\beta$ = 0.84, 95% CI = 0.02 to 1.66, $d$ = -0.44), with FIBRO-Out showing a more favourable effect; $p$-value after applying the Benjamini-Hochberg correction = 0.17).

At 6-months follow-up, the improvements of both FIBRO-On and FIBRO-Out compared to TAU persisted in reducing kinesiophobia (FIBRO-On: $\beta$ = -4.68, 95% CI = -6.82 to -2.55, $d$ = -0.97; FIBRO-Out: $\beta$ = -3.62, 95% CI = -5.77 to -1.46, $d$ = -0.75), reducing pain catastrophizing (FIBRO-On: $\beta$ = -6.49, 95% CI = -10.49 to -2.50, $d$ = -0.72; FIBRO-Out: $\beta$ = -4.58, 95% CI = -8.61 to -0.56, $d$ = -0.51), reducing psychological inflexibility (only in FIBRO-out: $\beta$ = 6.63, 95% CI = -11.82 to -1.45, $d$ = -0.58), and increasing pain knowledge (FIBRO-

On: $\beta$ = 2.13, 95% CI = 1.28 to 2.98, $d$ = 1.12; FIBRO-Out: $\beta$ = 2.27, 95% CI = 2.19 to 3.91, $d$ = 1.60). Regarding pain knowledge, there was a significant difference between the FIBRO-On and FIBRO-Out groups ($\beta$ = 0.92, 95% CI = 0.04 to 1.79, $d$ = -0.49), favouring FIBRO-Out ($p$-value after applying the Benjamini-Hochberg correction= 0.16). Details on the effects of interventions on potential mediators are displayed in Table 3.

### 3.6. Other Study Measures

#### *3.6.1. Patient Impression of Change*

The PGIC results (overall health) showed that 6 participants in the FIBRO-On group (8%) felt "much improved", 20 (26.7%) reported they "minimally improved", 33 (44%) indicated "no change", 4 (5.3%) reported feeling "minimally worse", 3 (4%) feeling "much worse", and 1 (1.3%) reported feeling "very much worse". 4 participants in the FIBRO-Out group (5.3%) indicated they had "much improved", 34 (45.3%) "minimally improved", 23 (30.7%) indicated "no change", 1 (1.3%) indicated feeling "minimally worse", and 3 (4%) "much worse". None of the participants indicated feeling "very much worse". No participant in any arm indicated a "very much improved" overall health. *T*-tests indicated a significant difference in favour of FIBRO-Out for the PGIC ($p$< 0.05). Similar results were also obtained for PSIC items, with a significant difference in the perceived improvement in work-related activities in favour of the FIBRO-Out group (see *Supplementary Table 3*).

#### *3.6.2. Treatment Expectancies/Credibility*

The average score on the expectancies/credibility questionnaire was higher in FIBRO-Out ($M$ = 8.25 -out of 10-; $SD$ = 1.24) compared to FIBRO-On ($M$ = 7.43; $SD$ = 2.00), and this difference was found to be statistically significant, $t$(123.213) = 3.04, $p$ = 0.003. Specifically, FIBRO-Out was perceived as very logical ($M$ = 8.32; $SD$ = 1.53) and expected to be satisfactory ($M$ = 8.52; $SD$ = 1.38), recommendable ($M$ = 8.40; $SD$ = 1.67), useful for treating other problems ($M$ = 8.01; $SD$ = 1.92), useful in the personal case ($M$ = 7.85; $SD$ = 1.96) and non-

aversive (*M* = 7.81; *SD* = 3.11). All scores, except for the items 'useful in the personal case' and 'non-aversive,' were significantly higher compared to FIBRO-On, although the latter also received good scores for being logical (*M* = 7.29; *SD* = 2.44), satisfactory (*M* = 7.67; *SD* = 2.13), recommendable (*M* = 7.48; *SD* = 2.62), useful for treating other problems (*M* = 7.03; *SD* = 2.69), useful in the personal case (*M* = 7.17; *SD* = 2.29) and non-aversive (*M* = 7.45; *SD* = 2.83).

#### *3.6.3. Patients' Opinion*

At post-treatment, the overall mean opinion about the treatment interventions was slightly better in the FIBRO-Out arm compared to FIBRO-On, although the difference was not statistically significant ($t(128) = 1{,}84$, $p = 0.068$). Specifically, FIBRO-Out was rated as very logical (*M* = 8.37; *SD* = 1.72), satisfactory (*M* = 8.14; *SD* = 1.90), recommendable (*M* = 8.81; *SD* = 1.83), useful for treating other problems (*M* = 8.30; *SD* = 1.93), useful in the personal case (*M* = 7.32; *SD* = 2.38), and non-aversive (*M* = 7.68; *SD* = 3.21). FIBRO-On also received good scores in general, for being logical (*M* = 7.81; *SD* = 2.34), satisfactory (*M* = 7.45; *SD* = 2.47), recommendable (*M* = 8.13; *SD* = 2.37), useful for treating other problems (*M* = 7.69; *SD* = 2.54), useful in the personal case (*M* = 6.46; *SD* = 2.93), and non-aversive (*M* = 7.48; *SD* = 2.85).

#### *3.6.4. Patients' Treatment Adherence*

There was a statistically significant difference in the mean number of sessions attended between the two intervention groups. Out of the 12 sessions, the mean number of sessions attended by the FIBRO-On group was 10.63 (*SD* = 3.12), which was higher than that compared to that of the FIBRO-Out group, with a mean of 8.88 (*SD* = 3.31); $t(148) = -3.32$, $p = 0.001$, $d = 0.54$.

The FIBRO-Out group showed a significantly higher ($p = 0.015$) mean weekly practice for homework exercises *during* the intervention compared to the FIBRO-On group (4.23 days

per week -*SD* = 1.58- vs 3.54 -*SD* = 1.62- in FIBRO-On). Specifically, the FIBRO-Out group reported a mean weekly practice of 5.10 days (*SD* = 1.97) for breathing, 4.33 (*SD* = 1.98) for relaxation, 3.67 (*SD* = 2.16) for mindfulness, 4.62 (*SD* = 2.02) for stretching, 3.44 (*SD* = 2.10) for strength exercises, and 4.22 (*SD* = 2.14) for walking. On the other hand, the FIBRO-On group reported a mean weekly practice of 4.48 (*SD* = 2.10) for breathing, 3.97 (*SD* = 2.13) for relaxation, 2.94 (*SD* = 2.29) for mindfulness, 2.54 (*SD* = 2.16) for strength exercises and 3.57 (*SD* = 2.25) for walking. There was a statistically significant difference for stretching exercises ($p = 0.015$), and strength exercises ($p = 0.017$), indicating that the FIBRO-Out group reported more weekly days of practice than the FIBRO-On group. There was no significant difference in the compromise with personal practice scores between the two groups *during* the intervention ($p > 0.05$); the FIBRO-On arm scored 6.06 out of 10 (*SD* = 2.24) and the FIBRO-Out scored 6.78 out of 10 (*SD* = 2.32).

The FIBRO-Out group continued to report a slightly greater frequency of mean homework practice *after* finishing the treatment (3.69 -*SD* = 1.36- vs 3.18 days per week -*SD* = 1.56-) compared to FIBRO-On group. However, this difference was no longer statistically significant ($p = 0.92$). No significant differences (all $p > 0.05$) emerged when comparing both groups for specific homework practices (breathing: 4.42 -*SD* = 2.02- vs 3.92 -*SD* = 2.01-; relaxation: 4.07 -*SD* = 2.02- vs 3.92 -*SD* = 1.88-; mindfulness: 2.88 -*SD* = 2.20- vs 2.52 -*SD* = 2.27-; stretching: 4.25 -*SD* = 1.73- vs 3.60 -*SD* = 2.02-; strength exercises: 2.72 -*SD* = 1.98- vs 2.35 -*SD* = 1.98-; walking: 3.78 -*SD* = 2.34- vs 3.08 -*SD* = 2.36-). There was no significant difference in the compromise with personal practice scores between the two groups after finishing the intervention ($p > 0.05$); the FIBRO-On arm scored 5.13 out of 10 (*SD* = 2.87) and the FIBRO-Out scored 5.52 out of 10 (*SD* = 2.49).

#### *3.6.5. Adverse Treatment Effects*

In the FIBRO-On group, one participant reported unspecified discomfort associated with therapeutic physical exercises. Another participant reported some initial adverse effects but subsequently described feeling better after therapy and expressed high appreciation for it. In the FIBRO-Out group, four participants reported experiencing some adverse effects. One participant reported feeling anxious when discussing a topic during a therapy session. Another participant indicated adverse effects from sitting outside in a cold, damp environment. Another individual reported feeling overwhelmed by the number of tasks and exercises, considering it a significant lifestyle change, leading to anxiety. Additionally, one participant reported experiencing adverse effects after engaging in mindfulness exercises but did not specify the nature of these effects.

#### 3.6.6. *Treatment Fidelity*

Therapists in the FIBRO-Out intervention obtained an average FFM score of 18.42 out of 20 (*SD* = 0.55), with individual therapist scores ranging from 17.95 to 19.46 points. Tandems of therapists (i.e., psychologist and physiotherapist) for the four FIBRO-Out groups showed an average FFM score of 18.75 out of 20 *(SD* = 0.53), with average tandem scores ranging from 18.07 to 19.17.

### 3.7. Mediation Analyses

Since no significant differences in FIQR scores were found between the two FIBROWALK arms at follow-up, they were combined to increase the statistical power of the mediation analysis. An average reduction of -4.63 points (-8.72, -0.40) in FIQR scores was observed for the combined FIBROWALK arms compared to TAU at the 6-month follow-up. The reduction in FIQR scores appeared to be partially explained by indirect effects via psychological inflexibility and kinesiophobia. Specifically, kinesiophobia and psychological inflexibility accounted for 47.6% and 19.0%, respectively, of the total absolute mediated effect. Pain

knowledge and pain catastrophizing accounted for 28.6% and 4.8%, respectively, although neither showed statistically significant indirect effects. See Table 4 and Figure 2 for further details. In addition, we also tested a model incorporating the psychological inflexibility subscales (avoidance and cognitive fusion); only avoidance emerged as a significant mediator (see *Supplementary Table 4*).

## 4. Discussion

The online and outdoor versions of the multicomponent FIBROWALK program were evaluated for their effectiveness in improving FM severity and secondary clinical and potential mediator variables, assessed at post-intervention and 6-month follow-up (3 months post-treatment). Consistent with our hypotheses, both formats significantly outperformed TAU, improving FM severity (large effect size) and most secondary outcomes at post-intervention (small-to-large effect sizes), with no differences between FIBROWALK arms. However, at 6-month follow-up, only the online format maintained its benefits over TAU for FM severity and pain intensity (with moderate effect sizes). Both intervention arms demonstrated statistically significant improvements in secondary outcomes, with moderate-to-large effect sizes, particularly at post-intervention and, to a lesser extent, at 6-month follow-up. As expected, the outdoor format demonstrated better adherence to homework exercises, while the online format resulted in higher session attendance. Although we anticipated lower satisfaction with the online format compared to FIBRO-Out, both interventions received similar ratings, with mean satisfaction scores around 8 out of 10. Attrition rates were also comparable (16–20% dropout) and consistent with the lower range reported for non-pharmacological chronic pain studies. [69,70] These low dropout rates, coupled with minimal adverse effects and significant improvements across diverse clinical outcomes, highlight the feasibility and effectiveness of both formats.

Consistent with prior research demonstrating the comparable effectiveness of online and in-person therapies [71,72], our findings suggest that online FIBROWALK may even exceed

face-to-face interventions in fostering mid-term improvements for individuals with FM. Indeed, online therapies are particularly effective in promoting self-management—a crucial factor for chronic conditions like FM—by fostering autonomy, enhancing patients' sense of competence and self-efficacy, and supporting the sustained benefits beyond the intervention period. [7,13] In contrast, in-person therapies may foster greater dependence on the therapist, potentially limiting mid-term benefits once therapeutic contact ends. [73] Notably, participants in the FIBRO-Out group reported higher overall satisfaction and perceived clinical improvement at the end of the intervention compared to FIBRO-On. This difference could be attributed to higher treatment expectations in the FIBRO-Out group [61] and the face-to-face format, which may strengthen perceived support and therapeutic alliance. [74,75] Additionally, participants in the FIBRO-Out group showed greater engagement with homework practices, suggesting that in-person interactions may help reinforce adherence to clinical recommendations.

Although the outdoor version demonstrated a large effect size at post-intervention in improving FM severity, its effectiveness was lower than a previous RCT of the original FIBROWALK program [20] ($d$ = 0.92 vs. $d$ = 1.86). An explanation could be that in the previous study, the program's developer, a psychologist and physiotherapist, delivered the therapy, whereas in the present study, multiple therapists conducted the sessions to enhance external validity and assess feasibility in real-world clinical settings. [37] Research suggests that interventions delivered by their developers often yield better outcomes [75], as their familiarity with the therapy reduces variability in implementation. However, treatment fidelity in the FIBRO-Out group was rated very high, indicating that reduced effectiveness was unlikely due to improper delivery. Other contextual variables may have influenced outcomes, including the number of sessions conducted indoors due to extreme weather conditions. Since FIBRO-Out groups were conducted year-round, exposure to extreme temperatures might have impacted both session quality and participant adherence, especially given the heightened temperature

sensitivity in individuals with FM. [76] While the outdoor FIBROWALK format was supported by evidence on the benefits of nature-based therapies for FM, adverse weather conditions nonetheless compromised participation and experience. [20,77] These findings underscore the importance of developing weather-adapted intervention formats.

Responder analyses (reported in *Supplementary Table 5*) revealed that homework practice, rather than session attendance, was key to clinical improvement, consistent with previous findings from other non-pharmacological interventions. [14] Blending online FIBROWALK, which showed a lower impact on homework engagement, with face-to-face outdoor sessions could enhance perceived therapist support and provide tailored recommendations to improve adherence. Responder analyses also highlighted the importance of addressing pre-treatment distress and sleep quality to maximize intervention effectiveness. [78] Additionally, baseline kinesiophobia, [79] pain, [13,80] and psychological inflexibility [81]—factors known to perpetuate pain through avoidance and deconditioning—should be prioritized in future FIBROWALK adaptations. Identifying patient profiles using clinical variables could further enable personalized care, shortening treatment duration and improving outcomes. [82]

Although both FIBRO-On and FIBRO-Out showed improvements post-treatment, the proportion of participants maintaining a clinically meaningful improvement declined by 6-month follow-up (3 months after the end of the interventions), suggesting partial loss of gains over time. In addition, signs of clinical worsening emerged in nearly a quarter of the online group, over a third of the outdoor group, and close to half of those receiving TAU. These patterns point to a vulnerability to deterioration over time, especially in the absence of structured support. Several factors may contribute to this outcome, including the fluctuating course of FM symptoms, limited post-treatment support, and individual variability in treatment response.[1,2] These considerations underscore the need for strategies to sustain long-term benefits, such as follow-up support or reinforcement mechanisms[22], including more frequent

monitoring (e.g., weekly assessments), reintroduction of active components, or booster sessions.[82,64]

Beyond improvements in clinical outcomes, both intervention formats produced significant changes in hypothesized mediators—psychological inflexibility, kinesiophobia, pain catastrophizing, and pain knowledge—relative to TAU. Notably, only psychological inflexibility and kinesiophobia emerged as significant mediators of treatment effects, consistent with their established role in mindfulness- and acceptance-based interventions and CBT.[14,83,84] Although mindfulness in FIBROWALK is not explicitly based on the psychological flexibility model, its components align with principles relevant to a range of chronic pain treatments. [85,86] Furthermore, although not statistically significant, increases in pain knowledge accounted for 28.6% of the total mediated effect. While this indirect effect did not reach statistical significance, pain knowledge may nonetheless represent a relevant mechanism warranting further investigation, as enhancing pain understanding has been proposed to reduce fear and maladaptive beliefs and is central to PSE.[57]

Our findings should be interpreted within the broader context of non-pharmacological interventions for FM, such as physical exercise, PSE, mindfulness, and CBT, which have shown moderate benefits in reducing symptoms and improving well-being. [17,18,87] FIBROWALK builds upon these approaches by integrating them into a structured multicomponent format designed to address both physical and psychological aspects simultaneously. This integrative model may offer a more comprehensive and feasible intervention for FM, as reflected in the improvements observed in FM severity and key psychological mechanisms like psychological inflexibility and kinesiophobia.

### 4.1. Further directions

Future research would benefit from adapting FIBROWALK to better support patients at risk of non-response, such as incorporating individual therapy or virtual CBT sessions for those

with higher anxiety or depression. Personalizing interventions based on key mediators and predictors, such as psychological flexibility or kinesiophobia, could enhance outcomes. [88,89] Improving psychological flexibility, a key factor in FIBROWALK's mid-term effectiveness, should be prioritized, particularly for the outdoor format, where sustained clinical improvements were lacking. Integrating elements of Acceptance and Commitment Therapy (ACT) into FIBROWALK's mindfulness component may further enhance its benefits, as ACT has proven effective in FM [90] and combining it with physical exercise offers additional advantages. [91]

Enhancing personal practice, especially in the FIBRO-On group, could also improve outcomes, as greater at-home engagement was linked to better responses. Digital tools such as apps or follow-up sessions could support sustained practice. Adding in-person sessions to the FIBRO-On program through blended or hybrid approaches may increase adherence, offering flexibility to address barriers like symptom flare-ups or scheduling conflicts. [92,93] Balancing online and in-person sessions based on patient profiles, with more face-to-face interactions for those with severe symptoms, may further optimize outcomes. [94]

The FIBRO-Out format could benefit from strategies to minimize the impact of adverse weather, such as scheduling sessions in milder seasons or using weather-adapted environments. Considering prior findings of better clinical outcomes with FIBRO-Out, [20] qualitative research could also help identify barriers and facilitators to optimize this format and enhance its effectiveness.

### 4.2. Limitations and Strengths

This study has some limitations. The broad inclusion criteria improved generalizability but may have increased variability in patient characteristics, potentially reducing internal validity. Outdoor sessions were affected by weather, raising questions about whether fully outdoor sessions under stable conditions might yield better outcomes. Future research should examine

the interaction between environmental factors and treatment effects and consider investing in weather-resistant outdoor spaces. Additionally, while the FIBRO-Out intervention involved multiple therapists, the FIBRO-On format relied solely on the program's creator, potentially limiting generalizability and introducing therapist-specific biases. Moreover, it is also possible that the study was underpowered to detect smaller differences between the two active conditions, since the trial was powered to detect medium effects between each active arm and TAU. In addition, the hospital administration required the inclusion of some participants awaiting a decision regarding permanent disability leave, which may have introduced response bias, as involvement in such claims could have led some individuals to underreport improvements, potentially attenuating treatment effects. Finally, as a multicomponent intervention, FIBROWALK presents the common challenge of isolating the most effective elements. While dismantling designs may be useful in future studies, we evaluate FIBROWALK as an integrated intervention, assuming its components are more effective together.

Despite these limitations, the study has notable strengths. Mediation analyses identified psychological inflexibility and kinesiophobia as key factors in FIBROWALK's mid-term effectiveness, providing an important target for enhancing future versions of the program. The rigorous RCT design, comprehensive outcome measures, and comparison of online and outdoor formats add to its significance. The study achieved high external validity, low missing data, and strong treatment fidelity. It is also the first to evaluate both formats with a 6-month follow-up. Another strength is that the outdoor format was delivered by multiple therapists without prior FIBROWALK experience, supporting its real-world feasibility and ecological validity. Additionally, it identified characteristics of clinical responders at post-intervention and follow-up, offering valuable insights for personalizing treatments to improve outcomes.

### 4.3. Conclusion

This study highlights the effectiveness and safety of both the online and outdoor formats of the multicomponent FIBROWALK program for individuals with FM. The online version demonstrated sustained mid-term benefits, making it particularly promising for wider implementation. Mediation analyses suggest that targeting psychological flexibility and kinesiophobia could further enhance these mid-term effects, emphasizing the need to integrate these variables more effectively in future iterations of the program. Additionally, identifying baseline sociodemographic and clinical factors associated with better treatment response offers valuable tools for tailoring interventions, enabling more personalized care and improving outcomes for patients at higher risk of non-response.

## 5. Disclosures

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### 5.2. Conflict of interest statement

The authors declare no conflicts of interest.

### 5.3. Registration

The protocol of the study was registered on ClinicalTrials.gov (NCT05377567)

### 5.4. Protocol

Serrat M, Ferrés S, Auer W, Almirall M, Lluch E, D'Amico F, Maes M, Lorente S, Navarrete J, Montero-Marín J, Neblett R, Nijs J, Borràs X, Luciano J V., Feliu-Soler A: Effectiveness, cost-utility and physiological underpinnings of the FIBROWALK multicomponent therapy in online and outdoor format in individuals with fibromyalgia: Study protocol of a randomized, controlled trial (On&Out study). Front Physiol 13:, 2022.

### 5.5. Authors' contribution

Mayte Serrat: conceptualization, supervision, and writing – review & editing. Estíbaliz Royuela-Colomer: investigation, data curation, software, formal analysis, methodology, visualization, and writing the original draft. William Auer and Sonia Ferrés: writing – review & editing. Míriam Almirall, Randy Neblett, Jo Nijs, Juan P. Sanabria-Mazo: writing – review & editing. Xavier Borràs and Juan V. Luciano: conceptualization, supervision, and writing – review & editing. Albert Feliu-Soler: conceptualization, funding acquisition, investigation, project administration, supervision, formal analysis, methodology, writing the original draft, and review & editing.

### 5.6. Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

### 5.7. Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this work, the authors used ChatGPT to improve some sentences of the article in terms of grammar and style. After using this tool, the authors reviewed and edited the content as needed and took full responsibility for the content of the publication.

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## 6. Figure Legends

**Figure 1**: Flowchart of the On&Out study.

**Figure 2:** Mediation model: Graphical representation of the direct and indirect effects in the mediation model of FIBROWALK vs. TAU. Standardized values. *$p < 0.05$; **$p < 0.005$; ***$p < 0.001$.

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Figure 1

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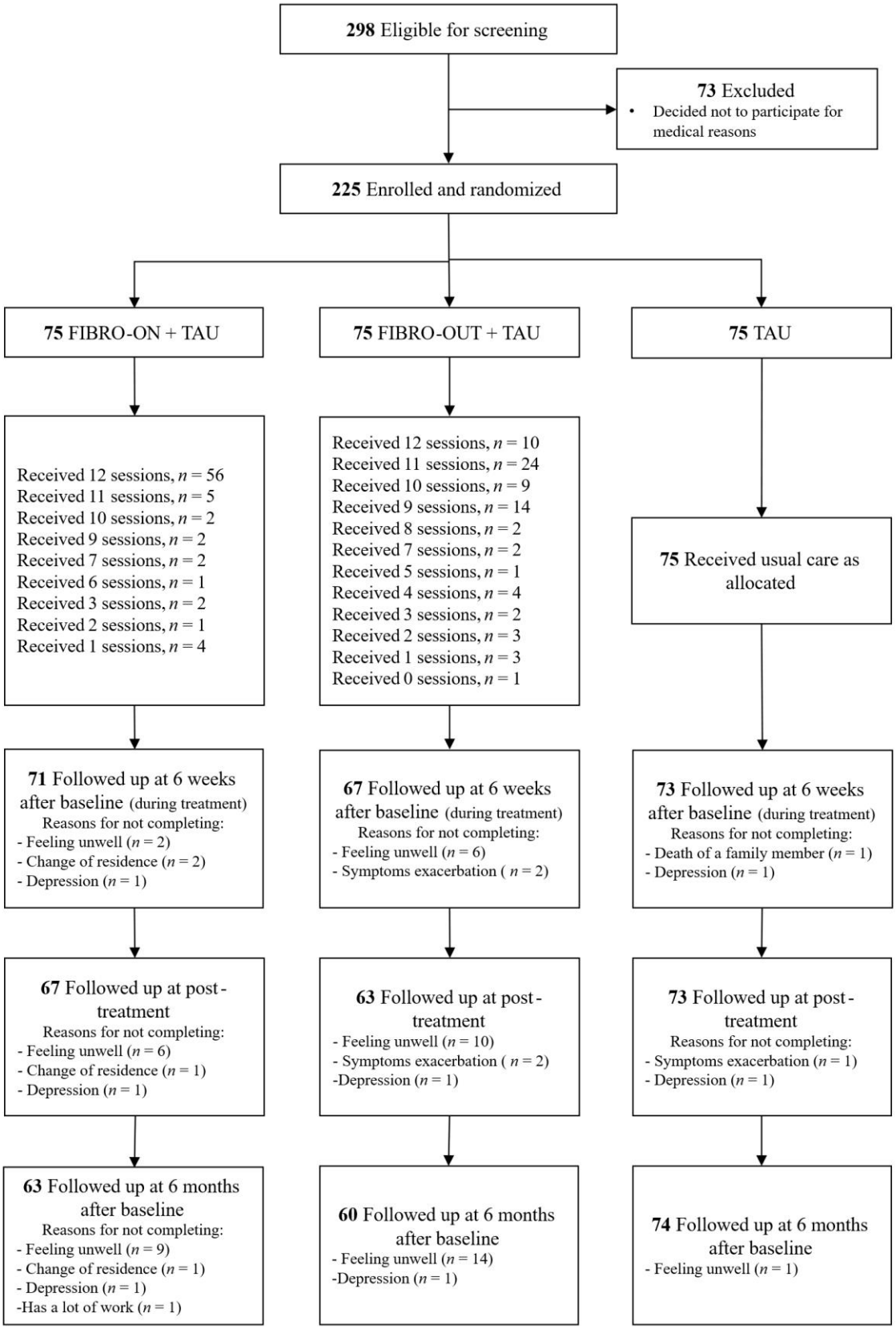

Figure 2

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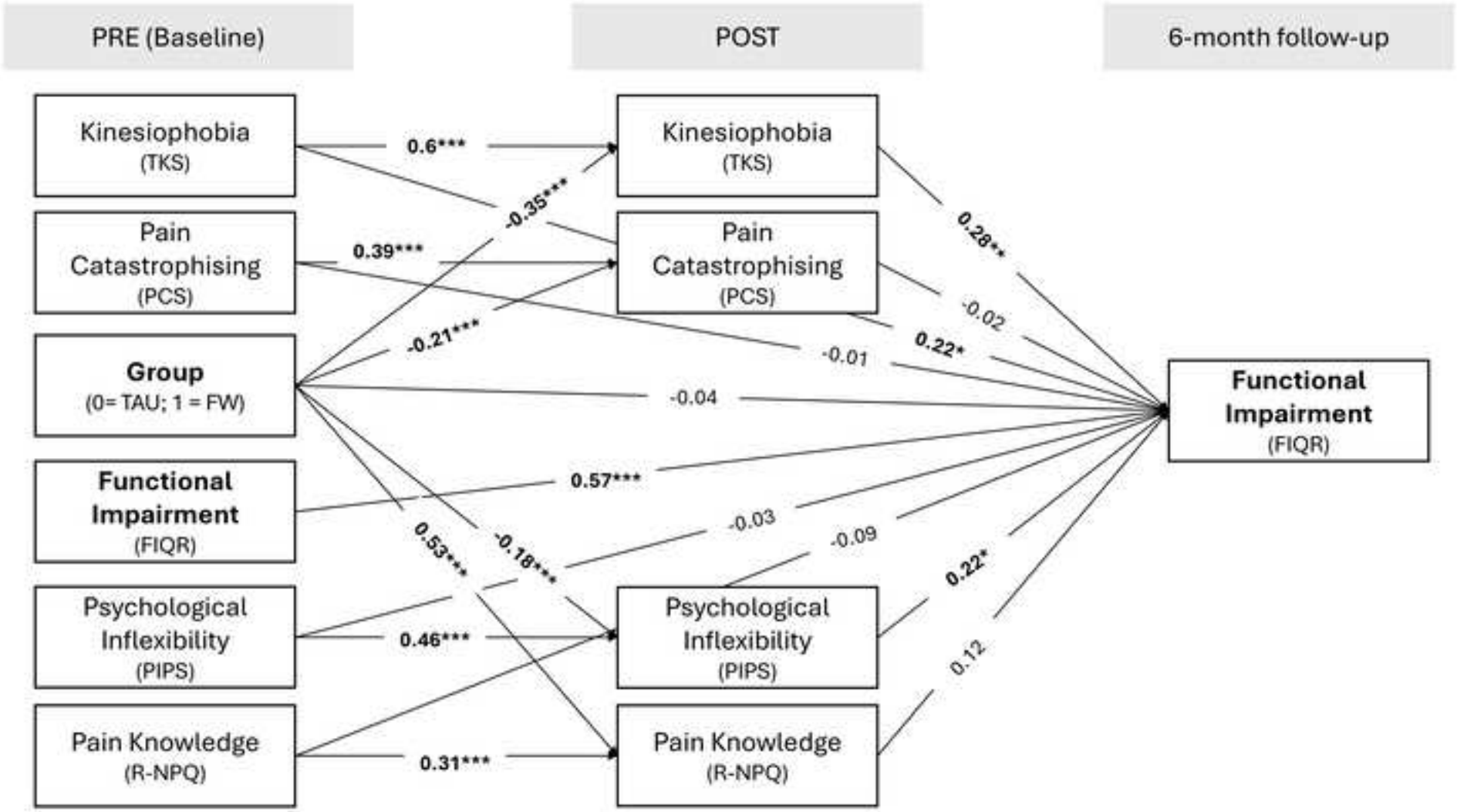

Table 1 Click here to access/download;Tables;Table 1_Revised_R2.docx

**Table 1**. Baseline Characteristics by Treatment Arm.

| | FIBRO-On (*n* = 75) | FIBRO-Out (*n* = 75) | TAU (*n* = 75) |
|---|---|---|---|
| **Gender**, *n* women (%) | 75 (100) | 72 (96) | 73 (97.3) |
| **Age**, mean (*SD*) | 52.6 (9.7) | 54.5 (10.1) | 55.7 (9.1) |
| **BMI**, mean (*SD*) | 28.1 (6.1) | 27.5 (5.7) | 29.1 (5.9) |
| **Marital status**, *n* (%) | | | |
| Single | 8 (10.7) | 12 (16) | 8 (10.7) |
| Married/with a partner | 50 (66.7) | 44 (58.7) | 48 (64) |
| Separated/Divorced | 14 (18.7) | 11 (14.7) | 16 (21.3) |
| Widowed | 3 (4) | 8 (10.7) | 3 (4) |
| **Living with a companion**, *n* (%) | 68 (90.7) | 65 (86.7) | 62 (82.7) |
| **Education level**, *n* (%) | | | |
| Illiterate | 0 (0.0) | 2 (2.7) | 2 (2.7) |
| Not graduate from primary school | 7 (9.3) | 4 (5.3) | 7 (9.3) |
| Primary school | 18 (24) | 20 (26.7) | 22 (29.3) |
| Secondary school | 31 (41.3) | 31 (41.3) | 32 (42.7) |
| University | 15 (20) | 17 (22.7) | 11 (14.7) |
| Others | 4 (5.3) | 1 (1.3) | 1 (1.3) |
| **Employment status**, *n* (%) | | | |
| Homemaker | 6 (8) | 4 (5.3) | 7 (9.3) |
| Paid employment | 22 (29.3) | 15 (20) | 19 (25.3) |
| Paid employment but in sick leave | 15 (20) | 21 (28) | 13 (17.3) |
| Unemployed with subsidy | 3 (4) | 6 (8) | 5 (6.7) |
| Unemployed without subsidy | 6 (8) | 6 (8) | 4 (5.3) |
| Retired/Pensioner | 5 (6.7) | 7 (9.3) | 12 (16) |
| Temporal disability | 5 (6.7) | 4 (5.3) | 4 (5.3) |
| Others | 13 (17.3) | 12 (16) | 11 (14.7) |
| **Clinical variables** | | | |
| Years diagnosis, mean (*SD*) | 13.9 (9.7) | 11.7 (9.1) | 16.9 (10.9) |
| Chronic fatigue syndrome, *n* (%) | 43 (57.3) | 43 (57.3) | 46 (61.3) |
| Rheumatoid arthritis, *n* (%) | 9 (12) | 9 (12) | 11 (14.7) |

| | | | |
|---|---|---|---|
| Multiple chemical sensitivity, *n* (%) | 9 (12) | 10 (13.3) | 9 (12) |
| Cancer, *n* (%) | 1 (1.3) | 1 (1.3) | 2 (2.7) |
| Depression, *n* (%) | 46 (61.3) | 53 (70.7) | 55 (73.3) |
| Anxiety, *n* (%) | 52 (69.3) | 53 (70.7) | 55 (73.3) |
| Irritable bowel syndrome, *n* (%) | 20 (26.7) | 15 (20) | 28 (37.3) |
| Osteoarthritis, *n* (%) | 39 (52) | 43 (57.3) | 51 (68) |
| **Applying for disability**, *n* (%) | 19 (25.3) | 26 (34.7) | 19 (25.3) |
| **Degree of disability**, *n* (%) | | | |
| No | 36 (48) | 33 (44) | 26 (34.7) |
| Less than 33% | 1 (1.3) | 1 (1.3) | 2 (2.7) |
| Between 33-66% | 24 (32) | 34 (45.3) | 29 (38.7) |
| More than 66% | 3 (14.7) | 6 (8) | 15 (20) |
| N/A | 3 (4) | 1 (1.3) | 3 (4) |
| **Medication**, *n* (%) | 71 (94.7) | 72 (96) | 70 (93.3) |
| Antidepressants | 53 (70.7) | 60 (80) | 63 (84) |
| Anxiolytics | 31 (41.3) | 29 (38.7) | 21 (28) |
| Sleep medications | 29 (38.7) | 30 (40) | 21 (28) |
| Anticonvulsants | 17 (22.7) | 20 (26.7) | 19 (25.3) |
| Muscle relaxants | 41 (54.7) | 41 (54.7) | 43 (57.3) |
| Anti-inflammatories | 65 (86.7) | 57 (76) | 49 (65.3) |
| Non-opioid analgesics | 67 (89.3) | 67 (89.3) | 65 (86.7) |
| Opioids | 18 (24) | 21 (28) | 20 (26.7) |

*Note.* FIBRO-On = online; FIBRO-Out = outdoor; TAU = treatment-as-usual; BMI = Body Mass Index.

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**Table 2.** Descriptive statistics and Between-Group Analyses for Primary and Secondary Outcomes (ITT approach)

| | **FIBRO-On** | **FIBRO-Out** | **TAU** | **TAU vs FIBRO-On** | | | **TAU vs FIBRO-Out** | | | **FIBRO-On vs FIBRO-Out** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean (*SD*) | Mean (*SD*) | Mean (*SD*) | *d* | *t*(*p*) | *β* (95% CI) | *d* | *t*(*p*) | *β* (95% CI) | *d* | *t*(*p*) | *β* (95% CI) |
| **Primary Outcome** | | | | | | | | | | | | |
| **FIQR (0-100)*** | | | | | | | | | | | | |
| Baseline | 73.08 (15.91) | 74.14 (15.10) | 70.59 (16.13) | | | | | | | | | |
| 6-week | 66.14 (18.38) | 68.44 (15.46) | 69.85 (15.36) | -0.53 | **-3.00 (0.003)** | -5.67 (-9.38; -1.96) | -0.46 | **-2.67 (0.008)** | -5.11 (-8.85; -1.36) | -0.05 | 0.30 (0.768) | 0.57 (-3.20; 4.34) |
| Post-intervention | 61.73 (20.79) | 64.43 (16.46) | 70.68 (16.08) | -1.00 | **-4.71 (<0.001)** | -10.68 (-15.13;-6.23) | -0.92 | **-4.33 (<0.001)** | -9.91 (-14.4; -5.42) | -0.07 | 0.33 (0.738) | 0.77 (-3.77; 5.32) |
| Follow-up | 64.97 (19.17) | 67.84 (15.94) | 69.54 (16.87) | -0.56 | **-2.49 (0.013)** | -6.02 (-10.78;-1.27) | -0.40 | -1.76 (0.079) | -4.29 (-9.08; 0.50) | -0.16 | 0.70 (0.486) | 1.73 (-3.15; 6.62) |
| **Secondary Outcomes** | | | | | | | | | | | | |
| **NRS-Pain (0-10)*** | | | | | | | | | | | | |
| Baseline | 7.88 (1.62) | 8.07 (1.42) | 7.73 (1.80) | | | | | | | | | |
| 6-week | 7.35 (1.77) | 7.54 (1.72) | 7.60 (1.62) | -0.22 | -1.19 (0.232) | -0.31 (-0.82; 0.20) | -0.27 | -1.56 (0.120) | -0.41 (-0.92; 0.11) | 0.07 | -0.37 (0.710) | -0.10 (-0.61; 0.42) |
| Post-intervention | 6.79 (2.18) | 6.84 (1.74) | 7.66 (1.97) | -0.68 | **-3.10 (0.002)** | -0.94 (-1.54;-0.35) | -0.81 | **-3.68 (<0.001)** | -1.12 (-1.72; -0.52) | 0.13 | -0.59 (0.556) | -0.18 (-0.79; 0.42) |
| Follow-up | 6.89 (2.20) | 7.38 (1.68) | 7.54 (1.92) | -0.50 | **-2.16 (0.031)** | -0.69 (-1.32; -0.06) | -0.29 | -1.16 (0.248) | -0.37 (-1.00; 0.26) | -0.23 | 0.97 (0.332) | 0.32 (-0.33; 0.96) |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **NRS-Fatigue (0-10)*** | | | | | | | | | | | | |
| Baseline | 7.87 (2.27) | 7.91 (2.04) | 7.29 (2.54) | | | | | | | | | |
| 6-week | 7.24 (2.30) | 6.94 (2.3) | 7.49 (2.24) | -0.38 | -1.82 (0.070) | -0.74 (-1.54; 0.06) | -0.58 | **-2.78 (0.006)** | -1.14 (-1.94;-0.33) | 0.21 | -0.97 (0.331) | -0.40 (-1.21; 0.41) |
| Post-intervention | 7.24 (2.05) | 7.22 (1.83) | 7.73 (2.16) | -0.50 | **-2.20 (0.028)** | -0.98 (-1.86; -0.10) | -0.56 | **-2.44 (0.015)** | -1.10 (-1.99;-0.21) | 0.06 | -0.26 (0.798) | -0.12 (-1.01; 0.78) |
| Follow-up | 7.38 (2.16) | 7.23 (2.04) | 7.51 (2.15) | -0.33 | -1.43 (0.153) | -0.66 (-1.55; 0.24) | -0.43 | -1.81 (0.070) | -0.84 (-1.74; 0.07) | 0.09 | -0.38 (0.702) | -0.18 (-1.10; 0.74) |
| **HADS-Anxiety (0-21)*** | | | | | | | | | | | | |
| Baseline | 12.97 (4.69) | 13.93 (3.92) | 13.88 (4.07) | | | | | | | | | |
| 6-week | 12.38 (4.86) | 13.43 (3.56) | 13.58 (4.27) | -0.09 | -0.48 (0.634) | -0.22 (-1.14; 0.70) | -0.01 | -0.03 (0.978) | -0.01 (-0.94; 0.92) | -0.08 | 0.44 (0.659) | 0.21 (-0.72; 1.14) |
| Post-intervention | 11.52 (5.27) | 12.76 (4.25) | 14.00 (4.07) | -0.51 | **-2.37 (0.018)** | -1.31 (-2.39; -0.23) | -0.43 | **-1.97 (0.050)** | -1.09 (-2.19; 0) | -0.08 | 0.38 (0.703) | 0.22 (-0.89; 1.32) |
| Follow-up | 12.19 (5.19) | 13.67 (4.23) | 13.31 (4.05) | -0.01 | -0.02 (0.981) | -0.01 (-1.16; 1.13) | 0.16 | 0.70 (0.482) | 0.41 (-0.74; 1.56) | -0.17 | 0.71 (0.476) | 0.43 (-0.75; 1.60) |
| **HADS-Depression (0-21)*** | | | | | | | | | | | | |
| Baseline | 12.17 (4.38) | 12.57 (4.13) | 11.8 (4.44) | | | | | | | | | |
| 6-week | 11.00 (4.92) | 11.76 (4.13) | 11.77 (4.34) | -0.50 | **-2.70 (0.007)** | -1.30 (-2.25; -0.36) | -0.23 | -1.25 (0.212) | -0.61 (-1.56; 0.35) | -0.27 | 1.42 (0.157) | 0.69 (-0.27; 1.65) |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Post-intervention | 10.69 (4.76) | 11.35 (4.85) | 12.45 (4.72) | -0.77 | **-3.54 (<0.001)** | -2.00 (-3.12; -0.89) | -0.62 | **-2.85 (0.004)** | -1.63 (-2.75; -0.51) | -0.14 | 0.65 (0.517) | 0.38 (-0.76; 1.51) |
| Follow-up | 11.4 (4.57) | 12.52 (4.80) | 11.64 (4.64) | -0.25 | -1.10 (0.270) | -0.66 (-1.83; 0.51) | 0.08 | 0.35 (0.728) | 0.21 (-0.97; 1.39) | -0.33 | 1.41 (0.158) | 0.87 (-0.34; 2.07) |
| **PSS (0-16)*** | | | | | | | | | | | | |
| Baseline | 9.00 (3.08) | 9.59 (2.72) | 9.25 (2.67) | | | | | | | | | |
| 6-week | 8.65 (2.95) | 9.24 (2.48) | 9.05 (2.43) | -0.08 | -0.44 (0.658) | -0.17 (-0.9; 0.57) | -0.05 | -0.26 (0.798) | -0.10 (-1.14; 0.67) | -0.04 | 0.18 (0.856) | 0.07 (-0.68; 0.82) |
| Post-intervention | 8.28 (3.51) | 9.05 (2.96) | 9.38 (2.71) | -0.41 | -1.88 (0.061) | -0.82 (-1.68; 0.04) | -0.29 | -1.30 (0.193) | -0.58 (-1.44; 0.29) | -0.12 | 0.55 (0.582) | 0.25 (-0.63; 1.12) |
| Follow-up | 8.65 (3.18) | 9.53 (2.84) | 9.53 (2.78) | -0.33 | -1.43 (0.153) | -0.66 (-1.56; 0.24) | -0.12 | -0.51 (0.611) | -0.24 (-1.14; 0.67) | -0.21 | 0.89 (0.372) | 0.42 (-0.50; 1.35) |
| **CSI-9 (0-36)*** | | | | | | | | | | | | |
| Baseline | 28.04 (5.81) | 27.97 (5.47) | 26.64 (5.81) | | | | | | | | | |
| 6-week | 26.56 (6.14) | 26.49 (5.81) | 26.19 (5.80) | -0.42 | -1.21 (0.225) | -0.89 (-2.32; 0.55) | -0.19 | -1.06 (0.290) | -0.78 (-2.23; 0.67) | -0.02 | 0.14 (0.887) | 0.10 (-1.35; 1.56) |
| Post-intervention | 25.61 (6.64) | 26.54 (5.77) | 27.03 (5.25) | -0.22 | **-2.91 (0.004)** | -2.53 (-4.24; -0.83) | -0.41 | -1.91 (0.057) | -1.67 (-3.39; 0.05) | -0.21 | 0.97 (0.333) | 0.86 (-0.88; 2.60) |
| Follow-up | 26.48 (6.6) | 27.38 (6.04) | 27.16 (5.43) | -0.62 | -1.85 (0.065) | -1.71 (-3.52; 0.11) | -0.26 | -1.12 (0.263) | -1.04 (-2.87; 0.78) | -0.16 | 0.70 (0.485) | 0.66 (-1.20; 2.53) |
| **SF-PF (0-100)*** | | | | | | | | | | | | |
| Baseline | 31.07 (19.16) | 30.53 (20.18) | 28.67 (20.62) | | | | | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6-week | 34.51 (22.54) | 31.94 (16.99) | 29.66 (18.86) | 0.21 | 1.17 (0.244) | 2.30 (-1.58; 6.19) | 0.01 | 0.07 (0.946) | 0.14 (-3.79; 4.06) | 0.20 | -1.08 (0.281) | -2.17 (-6.11; 1.78) |
| Post-intervention | 36.79 (22.97) | 32.78 (20.39) | 29.38 (19.72) | 0.37 | 1.73 (0.084) | 4.08 (-0.55; 8.72) | 0.03 | 0.15 (0.881) | 0.36 (-4.32; 5.04) | 0.34 | -1.54 (0.123) | -3.73 (-8.46; 1.01) |
| Follow-up | 35.40 (22.15) | 32.25 (19.56) | 29.73 (19.3) | 0.22 | 0.96 (0.337) | 2.42 (-2.52; 7.35) | -0.15 | -0.67 (0.503) | -1.70 (-6.67; 3.28) | 0.37 | -1.59 (0.112) | -4.11 (-9.19; 0.96) |
| **PSQI (0-15)*** | | | | | | | | | | | | |
| Baseline | 10.74 (3.39) | 9.99 (3.28) | 9.91 (3.15) | | | | | | | | | |
| 6-week | 10.08 (3.38) | 9.79 (3.56) | 10.51 (3.37) | -0.58 | **-2.81 (0.005)** | -1.23 (-2.09;-0.37) | -0.32 | -1.56 (0.118) | -0.67 (-1.52; 0.17) | -0.26 | 1.27 (0.205) | 0.56 (-0.30; 1.42) |
| Post-intervention | 9.98 (4.07) | 9.62 (3.23) | 10.87 (3.33) | -0.64 | **-2.73 (0.006)** | -1.38 (-2.37; -0.39) | -0.47 | **-2.01 (0.044)** | -1.00 (-1.98; -0.03) | -0.18 | 0.75 (0.456) | 0.38 (-0.61; 1.37) |
| Follow-up | 10.19 (3.82) | 9.83 (3.48) | 10.30 (3.17) | -0.19 | -0.77 (0.442) | -0.41 (-1.44; 0.63) | -0.12 | -0.51 (0.612) | -0.26 (-1.29; 0.76) | -0.07 | 0.26 (0.791) | 0.14 (-0.91; 1.19) |
| **MISCI (10-50)*** | | | | | | | | | | | | |
| Baseline | 22.60 (7.38) | 22.87 (8.37) | 24.56 (8.84) | | | | | | | | | |
| 6-week | 24.56 (7.92) | 24.18 (7.61) | 24.71 (8.18) | 0.42 | **2.34 (0.020)** | 2.11 (0.34; 3.89) | 0.15 | 0.82 (0.413) | 0.75 (-1.05; 2.55) | 0.27 | -1.48 (0.138) | -1.14 (-3.17; 0.44) |
| Post-intervention | 25.66 (9.04) | 25.17 (8.81) | 23.42 (8.09) | 0.87 | **4.08 (<0.001)** | 4.41 (2.28; 6.53) | 0.61 | **2.84 (0.005)** | 3.10 (0.96; 5.24) | 0.26 | -1.19 (0.236) | -1.31 (-3.48; 0.86) |
| Follow-up | 23.48 (9.04) | 23.35 (8.55) | 24.96 (9.12) | 0.16 | 0.70 (0.487) | 0.80 (-1.46; 3.06) | -0.07 | -0.29 (0.771) | -0.34 (-2.61; 1.94) | 0.23 | -0.96 (0.336) | -1.37 (-3.46; 1.18) |

*Note.* TAU = treatment-as-usual; FIBRO-On = online; FIBRO-Out = outdoor; FIQR = Fibromyalgia Impact Questionnaire; NRS = Numerical Rating Scale of Perceived Pain/Fatigue; HADS = Hospital Anxiety and Depression Scale; PSS = Perceived Stress Scale; CSI = Central Sensitization Inventory; SF-PF = Physical Function Subscale of the Short Form-36 Health Survey; PSQI = Pittsburgh Sleep Quality Index, brief version; MISCI = Multidimensional Inventory of Subjective Cognitive Impairment.

The number of participants varied across assessment periods due to dropouts (see flow chart). Significant values ($p < 0.05$) are shown in bold. We controlled for wave and baseline levels of the variable. Mean and SD are not adjusted.

* The baseline level of the variable is a significant covariate in the model.
$\beta$, regression coefficients; CI, confidence interval; *d*, Cohen's d as an effect size measure; ITT, intention-to-treat

When the Benjamini–Hochberg correction was applied to correct for multiple comparisons, the following effects were no longer significant: in TAU vs FIBRO-Out: 6-week NRS-Fatigue and post-intervention PSQI; TAU vs FIBRO-On: 6-week MISCI.

Click here to access/download;Tables;Table 3_R2.docx

**Table 3.** Descriptive statistics and Between-Group Analyses for Potential Mediators (ITT approach)

| | **FIBRO-On** | **FIBRO-Out** | **TAU** | **TAU vs FIBRO-On** | | | **TAU vs FIBRO-Out** | | | **FIBRO-On vs FIBRO-Out** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean (*SD*) | Mean (*SD*) | Mean (*SD*) | *d* | *t*(*p*) | *β* (95% CI) | *d* | *t*(*p*) | *β* (95% CI) | *d* | *t*(*p*) | *β* (95% CI) |
| **TSK (11-44)*** | | | | | | | | | | | | |
| Baseline | 31.38 (7.84) | 31.55 (8.18) | 30.99 (7.81) | | | | | | | | | |
| 6-week | 26.50 (7.21) | 27.13 (7.41) | 30.99 (8.34) | -0.97 | **-5.50 (<0.001)** | -4.67 (-6.33; -3.00) | -0.60 | **-3.37 (0.001)** | -2.90 (-4.58; -1.21) | -0.37 | **2.05 (0.041)** | 1.77 (0.08; 3.46) |
| Post-intervention | 23.89 (7.32) | 24.19 (7.71) | 30.10 (8.39) | -1.31 | **-6.19 (<0.001)** | -6.31 (-8.31; -4.31) | -1.04 | **-4.88 (<0.001)** | -5.02 (-7.04; -3.01) | -0.27 | 1.23 (0.217) | 1.29 (-0.76; 3.33) |
| Follow-up | 25.26 (7.80) | 25.16 (7.71) | 29.73 (8.34) | -0.97 | **-4.30 (<0.001)** | -4.68 (-6.82; -2.55) | -0.75 | **-3.30 (0.001)** | -3.62 (-5.77; -1.46) | -0.22 | 0.95 (0.341) | 1.07 (-1.13; 3.26) |
| **PCS (0-52)*** | | | | | | | | | | | | |
| Baseline | 28.98 (14.26) | 28.41 (14.32) | 26.59 (14.66) | | | | | | | | | |
| 6-week | 24.23 (13.41) | 25.03 (13.81) | 26.84 (13.80) | -0.35 | **-2.00 (0.046)** | -3.18 (-6.31; -0.06) | -0.27 | -1.50 (0.135) | -2.41 (-5.56; 0.75) | -0.09 | 0.48 (0.630) | 0.78 (-2.39; 3.95) |
| Post-intervention | 23.17 (14.29) | 23.70 (14.66) | 29.16 (13.05) | -0.73 | **-3.45 (0.001)** | -6.58 (-10.33;-2.84) | -0.66 | **-3.10 (0.002)** | -5.97 (-9.75; -2.20) | -0.07 | 0.31 (0.754) | 0.61 (-3.21; 4.43) |
| Follow-up | 23.85 (14.84) | 23.68 (14.64) | 29.05 (13.02) | -0.72 | **-3.19 (0.001)** | -6.49 (-10.49;-2.50) | -0.51 | **-2.24 (0.026)** | -4.58 (-8.61; -0.56) | -0.21 | 0.91 (0.362) | 1.91 (-2.20; 6.02) |
| **PIPS (7-84)*** | | | | | | | | | | | | |
| Baseline | 60.60 (18.44) | 61.2 (18.14) | 56.35 (18.50) | | | | | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 6-week | 56.59 (18.40) | 56.52 (18.27) | 55.49 (18.09) | -0.26 | -1.44 (0.151) | -3.01 (-7.13; 1.11) | -0.35 | -1.92 (0.055) | -4.08 (-8.24; 0.09) | 0.09 | -0.50 (0.617) | -1.06 (-5.25; 3.12) |
| Post-intervention | 51.73 (18.85) | 52.03 (18.98) | 57.67 (17.32) | -0.82 | **-3.78 (<0.001)** | -9.36 (-14.23; -4.50) | -0.85 | **-3.89 (<0.001)** | -9.74 (-14.65; -4.83) | 0.03 | -0.15 (0.882) | -0.37 (-5.34; 4.59) |
| Follow-up | 55.03 (19.88) | 54.92 (19.88) | 55.31 (18.5) | -0.35 | -1.54 (0.124) | -4.03 (-9.18; 1.11) | -0.58 | **-2.51 (0.012)** | -6.63 (-11.82; -1.45) | 0.23 | -0.97 (0.335) | -2.60 (-7.89; 2.69) |
| **R-NPQ (0-13)*** | | | | | | | | | | | | |
| Baseline | 4.23 (1.94) | 4.29 (2.03) | 4.79 (2.20) | | | | | | | | | |
| 6-week | 6.56 (2.27) | 6.48 (2.26) | 4.70 (2.40) | 1.20 | **6.64 (<0.001)** | 2.28 (1.60; 2.95) | 1.19 | **6.53 (<0.001)** | 3.05 (1.58; 2.95) | 0.01 | -0.04 (0.968) | -0.01 (-0.70; 0.67) |
| Post-intervention | 6.63 (2.08) | 6.60 (2.05) | 4.18 (2.47) | 1.50 | **6.99 (<0.001)** | 2.85 (2.05; 3.66) | 1.94 | **8.97 (<0.001)** | 3.69 (2.89; 4.50) | -0.44 | **2.02 (0.044)** | 0.84 (0.02; 1.66) |
| Follow-up | 6.03 (2.72) | 5.98 (2.69) | 4.27 (2.49) | 1.12 | **4.92 (<0.001)** | 2.13 (1.28; 2.98) | 1.60 | **6.99 (<0.001)** | 2.27 (2.19; 3.91) | -0.49 | **2.06 (0.040)** | 0.92 (0.04; 1.79) |

*Note.* TAU = treatment-as-usual; FIBRO-On = online; FIBRO-Out = outdoor; TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophising Scale; PIPS = Psychological Inflexibility in Pain Scale; R-NPQ = Revised Neurophysiology of Pain Questionnaire.

The number of participants varied across assessment periods due to dropouts (see flow chart). Significant values (*p*, 0.05) are shown in bold.

We controlled for wave and baseline levels of the variable. Mean and SD are not adjusted

* The baseline level of the variable is a significant covariate in the model.
*β*, regression coefficients; CI, confidence interval; *d*, Cohen's d as an effect size measure; ITT, intention-to-treat

When the Benjamini–Hochberg correction was applied to correct for multiple comparisons, the following effects were no longer significant: in TAU vs FIBRO-On 6-week PCS; in FIBRO-On vs FIBRO-Out: 6-week TKS; R-NPQ at post-intervention and follow-up.

Click here to access/download;Tables;Table 4_Revised.docx

**Table 4.** Results from the Mediation Analysis.

| Effect of interest | Estimate & 95%CI |
|---|---|
| Total effect (c' + indirect effects) | **-0.11 (-0.21, -0.01); *p* = .048** |
| Direct effect (c'):<br>Grup → FIQR follow-up | -0.04 (-0.17, 0.09); *p* = .563 |
| Indirect effect Kinesiophobia (TKS):<br>Grup → TKS post →FIQR follow-up | **-0.1 (-0.16, -0.3); *p* = .003** |
| Indirect effect Pain Catastrophising (PCS):<br>Grup → PCS post →FIQR follow-up | 0.01 (-0.04, 0.04); *p* = .872 |
| Indirect effect Psychological Inflexibility (PIPS):<br>Grup → PIPS post →FIQR follow-up | **-0.04 (-0.08, -0.01); *p* = .042** |
| Indirect effect Pain Knowledge (R-NPQ):<br>Grup → R-NPQ post →FIQR follow-up | 0.06 (-0.01, 0.14); *p* = .136 |

*Note.* Standardised regression coefficients are presented. CI from *n*=5000 Bootstraping samples. c' = effect of group (FIBROWAL vs. TAU) on functional impairment (FIQR) at 6-month follow-up.

**Supplementary File 1**

| **FIBROWALK Fidelity Measure (FFM)**<br><br>***Please indicate the therapist's degree of compliance with each of the following statements.*** | **0 (not met)** | **1 (rarely met)** | **2 (sometimes met)** | **3 (often met)** | **4 (always met)** |
|---|---|---|---|---|---|
| **1-General organization** | | | | | |
| 1. The established sessions (number and duration) are respected: 12 sessions of 2 hours per week. | **0** | **1** | **2** | **3** | **4** |
| 2. The scheduled times for each session component are followed: 15 minutes for review, 1 hour for the conceptual phase, 40 minutes for the exercise phase, and 5 minutes for homework. | **0** | **1** | **2** | **3** | **4** |
| 3. The sequence of session content is followed as prescribed.. | **0** | **1** | **2** | **3** | **4** |
| **Subtotal_1 - General organization (from 0 to 4)** | **/3 = _____** | | | | |
| **2-Knowledge of the therapist** | | | | | |
| 1. The core concepts of the FIBROWALK program are explained according to the manual, considering only the content delivered by the physiotherapist (PNE and TE) and/or the psychologist (CBT and MT), as applicable. | **0** | **1** | **2** | **3** | **4** |
| 2. The contents of TE, CBT, and MT are presented within the theoretical framework of PNE, ensuring conceptual consistency with its theoretical model. | **0** | **1** | **2** | **3** | **4** |
| **Subtotal_2 - Knowledge of the therapist (from 0 to 4)** | **/2 = _____** | | | | |
| **3-Therapist's skills to apply motivational interviewing:** | | | | | |
| 1. Demonstrates collaboration (showing respect for the individual to activate their motivation and personal resources for change). | **0** | **1** | **2** | **3** | **4** |
| 2. Demonstrates acceptance (maintains an open, non-judgmental attitude, refraining from approving or disapproving behavior, fostering a supportive communication style). | **0** | **1** | **2** | **3** | **4** |

| | | | | | |
|---|---|---|---|---|---|
| 3. It presents compassion (understood as the active promotion of the well-being of others and the prioritization of their needs, and not as pity or pity for their suffering). | **0** | **1** | **2** | **3** | **4** |
| 4. Demonstrates evocation (believes individuals possess the capacity for change and seeks to activate their internal resources to initiate that change). | **0** | **1** | **2** | **3** | **4** |
| **Subtotal_3 - Therapist's skills in applying motivational interviewing (0 to 4)** | **/4 = _____** | | | | |
| **4-The therapist's skills of a general nature** | | | | | |
| 1. Displays confidence (demonstrates mastery of the program content and its application). | **0** | **1** | **2** | **3** | **4** |
| 2. Communicates assertively (expresses emotions and thoughts appropriately, without hostility or aggression). | **0** | **1** | **2** | **3** | **4** |
| 3. Displays empathy (demonstrates understanding, respect, support, warmth, and commitment by putting themselves in the participant's position). | **0** | **1** | **2** | **3** | **4** |
| 4. Demonstrates responsiveness (answers participants' questions using scientific knowledge while adapting explanations to their level of understanding).. | **0** | **1** | **2** | **3** | **4** |
| 5. Facilitates recognizing discrepancy (helps participants recognize the gap between their current behavior and personal goals). | **0** | **1** | **2** | **3** | **4** |
| 6. Promotes self-efficacy (supports belief in the possibility of change, increasing the likelihood of its occurrence). | **0** | **1** | **2** | **3** | **4** |
| 7. Addresses discordance (clarifies the participant's freedom of choice while exploring ambivalence and internal motivations to increase the likelihood of change). | **0** | **1** | **2** | **3** | **4** |
| **Subtotal_4 - Therapist's general skills (from 0 to 4)** | **/7 = _____** | | | | |
| **5-Group management** | | | | | |
| 1. Manages the group effectively (encourages participation from quieter members, limits dominance by more vocal participants, and facilitates the acquisition of new skills and knowledge). | **0** | **1** | **2** | **3** | **4** |

| | | | | | |
|---|---|---|---|---|---|
| 2. Creates a safe learning environment (politely and efficiently, encourages participants to ask questions about the therapy without disclosing personal medical histories). | **0** | **1** | **2** | **3** | **4** |
| 3. Maintains group cohesion (fosters a sense of unity among participants even without formal introductions). | **0** | **1** | **2** | **3** | **4** |
| **Subtotal_5 - Group management (from 0 to 4)** | **/3 = _____** | | | | |
| **Total (Sum of subtotals 1,2,3,4 and 5; score from 0 to 20)** | | | | | |

**FIBROWALK Fidelity Measure (FW-Fidelity Measure)**

**About FW-Fidelity Measure**

This measure aims to assist clinicians and researchers who wish to apply the FIBROWALK therapy in clinical practice or research projects. It can be used both for self-assessment and evaluating other clinicians. The key areas evaluated in FIBROWALK include:

- General organization
- Therapist's knowledge
- Therapist's skills (motivational interviewing and general skills)
- Group management

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**Definitions**

**General Organization**

The FIBROWALK therapy consists of four core components: PSE (Pain Science Education), TE (Therapeutic Exercise), CBT (Cognitive Behavioural Therapy), and MT (Mindfulness Training). Each component follows a specific sequence and duration. It is essential to respect the dosage of each component and its distribution over time.

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**Therapist's Knowledge**

Therapists must have a solid theoretical understanding of FIBROWALK components (delivered by one or more clinical therapists), ensuring that the concepts outlined for each are correctly explained. Additionally, they must have a deep understanding of fibromyalgia, its consequences, and its impact to establish assertive and constructive communication with patients.

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**Therapist's Skills**

**Motivational Interviewing Skills:**
The correct therapeutic attitude is crucial for successful implementation of FIBROWALK. This includes:

- **Collaboration:** Demonstrating absolute respect for the patient, activating their motivation and personal resources for change.
- **Acceptance:** Maintaining an open, non-judgmental attitude without approving or disapproving the patient's behavior, fostering a supportive communication style.
- **Compassion:** Actively promoting the patient's well-being by prioritizing their needs without showing pity.
- **Evocation:** Believing that patients possess the capacity for change and activating those internal resources to initiate transformation.

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**General Skills:**

- **Confidence:** Showing mastery of the program's content and its implementation.
- **Assertiveness:** Expressing thoughts and emotions appropriately, without hostility or aggression.
- **Empathy:** Demonstrating understanding, respect, support, warmth, and commitment by putting oneself in the participants' position.
- **Responsiveness:** Answering participants' questions with scientific knowledge adapted to their level of understanding.
- **Discrepancy Creation:** Helping participants recognize the gap between their current behavior and personal goals.
- **Self-Efficacy Promotion:** Encouraging belief in the possibility of change, increasing the likelihood of achieving it.
- **Addressing Discordance:** Clarifying the patient's freedom of choice while exploring ambivalence and internal motivations toward change.

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**Group Management**

- **Group Control:** Managing speaking time effectively, encouraging quieter participants to speak, and limiting dominance by more vocal members.
- **Creating Safe Contexts:** Politely and efficiently fostering a learning environment, discouraging the discussion of personal medical histories while encouraging therapy-related questions.
- **Group Cohesion:** Maintaining a sense of unity among participants, even without formal introductions.

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**How to Administer the FFM**

**Procedure**

The evaluator must possess a thorough and demonstrable understanding of the FIBROWALK program's contents and dynamics. Before starting a session, they should familiarize themselves with the evaluation items.

The evaluator will review at least three sessions (one per month) of the intervention, either through video recordings or direct observation, and complete the FFM. All items will be scored on a scale from 0 to 4.

- 0 = Not met
- 1 = Rarely met
- 2 = Sometimes met
- 3 = Often met
- 4 = Always met

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**Scoring**

Each section of the scale has a maximum score of 4 points, based on the average of its items. The total score is obtained by summing the scores of all five sections, ranging from 0 to 20 points.

The five evaluated sections are:

1. **General Organization:** (3 items)
2. **Therapist's Knowledge:** (2 items)
3. **Motivational Interviewing Skills:** (4 items)
4. **General Therapist Skills:** (7 items)
5. **Group Management:** (3 items)

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**Supplementary File 2**

**Differences between completers and non-completers**

There were differences between the participants who completed the follow-up (i.e., "completers", $n$ = 197) and those who failed to complete the follow-up (i.e., "non-completers"; $n$ = 28). Results showed significant differences in marital status, education, and medication. Regarding marital status, there was a higher proportion of single and coupled individuals in the completer group compared to the non-completer group, $\chi^2(3, N = 225) = 16.31$; $p = 0.001$. Regarding education, there was a higher proportion of participants with no studies in the non-completers group, $\chi^2(5, N = 225) = 15.73$; $p = 0.008$. Finally, a higher proportion of non-completers reported that they were currently taking medication, $\chi^2(1, N = 225) = 5.08$; $p = 0.024$. Significant differences were also found in the baseline scores for psychological inflexibility ($t(44.35) = 2.19$, $p = 0.034$) and pain knowledge ($t(223) = 2.35$, $p = 0.020$), with completers scoring lower in psychological inflexibility and higher in pain knowledge than non-completers.

**Number Needed to Treat (NNT)**

A total of 25 patients (36.5%) in FIBRO-Out, 25 (37.3%) in FIBRO-On, and 6 (8.2%) in TAU reached the criterion of ≥ 20% FIQR reduction at post-treatment assessment (i.e., post-treatment responders). The absolute risk reduction (ARR) in FIBRO-Out vs TAU was 28.29% (95% CI = 14.83% to 41.74%) with NNT = 4 (95% CI = 2.4 to 6.7), meaning that it is necessary to treat four patients to identify one additional responder in the active group compared to TAU. Like FIBRO-Out, the ARR in FIBRO-On vs TAU was 29.09% (95% CI = 15.91% to 42.28%) with NNT = 4 (95% CI = 2.4 to 6.3). The ARR in FIBRO-Out vs FIBRO-On was 0.81% (95% CI = -15.79% to 17.40%) with NNT = 125. Because, in this case, the 95% CI for the ARR extends from a negative number (FIBRO-On may harm) to a positive number (FIBRO-On may

benefit), the NNT result is unreliable. In other words, we cannot say with 95% certainty whether FIBRO-On is harmful, has no effect, or is helpful compared with FIBRO-Out.

At the 6-month follow-up, a total of 12 patients (20%) in FIBRO-Out, 15 (23.8%) in FIBRO-On, and 9 (12.2%) in TAU reached the criterion of ≥ 20% FIQR reduction (follow-up responders). The ARR in FIBRO-Out vs TAU was 7.84% (95% CI = -4.73% to 20.40%) with NNT = 13. The ARR in FIBRO-On vs TAU was 11.65% (95% CI = -1.24% to 24.53%) with NNT = 9. The ARR in the FIBRO-Out vs FIBRO-On comparison was 3.81% (95% CI = -10.79% to 18.41%), and the NNT is 27. Since the 95% CI for the ARR ranged from a negative number to a positive number for NNT analyses at the 6-month follow-up, the NNT result is not reliable and we cannot say whether FIBRO-On or FIBRO-Out (compared to TAU) is harmful, has no effect, or is useful. The same is true when comparing FIBRO-On to FIBRO-Out.

**Per-Protocol Approach (PPA)**

Based on the PPA, 28 participants who attended less than 9 out of 12 sessions were excluded. The per-protocol sample size was distributed as follows: in the FIBRO-On arm, the baseline, 6-week, post-intervention, and 6-month follow-up sample sizes were *n*= 65, 64, 64 and 61, respectively. In the FIBRO-Out arm, the sample sizes were *n* = 57 (baseline), 54 (6-week), 53 (post-intervention) and 54 (follow-up), respectively.

When the PPA analyses were conducted, a similar pattern emerged, with generally larger effect sizes compared to the ITT analyses. In terms of clinical measures, statistical significance was observed in CSI scores in the FIBRO-Out post-intervention ($p$ = 0.21, $d$ = 0.53), whereas the statistical significance previously observed in PSQI in FIBRO-Out post-intervention disappeared ($p$ = 0.093, $d$ = 0.41). Regarding potential mediators, FIBRO-On showed statistically greater reductions in kinesiophobia compared to FIBRO-Out ($p$ = 0.06, $d$ = 0.37). However, this effect disappeared in the PPA analysis at the 6-week mid-intervention evaluation. Additionally, FIBRO-Out showed statistically greater reductions in psychological

inflexibility at mid-intervention compared to TAU. Differences in PPA analyses can be found in the Supplementary Table 1 and Table 2.

**Baseline characterization of FIBROWALK clinical responders**

Responders in both arms shared similar characteristics, with the only notable difference being that FIBRO-On responders at post-intervention attended significantly more therapy sessions than FIBRO-Out responders (9.96 ± 1.26 vs. 11.92 ± 0.40; $p < 0.001$). Similarly, at follow-up, FIBRO-On responders had higher mean session attendance (9.67 ± 1.30 vs. 11.87 ± 0.52; $p < 0.001$), lower homework practice frequency during treatment (5.63 ± 0.85 vs. 3.91 ± 1.20; $p < 0.001$), and lower perceived stress levels (9.92 ± 2.19 vs. 7.27 ± 2.55; $p = 0.009$) compared to FIBRO-Out responders.

Given the consistent direction of differences between responders and non-responders across both treatment arms, the high similarity in responder profiles between the FIBRO-On and FIBRO-Out groups, and to ensure adequate representation of responders (particularly at follow-up) in the comparative analyses, we pooled the samples from both FIBROWALK arms for further analyses. The details of these comparative analyses are available in Supplementary Table 5.

When comparing responders ($n = 48$) vs. non-responders ($n = 82$) at post-intervention in the FIBROWALK arms, statistically significant differences at post-treatment were observed between responders and non-responders in several variables, including age ($p = 0.014$), BMI ($p = 0.002$), HADS-Depression ($p = 0.002$), PSS ($p = 0.006$), CSI ($p = 0.001$), PSQI ($p = 0.038$), TSK ($p = 0.029$), PCS ($p = 0.005$), PIPS ($p = 0.017$), Expectancies/Credibility ($p = 0.032$), Days/week of homework during treatment ($p = 0.005$), Commitment to homework during treatment ($p = 0.009$), Days/week of homework after treatment ($p = 0.001$), and Commitment to homework after treatment ($p = 0.042$). Responders at post-treatment were characterized by being older, having a higher Body Mass Index (BMI), lower depression scores (HADS-

Depression), lower perceived stress scores (PSS), lower Central Sensitisation Inventory (CSI) scores, better sleep quality (PSQI), less kinesiophobia (TSK), less pain catastrophizing (PCS), lower psychological inflexibility (PIPS), better scores in expectancies and credibility, and higher adherence to homework, both during and after the therapy.

At follow-up, significant differences between responders ($n$ = 27) and non-responders ($n$ = 96) were found in years since diagnosis ($p$ = 0.048), multiple chemical sensitivity diagnosis ($p$ = 0.039), anxiety diagnosis ($p$ = 0.015), PIPS ($p$ = 0.044), Days/week of homework during treatment ($p$ = 0.007), Commitment to homework during treatment ($p$ = 0.031), Days/week of homework after treatment ($p$ = 0.015), and Commitment to homework after treatment ($p$ = 0.047). Responders at follow-up were characterized, compared to non-responders, by having more years since diagnosis, a higher prevalence of multiple chemical sensitivity, a higher prevalence of anxiety diagnosis, higher commitment to homework practices both during and after therapy, as well as a higher frequency of practice during and after therapy. No significant differences were found for the remaining variables (see Supplementary Table 5).

**Supplementary Table 1.** Descriptive statistics and Between-Group Analyses for Primary and Secondary Outcomes (PPA)

| | FIBRO-On | FIBRO-Out | TAU | TAU vs FIBRO-On | | | TAU vs FIBRO-Out | | | FIBRO-On vs FIBRO-Out | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean (*SD*) | Mean (*SD*) | Mean (*SD*) | *d* | *t*(*p*) | $\beta$ (95% CI) | *d* | *t*(*p*) | $\beta$ (95% CI) | *d* | *t*(*p*) | $\beta$ (95% CI) |
| **Primary Outcome** | | | | | | | | | | | | |
| **FIQR (0-100)*** | | | | | | | | | | | | |
| Baseline | 73.13 (15.92) | 72.98 (14.00) | 70.59 (16.13) | | | | | | | | | |
| 6-week | 65.67 (18.47) | 66.11 (15.62) | 69.85 (15.36) | -0.59 | **-3.30 (0.001)** | -6.33 (-10.10; -2.56) | -0.55 | **-2.94 (0.003)** | -5.90 (-9.84; -1.96) | -0.04 | 0.21 (0.836) | 0.43 (-3.63; 4.49) |
| Post-intervention | 61.32 (20.65) | 62.88 (16.51) | 70.68 (16.08) | -1.08 | **-5.07 (<0.001)** | -11.67 (-16.19; -7.15) | -0.97 | **-4.31 (<0.001)** | -10.40 (-15.14; -5.67) | -0.12 | 0.51 (0.612) | 1.26 (-3.62; 6.15) |
| Follow-up | 65.34 (19.29) | 67.52 (15.61) | 69.54 (16.87) | -0.59 | **-2.58 (0.010)** | -6.35 (-11.20; -1.51) | -0.39 | -1.62 (0.106) | -4.15 (-9.18; 0.88) | -0.21 | 0.83 (0.407) | 2.21 (-3.01; 7.43) |
| **Secondary Outcomes** | | | | | | | | | | | | |
| **NRS-Pain (0-10)*** | | | | | | | | | | | | |
| Baseline | 7.85 (1.59) | 7.89 (1.36) | 7.73 (1.80) | | | | | | | | | |
| 6-week | 7.27 (1.80) | 7.22 (1.72) | 7.60 (1.62) | -0.28 | -1.43 (0.153) | -0.39 (-0.92; 0.14) | -0.37 | -1.87 (0.062) | -0.53 (-1.09; 0.03) | 0.10 | -0.49 (0.625) | -0.14 (-0.72; 0.43) |
| Post-intervention | 6.75 (2.21) | 6.60 (1.75) | 7.66 (1.97) | -0.70 | **-3.15 (0.002)** | -1.00 (-1.62; -0.38) | -0.88 | **-3.76 (<0.001)** | -1.24 (-1.89; -0.59) | 0.18 | -0.73 (0.467) | -0.25 (-0.92; 0.42) |
| Follow-up | 6.93 (2.17) | 7.31 (1.62) | 7.54 (1.92) | -0.47 | **-1.99 (0.046)** | -0.66 (-1.32, -0.01) | -0.27 | -1.11 (0.268) | -0.38 (-1.06; 0.30) | -0.20 | 0.78 (0.443) | 0.28 (-0.42; 0.98) |
| **NRS-Fatigue (0-10)*** | | | | | | | | | | | | |
| Baseline | 7.83 (2.16) | 7.73 (2.03) | 7.29 (2.54) | | | | | | | | | |
| 6-week | 7.23 (2.21) | 6.85 (2.18) | 7.49 (2.24) | -0.38 | -1.81 (0.071) | -0.74 (-1.54; 0.06) | -0.53 | **-2.40 (0.017)** | -1.03 (-1.87; -0.19) | 0.15 | -0.65 (0.516) | -0.29 (-1.15; 0.58) |
| Post-intervention | 7.19 (2.08) | 7.06 (1.71) | 7.73 (2.16) | -0.53 | **-2.28 (0.023)** | -1.03 (-1.92; -0.14) | -0.56 | **-2.28 (0.023)** | -1.08 (-2.01; -0.15) | 0.03 | -0.10 (0.923) | -0.05 (-1.00; 0.91) |
| Follow-up | 7.46 (2.08) | 7.24 (1.95) | 7.51 (2.15) | -0.30 | -1.26 (0.209) | -0.58 (-1.49; 0.33) | -0.36 | -1.43 (0.152) | -0.69 (-1.63; 0.25) | 0.06 | -0.21 (0.831) | -0.11 (-1.09; 0.87) |
| **HADS-Anxiety (0-21)*** | | | | | | | | | | | | |
| Baseline | 12.85 (4.81) | 14.00 (3.84) | 13.88 (4.07) | | | | | | | | | |
| 6-week | 11.92 (4.81) | 13.41 (3.52) | 13.58 (4.27) | -0.21 | -1.11 (0.267) | -0.52 (-1.45; 0.40) | -0.05 | -0.23 (0.817) | -0.01 (-1.08; 0.85) | -0.16 | 0.81 (0.420) | 0.41 (-0.59; 1.40) |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Post-intervention | 11.48 (5.25) | 12.81 (4.41) | 14.00 (4.07) | -0.55 | **-2.51 (0.012)** | -1.39 (-2.48; -0.30) | -0.46 | **-2.01 (0.044)** | -1.09 (-2.31; -0.03) | -0.09 | 0.37 (0.714) | 0.22 (-0.96; 1.39) |
| Follow-up | 12.13 (5.26) | 13.91 (4.27) | 13.31 (4.05) | -0.04 | -0.18 (0.855) | -0.11 (-1.26; 1.04) | 0.21 | 0.87 (0.386) | 0.41 (-0.67; 1.73) | -0.25 | 1.01 (0.315) | 0.64 (-0.61; 1.88) |
| **HADS-Depression (0-21)*** | | | | | | | | | | | | |
| Baseline | 12.26 (4.45) | 12.75 (4.23) | 11.8 (4.44) | | | | | | | | | |
| 6-week | 10.91 (5.03) | 11.76 (4.41) | 11.77 (4.34) | -0.50 | **-2.72 (0.007)** | -1.32 (-2.28; -0.37) | -0.31 | -1.25 (0.212) | -0.61 (-1.56; 0.35) | -0.19 | 0.97 (0.332) | 0.51 (-0.52; 1.54) |
| Post-intervention | 10.52 (4.72) | 11.64 (4.94) | 12.45 (4.72) | -0.85 | **-3.88 (<0.001)** | -2.23 (-3.36; -1.10) | -0.59 | **-2.85 (0.004)** | -1.63 (-2.75; -0.51) | -0.26 | 1.08 (0.279) | 0.67 (-0.55; 1.89) |
| Follow-up | 11.48 (4.62) | 12.48 (4.84) | 11.64 (4.64) | -0.23 | -0.98 (0.329) | -0.60 (-1.79; 0.60) | 0.01 | 0.35 (0.728) | 0.21 (-0.97; 1.39) | -0.24 | 0.95 (0.342) | 0.63 (-0.67; 1.92) |
| **PSS (0-16)*** | | | | | | | | | | | | |
| Baseline | 9.06 (3.23) | 9.63 (2.88) | 9.25 (2.67) | | | | | | | | | |
| 6-week | 8.53 (3.00) | 9.07 (2.60) | 9.05 (2.43) | -0.15 | -0.89 (0.426) | -0.31 (-1.62; 0.23) | -0.13 | -0.66 (0.509) | -0.27 (-1.07; 0.53) | -0.02 | 0.10 (0.923) | 0.04 (-0.78; 0.86) |
| Post-intervention | 8.17 (3.46) | 9.04 (3.01) | 9.38 (2.71) | -0.50 | -2.24 (**0.025**) | -1.01 (-1.89; -0.12) | -0.34 | -1.42 (0.155) | -0.67 (-1.60; 0.25) | -0.17 | 0.69 (0.489) | 0.34 (-0.62: 1.29) |
| Follow-up | 8.66 (3.23) | 9.57 (2.78) | 9.53 (2.78) | -0.35 | -1.47 (0.142) | -0.69 (-0.23; 1.62) | -0.14 | -0.56 (0.572) | -0.28 (-1.24; 0.68) | -0.21 | 0.82 (0.412) | 0.42 (-0.58; 1.41) |
| **CSI (0-36)*** | | | | | | | | | | | | |
| Baseline | 27.86 (6.08) | 28.16 (5.67) | 26.64 (5.81) | | | | | | | | | |
| 6-week | 26.31 (6.25) | 26.78 (5.76) | 26.19 (5.80) | -0.24 | -1.29 (0.199) | -0.97 (-2.45; 0.51) | -0.17 | -0.87 (0.383) | -0.78 (-2.24; 0.86) | -0.07 | 0.34 (0.73o) | 0.10 (-1.32; 1.88) |
| Post-intervention | 25.31 (6.60) | 26.32 (5.97) | 27.03 (5.25) | -0.68 | **-3.13 (0.002)** | -2.80 (-4.56; -1.05) | -0.53 | **-2.30 (0.021)** | -1.67 (-4.00; -0.32) | -0.16 | 0.67 (0.505) | 0.86 (-1.25: 2.54) |
| Follow-up | 26.46 (6.71) | 27.13 (6.08) | 27.16 (5.43) | -0.41 | -1.76 (0.079) | -1.67 (-3.53; 0.19) | -0.37 | -1.55 (0.263) | -1.04 (-3.46; 0.41) | -0.04 | 0.14 (0.888) | 0.66 (-1.86; 2.15) |
| **SF-PF (0-100)*** | | | | | | | | | | | | |
| Baseline | 30.77 (18.82) | 31.34 (18.94) | 28.67 (20.62) | | | | | | | | | |
| 6-week | 34.53 (22.00) | 32.22 (17.58) | 29.66 (18.86) | 0.24 | 1.33 (0.183) | 2.75 (-1.30; 6.79) | 0.01 | 0.07 (0.946) | 0.14 (-3.79; 4.06) | 0.25 | -1.27 (0.205) | -2.82 (-7.18; 1.54) |
| Post-intervention | 36.72 (22.61) | 32.92 (21.06) | 29.38 (19.72) | 0.42 | 1.93 (0.055) | 4.70 (-0.11; 9.51) | 0.04 | 0.15 (0.881) | 0.36 (-4.32; 5.04) | 0.38 | -1.61 (0.108) | -4.26 (-9.45; 0.94) |
| Follow-up | 34.43 (21.35) | 32.13 (19.61) | 29.73 (19.3) | 0.21 | 0.90 (0.368) | 2.35 (-2.77; 7.46) | -0.10 | -0.67 (0.503) | -1.70 (-6.67; 3.28) | 0.31 | -1.23 (0.120) | -3.45 (-8.96; 2.07) |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PSQI (0-15)*** | | | | | | | | | | | | |
| Baseline | 10.76 (3.54) | 9.79 (3.13) | 9.91 (3.15) | | | | | | | | | |
| 6-week | 10.00 (3.44) | 9.77 (3.57) | 10.51 (3.37) | -0.55 | **-2.62 (0.009)** | -1.18 (-2.07; -0.30) | -0.31 | -1.46 (0.145) | -0.67 (-1.56; 0.23) | -0.24 | 1.09 (0.276) | 0.52 (-0.42; 1.45) |
| Post-intervention | 9.88 (4.10) | 9.71 (3.21) | 10.87 (3.33) | -0.66 | **-2.77 (0.006)** | -1.44 (-2.46; -0.42) | -0.41 | -1.68 (0.093) | -0.89 (-1.94; 0.15) | -0.25 | 0.99 (0.322) | 0.54 (-0.53; 1.62) |
| Follow-up | 10.14 (3.84) | 9.77 (3.20) | 10.30 (3.17) | -0.21 | -0.82 (0.414) | -0.44 (-1.51; 0.62) | -0.15 | -0.69 (0.550) | -0.33 (-1.42; 0.76) | -0.05 | 0.20 (0.844) | 0.11 (-1.01; 1.24) |
| **MISCI (10-50)*** | | | | | | | | | | | | |
| Baseline | 21.88 (7.34) | 22.57 (8.59) | 24.56 (8.84) | | | | | | | | | |
| 6-week | 24.64 (8.21) | 24.63 (7.51) | 24.71 (8.18) | 0.55 | **2.77 (0.003)** | 3.01 (0.96; 4.57) | 0.31 | 1.66 (0.098) | 1.60 (-0.29; 3.49) | 0.23 | -1.18 (0.238) | -1.17 (-3.12; 0.78) |
| Post-intervention | 25.25 (8.87) | 25.58 (8.67) | 23.42 (8.09) | 0.91 | **4.58 (<0.001)** | 4.20 (2.44; 6.72) | 0.81 | **3.56 (<0.001)** | 4.07 (1.82; 6.31) | 0.10 | -0.44 (0.664) | -0.51 (-2.83: 1.80) |
| Follow-up | 23.26 (9.08) | 23.33 (8.37) | 24.96 (9.12) | 0.20 | 1.00 (0.387) | 0.87 (-1.27; 3.28) | 0.04 | 0.16 (0.871) | 0.20 (-2.17; 2.56) | 0.16 | -0.65 (0.518) | -0.81 (-3.26; 1.64) |

*Note.* TAU = treatment-as-usual; FIBRO-On = online; FIBRO-Out = outdoor; FIQR = Fibromyalgia Impact Questionnaire; NRS = Numerical Rating Scale of Perceived Pain/Fatigue; HADS = Hospital Anxiety and Depression Scale; PSS = Perceived Stress Scale; CSI = Central Sensitization Inventory; SF-PF = Physical Function Subscale of the Short Form-36 Health Survey; PSQI = Pittsburgh Sleep Quality Index, brief version; MISCI = Multidimensional Inventory of Subjective Cognitive Impairment.

The number of participants varied across assessment periods due to dropouts (see flow chart). Significant values ($p < 0.05$) are shown in bold. We controlled for wave and baseline levels of the variable. Mean and SD are not adjusted.

* The baseline level of the variable is a significant covariate in the model.
$\beta$, regression coefficients; CI, confidence interval; *d*, Cohen's d as an effect size measure; PPA, per-protocol approach.

When the Benjamini–Hochberg correction was applied to correct for multiple comparisons, the following effects were no longer significant: in TAU vs FIBRO-On Follow-up NRS-Pain, Post-intervention PSS; in TAU vs FIBRO-Out 6-week and Post-intervention NRS-Fatigue, Post-intervention HADS-Anxiety, Post-intervention CSI.

**Supplementary Table 2.** Descriptive statistics and Between-Group Analyses for Potential Mediators (PPA)

| | **FIBRO-On** | **FIBRO-Out** | **TAU** | **TAU vs FIBRO-On** | | | **TAU vs FIBRO-Out** | | | **FIBRO-On vs FIBRO-Out** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Mean (*SD*) | Mean (*SD*) | Mean (*SD*) | *d* | *t*(*p*) | *β* (95% CI) | *d* | *t*(*p*) | *β* (95% CI) | *d* | *t*(*p*) | *β* (95% CI) |
| **TSK (11-44)*** | | | | | | | | | | | | |
| Baseline | 30.27 (7.60) | 30.16 (7.47) | 30.99 (7.81) | | | | | | | | | |
| 6-week | 27.67 (6.39) | 27.06 (6.51) | 30.99 (8.34) | -1.00 | **-5.57 (<0.001)** | -4.92 (-6.65; -3.19) | -0.63 | **-3.36 (0.001)** | -3.10 (-4.92; -1.29) | -0.37 | 1.91 (0.057) | 1.82 (-0.05; 3.69) |
| Post-intervention | 24.54 (6.51) | 24.09 (6.51) | 30.10 (8.39) | -1.34 | **-6.24 (<0.001)** | -6.60 (-8.68; -4.52) | -1.05 | **-4.65 (<0.001)** | -5.16 (-7.33; -2.98) | -0.27 | 1.26 (0.207) | 1.44 (-0.80; 3.69) |
| Follow-up | 25.22 (7.21) | 25.35 (7.22) | 29.73 (8.34) | -0.96 | **-4.17 (<0.001)** | -4.72 (-6.94; -2.50) | -0.71 | **-2.96 (0.003)** | -3.48 (-5.79; -1.17) | -0.22 | 1.02 (0.310) | 1.24 (-1.15; 3.63) |
| **PCS (0-52)*** | | | | | | | | | | | | |
| Baseline | 28.40 (13.65) | 28.09 (13.01) | 26.59 (14.66) | | | | | | | | | |
| 6-week | 25.49 (12.89) | 25.28 (12.92) | 26.84 (13.80) | -0.52 | **-2.88 (0.004)** | -3.18 (-7.58; -1.43) | -0.30 | -1.58 (0.115) | -2.59 (-5.80; 0.63) | -0.22 | 1.13 (0.257) | 1.92 (-1.40; 5.23) |
| Post-intervention | 24.6 (13.27) | 24.60 (13.35) | 29.16 (13.05) | -0.91 | **-4.26 (<0.001)** | -6.58 (-11.66; -4.30) | -0.66 | **-2.94 (0.003)** | -5.77 (-9.62; -1.91) | -0.25 | 1.09 (0.275) | 2.21 (-1.76; 6.19) |
| Follow-up | 25.73 (14.11) | 25.63 (13.93) | 29.05 (13.02) | -0.82 | **-3.56 (<0.001)** | -6.49 (-11.06; -3.19) | -0.55 | **-2.31 (0.021)** | -4.81 (-8.90; -0.72) | -0.27 | 1.07 (0.283) | 2.32 (-1.92: 6.56) |
| **PIPS (7-84)*** | | | | | | | | | | | | |
| Baseline | 63.81 (15.19) | 63.77 (15.72) | 56.35 (18.50) | | | | | | | | | |
| 6-week | 58.93 (16.32) | 58.02 (16.28) | 55.49 (18.09) | -0.24 | -1.27 (0.203) | -2.73 (-6.94; 1.48) | -0.41 | **-2.08 (0.038)** | -4.65 (-9.06; -0.25) | 0.17 | -0.83 (0.406) | -1.92 (-6.46; 2.62) |
| Post-intervention | 55.43 (15.82) | 54.70 (15.69) | 57.67 (17.32) | -0.84 | **-3.84 (<0.001)** | -9.70 (-14.66; -4.75) | -0.89 | **-3.86 (<0.001)** | -10.21 (-15.40; -5.02) | 0.04 | -0.18 (0.854) | -0.50 (-5.85; 4.85) |
| Follow-up | 56.45 (16.4) | 55.15 (16.28) | 55.31 (18.5) | -0.36 | -1.54 (0.125) | -4.11 (-9.35; 1.14) | -0.67 | **-2.78 (0.006)** | -7.70 (-13.15; -2.25) | 0.31 | -1.25 (0.213) | -3.59 (-9.24: 2.06) |
| **R-NPQ (0-13)*** | | | | | | | | | | | | |
| Baseline | 4.48 (2.17) | 4.88 (2.09) | 4.79 (2.20) | | | | | | | | | |
| 6-week | 6.70 (2.17) | 6.98 (1.93) | 4.70 (2.40) | 1.27 | **6.86 (<0.001)** | 2.42 (1.73; 3.12) | 1.19 | **6.13 (<0.001)** | 3.27 (1.54; 2.99) | 0.08 | -0.41 (0.680) | -0.16 (-0.91; 0.59) |
| Post-intervention | 7.67 (2.02) | 7.85 (1.97) | 4.18 (2.47) | 1.56 | **7.14 (<0.001)** | 2.99 (2.17; 3.81) | 1.92 | **8.39 (<0.001)** | 3.67 (2.81; 4.53) | -0.36 | 1.52 (0.129) | 0.69 (-0.20: 1.57) |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Follow-up | 7.22 (2.09) | 7.33 (2.04) | 4.27 (2.49) | 1.18 | **5.08 (<0.001)** | 2.25 (1.38; 3.12) | 1.58 | **6.55 (<0.001)** | 3.02 (2.11; 3.92) | -0.40 | 1.59 (0.111) | 0.76 (-0.18; 1.70) |

*Note*. TAU = treatment-as-usual; FIBRO-On = online; FIBRO-Out = outdoor; TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophising Scale; PIPS = Psychological Inflexibility in Pain Scale; R-NPQ = Revised Neurophysiology of Pain Questionnaire.

The number of participants varied across assessment periods due to dropouts (see flow chart). Significant values (*p*, 0.05) are shown in bold.

We controlled for wave and baseline level of the variable. Mean and SD are not adjusted

* The baseline level of the variable is a significant covariate in the model.
*β*, regression coefficients; CI, confidence interval; *d*, Cohen's d as an effect size measure; PPA, per-protocol approach.

When the Benjamini–Hochberg correction was applied to correct for multiple comparisons, the following effects were no longer significant: in TAU vs FIBRO-On 6-week PCS; in TAU vs FIBRO-Out 6-week PIPS.

**Supplementary Table 3.** PGIC and PSIC results (*n*, %)

| | | PGIC* | PSIC-1 | PSIC-2 | PSIC-3* | PSIC-4 | PSIC-5 |
|---|---|---|---|---|---|---|---|
| **Mean (*SD*)** | FIBRO-On | 3.72 (0.98) | 3.69 (1.10) | 3.76 (0.96) | 4.31 (1.18) | 3.90 (1.44) | 4.01 (1.12) |
| | FIBRO-Out | 3.38 (0.71) | 3.38 (0.83) | 3.54 (0.86) | 3.84 (0.94) | 3.54 (0.90) | 3.79 (0.81) |
| **Very much improved** | FIBRO-On | 0 | 1 (1.3) | 1 (1.3) | 0 | 2 (2.7) | 1 (1.3) |
| | FIBRO-Out | 0 | 2 (2.7) | 1 (1.3) | 1 (1.3) | 1 (1.3) | 0 |
| **Much improved** | FIBRO-On | 6 (8) | 8 (10.7) | 6 (8.0) | 2 (2.7) | 10 (13.3) | 3 (4.0) |
| | FIBRO-Out | 4 (5.3) | 4 (5.3) | 5 (6.7) | 2 (2.7) | 4 (5.3) | 3 (4.0) |
| **Minimally improved** | FIBRO-On | 20 (26.7) | 16 (21.3) | 11 (14.7) | 11 (14.7) | 11 (14.7) | 15 (20.0) |
| | FIBRO-Out | 34 (45.3) | 29 (38.7) | 21 (28.0) | 16 (21.3) | 25 (33.3) | 17 (22.7) |
| **No change** | FIBRO-On | 33 (44.0) | 34 (45.3) | 43 (57.3) | 35 (46.7) | 29 (38.7) | 33 (44.0) |
| | FIBRO-Out | 23 (30.7) | 24 (32.0) | 33 (44.0) | 35 (46.7) | 29 (38.7) | 35 (46.7) |
| **Minimally worse** | FIBRO-On | 4 (5.3) | 4 (5.3) | 3 (4.0) | 7 (9.3) | 4 (5.3) | 6 (8.0) |
| | FIBRO-Out | 1 (1.3) | 4 (5.3) | 1 (1.3) | 6 (8.0) | 1 (1.3) | 6 (8.0) |
| **Much worse** | FIBRO-On | 3 (4.0) | 2 (2.7) | 2 (2.7) | 7 (9.3) | 7 (9.3) | 8 (10.7) |
| | FIBRO-Out | 1 (1.3) | 0 | 2 (2.7) | 2 (2.7) | 3 (4.0) | 2 (2.7) |
| **Very much worse** | FIBRO-On | 1 (1.3) | 2 (2.7) | 1 (1.3) | 5 (6.7) | 4 (5.3) | 1 (1.3) |
| | FIBRO-Out | 0 | 0 | 0 | 1 (1.3) | 0 | 0 |

*Note.* PGIC = Patient's Global Impression of Change, PSIC = Patient's Specific Impression of Change, PSIC-1 = Physical function, PSIC-2 = Social activities, PSIC-3 = Work-related activities, PSIC-4 = Mood, PSIC-5 = Pain. * $p < 0.05$. Higher scores indicate less perceived improvement (from 1-much better- to 7 -much worse-).

**Supplementary Table 4.** Results from the mediation analysis (including the PIPS' subscales).

| Effect of interest | Estimate & 95%CI |
|---|---|
| Total effect (c' + indirect effects) | **-0.10 (-0.21, 0.); *p* = .056** |
| Direct effect (c'):<br>Grup → FIQR follow-up | -0.05 (-0.17, 0.08); *p* = .498 |
| Indirect effect Kinesiophobia (TKS):<br>Grup → TKS post →FIQR follow-up | **-0.09 (-0.15, -0.03); *p* = .004** |
| Indirect effect Pain Catastrophising (PCS):<br>Grup → PCS post →FIQR follow-up | 0.01 (-0.03, 0.05); *p* = .678 |
| Indirect effect Psychological Inflexibility (PIPS)-Avoidance:<br>Grup → Avoidance post →FIQR follow-up | **-0.06 (-0.12, -0.01); *p* = .017** |
| Indirect effect Psychological Inflexibility (PIPS)-Cognitive fusion: | -0.01 (-0.01, 0.03); *p* = .390 |

| | |
|---|---|
| Grup → Cognitive fusion post →FIQR follow-up | |
| Indirect effect Pain Knowledge (R-NPQ): Grup → R-NPQ post →FIQR follow-up | 0.07 (-0.01, 0.26); $p$ = .061 |

*Note.* Standardised regression coefficients are presented. CI from *n*=5000 Bootstraping samples. c' = effect of group (FIBROWAL vs. TAU) on functional impairment (FIQR) at 6-month follow-up.

**Supplementary Table 5**. Baseline and treatment-related variables comparisons between responders and non-responders (at post-intervention and at 6-month follow-up) to FIBROWALK interventions

| | **Post-treatment** | | | **6-month Follow-up** | | |
|---|---|---|---|---|---|---|
| | **Responders (n= 48)** | **Non-responders (n= 82)** | ***p*** | **Responders (n= 27)** | **Non-responders (n= 96)** | ***p*** |
| **Group allocation**, *n* FIBRO-On (%) | 25 (52.10) | 42 (51.20) | n.s. | 15 (55.60) | 48 (50.00) | n.s. |
| **Sociodemographic variables** | | | | | | |
| **Sex**, *n* females (%) | 48 (100) | 79 (96.30) | n.s. | 26 (96.30) | 94 (97.90) | n.s. |
| **Age**, mean (*SD*) | 55.98 (9.70) | 51.80 (8.96) | **0.014** | 55.96 (9.74) | 52.78 (9.16) | n.s. |
| **BMI**, mean (*SD*) | 30.01 (6.05) | 26.59 (5.67) | **0.002** | 29.62 (6.64) | 27.29 (5.86) | n.s. |
| **Marital status**, *n* (%) | | | n.s. | | | n.s. |
| Single | 2 (4.20) | 10 (12.20) | | 1 (3.70) | 9 (9.40) | |
| Married/with a partner | 33 (68.80) | 54 (65.90) | | 21 (77.80) | 62 (64.60) | |
| Separated/Divorced | 10 (20.80) | 11 (13.40) | | 3 (11.10) | 18 (18.80) | |
| Widowed | 3 (6.30) | 7 (8.50) | | 2 (7.40) | 7 (7.30) | |
| **Living with a companion**, *n* (%) | 43 (89.60) | 72 (87.80) | n.s. | 26 (96.30) | 83 (86.50) | n.s. |
| **Education level**, *n* (%) | | | n.s. | | | n.s. |
| Illiterate | 0 (0.00) | 0 (0.00) | | 0 (0.00) | 0 (0.00) | |
| Not graduate from primary school | 6 (12.50) | 3 (3.70) | | 5 (18.50) | 4 (4.20) | |
| Primary school | 11 (22.90) | 21 (25.60) | | 8 (29.60) | 22 (22.90) | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Secondary school | 19 (39.60) | 36 (43.90) | | 8 (29.60) | 43 (44.80) | |
| University | 12 (25.00) | 17 (20.70) | | 6 (22.20) | 22 (22.90) | |
| Others | 0 (0.00) | 5 (6.10) | | 0 (0.00) | 5 (5.20) | |
| **Employment status**, *n* (%) | | | n.s. | | | n.s. |
| Homemaker | 5 (10.40) | 4 (4.90) | | 2 (7.40) | 5 (5.20) | |
| Paid employment | 13 (27.10) | 24 (29.30) | | 7 (25.90) | 28 (29.20) | |
| Paid employment but in sick leave | 7 (14.60) | 24 (29.30) | | 5 (18.50) | 26 (27.10) | |
| Unemployed with subsidy | 2 (4.20) | 5 (6.10) | | 2 (7.40) | 4 (4.20) | |
| Unemployed without subsidy | 3 (6.30) | 8 (9.80) | | 2 (7.40) | 8 (8.30) | |
| Retired/Pensioner | 4 (8.30) | 2 (2.40) | | 2 (7.40) | 5 (5.20) | |
| Temporal disability | 3 (6.30) | 6 (7.30) | | 2 (7.40) | 5 (5.20) | |
| Others | 11 (22.90) | 9 (11.0) | | 5 (18.50) | 15 (15.60) | |
| **Clinical variables** | | | | | | |
| Years diagnosis, mean (*SD*) | 15.04 (9.88) | 11.80 (9.44) | n.s. | 16.26 (11.12) | 12.08 (9.11) | **0.048** |
| Chronic fatigue syndrome, *n* (%) | 27 (56.30) | 48 (58.50) | n.s. | 18 (66.70) | 52 (54.20) | n.s. |
| Rheumatoid arthritis, *n* (%) | 6 (12.50) | 11 (13.40) | n.s. | 5 (18.50) | 10 (10.40) | n.s. |
| Multiple chemical sensitivity, *n* (%) | 7 (14.60) | 10 (12.20) | n.s. | 7 (25.90) | 10 (10.40) | **0.039** |
| Cancer, *n* (%) | 1 (2.10) | 1 (1.20) | n.s. | 0 (0.00) | 2 (2.10) | n.s. |
| Depression, *n* (%) | 31 (64.60) | 55 (67.10) | n.s. | 19 (70.40) | 64 (66.70) | n.s. |
| Anxiety, *n* (%) | 32 (66.70) | 59 (72.00) | n.s. | 14 (51.90) | 73 (76.00) | **0.015** |

| | | | | | | |
|---|---|---|---|---|---|---|
| Irritable bowel syndrome, *n* (%) | 12 (25.00) | 20 (24.40) | n.s. | 7 (25.90) | 24 (25.00) | n.s. |
| Osteoarthritis, *n* (%) | 29 (60.40) | 41 (50.00) | n.s. | 13 (48.10) | 53 (55.20) | n.s. |
| **Pending Disability Claim**, *n* (%) | 12 (25.00) | 30 (36.60) | n.s. | 7 (25.90) | 32 (33.30) | n.s. |
| **Degree of Disability**, *n* (%) | | | n.s. | | | n.s. |
| No Disability | 23 (47.90) | 36 (43.90) | | 10 (37.00) | 46 (47.90) | |
| Less than 33% | 1 (2.10) | 1 (1.20) | | 0 (0.00) | 2 (2.10) | |
| Between 33-66% | 14 (29.20) | 38 (46.30) | | 12 (44.40) | 36 (37.50) | |
| More than 66% | 9 (18.80) | 5 (6.10) | | 5 (18.50) | 10 (10.40) | |
| N/A | 1 (2.10) | 2 (2.40) | | 0 (0.00) | 2 (2.10) | |
| **Medication**, *n* (%) | | | | | | |
| Antidepressants, *n* (%) | 38 (79.20) | 62 (75.60) | n.s. | 21 (77.80) | 74 (77.10) | n.s. |
| Analgesics, *n* (%) | 45 (93.80) | 73 (89.00) | n.s. | 24 (88.90) | 87 (90.60) | n.s. |
| Anticonvulsants, *n* (%) | 9 (18.80) | 24 (29.30) | n.s. | 6 (22.20) | 26 (27.10) | n.s. |
| **Clinical Outcomes** | | | | | | |
| FIQR | 70.42 (14.83) | 75.00 (15.56) | n.s. | 72.98 (14.44) | 72.43 (16.01) | n.s. |
| NRS-Pain | 7.67 (1.46) | 8.06 (1.46) | n.s. | 7.89 (1.42) | 7.86 (1.526) | n.s. |
| NRS-Fatigue | 7.44 (2.02) | 8.09 (2.17) | n.s. | 7.78 (2.39) | 7.80 (2.11) | n.s. |
| HADS-Anxiety | 12.29 (4.62) | 13.79 (4.29) | n.s. | 12.00 (5.18) | 13.67 (4.24) | n.s. |
| HADS-Depression | 10.83 (4.27) | 13.27 (4.15) | **0.002** | 11.37 (4.76) | 12.67 (4.26) | n.s. |
| PSS | 8.31 (3.07) | 9.79 (2.84) | **0.006** | 8.44 (2.71) | 9.50 (3.09) | n.s. |

| | | | | | | |
|---|---|---|---|---|---|---|
| CSI | 25.67 (5.93) | 29.00 (5.02) | **0.001** | 27.15 (5.39) | 27.96 (5.77) | n.s. |
| SF-PF | 35.63 (20.52) | 28.96 (18.24) | n.s. | 31.11 (16.43) | 32.97 (20.29) | n.s. |
| PSQI | 9.39 (3.94) | 10.73 (2.96) | **0.038** | 9.72 (3.87) | 10.43 (3.35) | n.s. |
| MISCI | 23.52 (8.32) | 22.16 (7.61) | n.s. | 23.26 (8.44) | 22.41 (8.11) | n.s. |
| **Potential Mediators** | | | | | | |
| TSK | 29.02 (8.59) | 32.09 (7.00) | **0.029** | 28.48 (9.36) | 31.17 (7.07) | n.s. |
| PCS | 25.35 (14.00) | 30.28 (13.52) | **0.005** | 25.59 (12.78) | 28.86 (14.18) | n.s. |
| PIPS | 57.38 (18.17) | 64.71 (15.81) | **0.017** | 55.85 (19.84) | 663.47 (16.40) | **0.044** |
| R-NPQ | 4.90 (1.95) | 4.21 (2.11) | n.s. | 4.44 (1.74) | 4.57 (2.14) | n.s. |
| **Treatment Expectancies and Adherence** | | | | | | |
| Expectancies/Credibility | 7.21 (1.52) | 6.64 (1.42) | **0.032** | 6.58 (2.14) | 6.98 (1.19) | n.s. |
| Number of Sessions Attended | 10.98 (1.34) | 10.44 (2.57) | n.s. | 10.89 (1.45) | 10.80 (2.06) | n.s. |
| *Days/week Homework During Intervention | 4.40 (156) | 3.57 (1.61) | **0.005** | 4.67 (1.35) | 3.74 (1.62) | **0.007** |
| Commitment to Homework During Intervention | 7.10 (2.19) | 6.00 (2.37) | **0.009** | 7.41 (1.80) | 6.36 (2.29) | **0.031** |
| *Days/week with Homework After Intervention | 3.97 (1.48) | 3.06 (1.39) | **0.001** | 4.04 (1.27) | 3.26 (1.50) | **0.015** |
| Commitment to Homework After Intervention | 5.93 (2.74) | 4.91 (2.62) | **0.042** | 6.22 (2.21) | 5.06 (2.76) | **0.047** |

*Note*. Responders were calculated according to the percentage of change in Fibromyalgia Impact Questionnaire -Revised -FIQR- (≥20% improvement= responder, < 20% = non-responder). * This value corresponds to the average frequency of specific therapeutic practices (i.e., breathing, relaxation, mindfulness, stretching and strength exercises, walking) per week (i.e., days/week). FIBRO-On = online; FIBRO-Out = outdoor; TAU = treatment-as-usual;

BMI = Body Mass Index.FIQR = Fibromyalgia Impact Questionnaire; NRS = Numerical Rating Scale of Perceived Pain/Fatigue; HADS = Hospital Anxiety and Depression Scale; PSS = Perceived Stress Scale; CSI = Central Sensitization Inventory; SF-PF = Physical Function Subscale of the Short Form-36 Health Survey; PSQI = Pittsburgh Sleep Quality Index, brief version; MISCI = Multidimensional Inventory of Subjective Cognitive Impairment. TSK = Tampa Scale for Kinesiophobia; PCS = Pain Catastrophising Scale; PIPS = Psychological Inflexibility in Pain Scale; R-NPQ = Revised Neurophysiology of Pain Questionnaire.

# CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a randomised trial in the title | 1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 2 |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | 3-5 |
| | 2b | Specific objectives or hypotheses | 4, 5 |
| **Methods** | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 5 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | NA |
| Participants | 4a | Eligibility criteria for participants | 6, 7 |
| | 4b | Settings and locations where the data were collected | 7 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 8-10 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 11-16 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | 7 |
| Sample size | 7a | How sample size was determined | 6 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | NA |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | 6 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 6 |
| Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 6 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 6 |

| | | | |
|---|---|---|---|
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 7, 8 |
| | 11b | If relevant, description of the similarity of interventions | NA |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 16, 17 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | 17-19 |
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 19 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 7 |
| | 14b | Why the trial ended or was stopped | NA |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 1 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Figure 1 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Pages 20-22, Table 2, Table 3 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | NA |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | 23-27 Supplementary materials |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | 26 |
| **Discussion** | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 31, 32 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | 27-32 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 27-32 |
| **Other information** | | | |
| Registration | 23 | Registration number and name of trial registry | 33 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | 34 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 33 |

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. 2010;8:18.
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*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.

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