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Original article

The feasibility and acceptability of outdoor sessions as an add-on of an online multicomponent program (FIBROWALK) for fibromyalgia: A pilot randomized controlled trial

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ABSTRACT

Introduction and objectives: The given text describes a pilot randomized controlled trial aimed at evaluating the feasibility and acceptability of outdoor sessions as an add-on to an online multicomponent program (FIBROWALK) for fibromyalgia (FM) patients.
Materials and methods: The trial involved 110 participants with FM (99% women; mean age of 51.89 ± 1.89 years) from a tertiary hospital in Spain who were randomly assigned to either the online FIBROWALK program ($n = 38$) or the blended FIBROWALK program arm ($n = 61$; online FIBROWALK plus 4 outdoor sessions).
Results: Overall, attrition was minimal (14.01%) and adherence to the outdoor session was modest (52% of the group attended at least one outdoor session). Participants' expectations and opinions were positive. Paired-samples *t*-tests for examining within-group differences showed that participants in each arm had significantly improved functional impairment, anxious-depressive symptomatology, physical function, and fear of pain symptoms. Analysis of covariance for examining between-group differences showed that the blended FIBROWALK had a significantly higher effect on psychological distress than the online FIBROWALK ($F(1,96) = 4.23$; $p = .042$; Cohen's $d = .60$).
Conclusions: These results suggest that the blended program was feasible, secure, and acceptable to the participants. Although the online FIBROWALK program alone may be sufficient for managing fibromyalgia symptoms, the addition of outdoor sessions may provide significant additional benefits. Future definitive randomized controlled trials are warranted.

Viabilidad y aceptabilidad de añadir sesiones al aire libre como complemento de un programa multicomponente online (FIBROWALK) para la fibromialgia: un ensayo piloto controlado y aleatorizado

RESUMEN

Introducción y objetivos: El presente estudio es un ensayo piloto controlado y aleatorizado que tiene como objetivo evaluar la viabilidad y la aceptabilidad de añadir sesiones de terapia realizadas al aire libre *(outdoor)* a un programa multicomponente en formato online (FIBROWALK) para pacientes con fibromialgia (FM).

Palabras clave:
Fibromialgia
Intervención multicomponente
En línea

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Tratamiento combinado
FIBROWALK

Métodos: El ensayo involucró a 110 participantes con FM (99% mujeres; edad media de 51,89 ± 1,89 años) de un hospital terciario en España, quienes fueron asignados aleatoriamente al programa FIBROWALK online (n = 38) o a la rama del programa FIBROWALK combinado (n = 61; FIBROWALK online más 4 sesiones al aire libre).
Resultados: En general, la tasa de abandono fue mínima (14,01%) y la adherencia a las sesiones al aire libre fue modesta (el 52% del grupo asistió al menos a una sesión al aire libre). Las expectativas y las opiniones de los participantes fueron positivas en ambas ramas de tratamiento. Las pruebas t de muestras emparejadas para examinar las diferencias dentro de cada grupo mostraron que los participantes de ambas ramas del estudio mejoraron significativamente en cuanto a la discapacidad funcional, la sintomatología ansioso-depresiva, la función física y el miedo al dolor. El análisis de covarianza mostró que los participantes asignados al programa FIBROWALK combinado experimentaron mejoras significativamente superiores en malestar psicológico en comparación a los asignados al programa FIBROWALK online (F(1,96) = 4,23; p = 0,042; d de Cohen = 0,60).
Conclusión: El programa combinado fue viable, seguro y aceptable para los participantes. Aunque el programa FIBROWALK online por sí solo parecería ser útil para los pacientes con fibromialgia, la adición de sesiones al aire libre podría proporcionar beneficios adicionales significativos. Es necesario realizar ensayos controlados aleatorizados definitivos.

Introduction

Fibromyalgia (FM) is a chronic syndrome characterized by widespread musculoskeletal pain, fatigue, sleep disturbances, and cognitive problems.[1] Its prevalence ranges from 2% to 4% across different countries worldwide,[2] and it is more prevalent among women.[3] FM not only affects physical well-being, but individuals with FM also usually report high psychological distress, low quality of life, social isolation, self-stigma, decreased productivity, increased absenteeism, and higher rates of unemployment.[4,5]

Current therapeutic approaches for FM include nonpharmacological therapies such as pain neuroscience education (PNE), cognitive-behavioral therapy (CBT), therapeutic exercise, and mindfulness practice,[6] alongside pharmacological therapies.[1] In recent years, there has been growing interest in developing multicomponent treatments for FM management, including these therapeutic components.[6]

These components seem to have synergistic effects when delivered together and provide additional benefits for symptom management and quality of life. Specifically, multicomponent therapy has demonstrated robust evidence for alleviating pain, fatigue, and depressed mood. Moreover, it enhances self-efficacy and physical fitness in the short term.[13] An example of a combination of these therapeutic components is FIBROWALK, a multicomponent package designed to improve the physical and psychological well-being of individuals with FM.[7]

Both face-to-face and online formats of FIBROWALK have demonstrated to diminish impairment-related symptoms, alleviate depression and anxiety, and enhance physical functioning in FM patients compared with treatment-as-usual (TAU).[7–10] Indeed, the online format of FIBROWALK has several advantages over the in-person format, particularly in terms of participant attrition and adherence. Full adherence to the online FIBROWALK program was observed, and attrition was lower than that observed in the in-person version of the program (9% vs. 24%).[10] Online interventions address logistical challenges, improve accessibility, reduce healthcare costs, and alleviate the burden on healthcare systems.[11] In contrast, the in-person format demonstrated greater clinical effects and a higher proportion of treatment responders.[9]

Considering both the advantages and disadvantages of online FIBROWALK and the original face-to-face version, the present study sought to explore the acceptability and potential benefits of four additional outdoor sessions in the online FIBROWALK in a sample of FM patients. Hence, as the primary aim, this pilot examined indicators of feasibility and acceptability of a blended FIBROWALK (online FIBROWALK plus four outdoor sessions), In addition, we explored the effects of the blended format on FM functional impairment, anxious-depressive symptomatology, physical function, and fear of pain symptoms by comparing it with the regular online format.

Materials & methods

Participants

A total of 110 participants diagnosed with FM (99% women) were recruited from the Central Sensitivity Syndromes Specialized Unit (CSSSU) at the Vall d'Hebron University Hospital (Spain). Table 1 presents the sociodemographic characteristics of the study participants. No significant differences were found between the groups at baseline in terms of the general measures or clinical outcomes.

To be eligible for participation, individuals had to meet the following criteria: (a) a diagnosis of FM according to the 2010/2011 American College of Rheumatology (ACR) criteria,[12] (b) 18 years of age or older, and (c) fluent in Spanish. Individuals with terminal illnesses or scheduled treatments that could disrupt their participation in the study were excluded (n = 19). Recruitment for the study was conducted from February to March 2022, and the interventions were conducted from April to July 2022. The flow of participants through the study is shown in Fig. 1.

Study design

This was a 12-week, randomized controlled trial in which recruited participants were randomly assigned to online FIBROWALK (n = 39) or blended FIBROWALK (n = 71). The blended study arm was divided into two subgroups: four outdoor sessions at the park (n = 35) and four outdoor sessions at the beach (n = 36).

Procedure

All procedures followed the ethical standards established in the 1964 Declaration of Helsinki and its subsequent revisions. The FIBROWALK study protocol was approved by the the Ethical Committee of Clinical Investigation of Vall d'Hebron Hospital (code: PR(AG)249/2020) and registered on ClinicalTrials.gov (NCT05395832). This study adhered to the guidelines specified by the Consolidated Standards of Reporting Trials (CONSORT).[13]

Table 1
Sociodemographic and clinical characteristics of the participants.

	Online FIBROWALK (*n* = 39)	Blended FIBROWALK (*n* = 71)	*p*
Women, *n* (%)	39 (100)	70 (98.59)	.46
Age (years), *M* (SD)	51.69 (1.55)	52 (1.10)	.87
Married or in couple, *n* (%)	21 (53.85)	41 (57.75)	.62
Not living alone, *n* (%)	32 (82.05)	54 (76.06)	.47
Secondary education	16 (41.03)	31 (43.66)	.89
Employment status – on leave, *n* (%)	13 (33.33)	27 (38.03)	.11
Without incapacity certificate, *n* (%)	18 (46.15)	34 (47.89)	.85
Incapacity certificate requested, *n* (%)	14 (35.90)	26 (36.62)	.40
BMI, *M* (SD)	27.49 (0.89)	28.33 (0.78)	.50
Years of illness, *M* (SD)	14.05 (1.78)	11 (1.06)	.12
Chronic fatigue syndrome, *n* (%)	31 (79.49)	54 (76.06)	.68

Note. The values represent means and SD or frequency and percentages in their respective order of presentation. BMI = body mass index; FIQR = Revised Fibromyalgia Impact Questionnaire; TSK = Tampa Scale for Kinesiophobia; HADS = Hospital Anxiety and Depression Scale; PF-SF-36 = Physical functioning subscale of the SF-36 Health Survey.

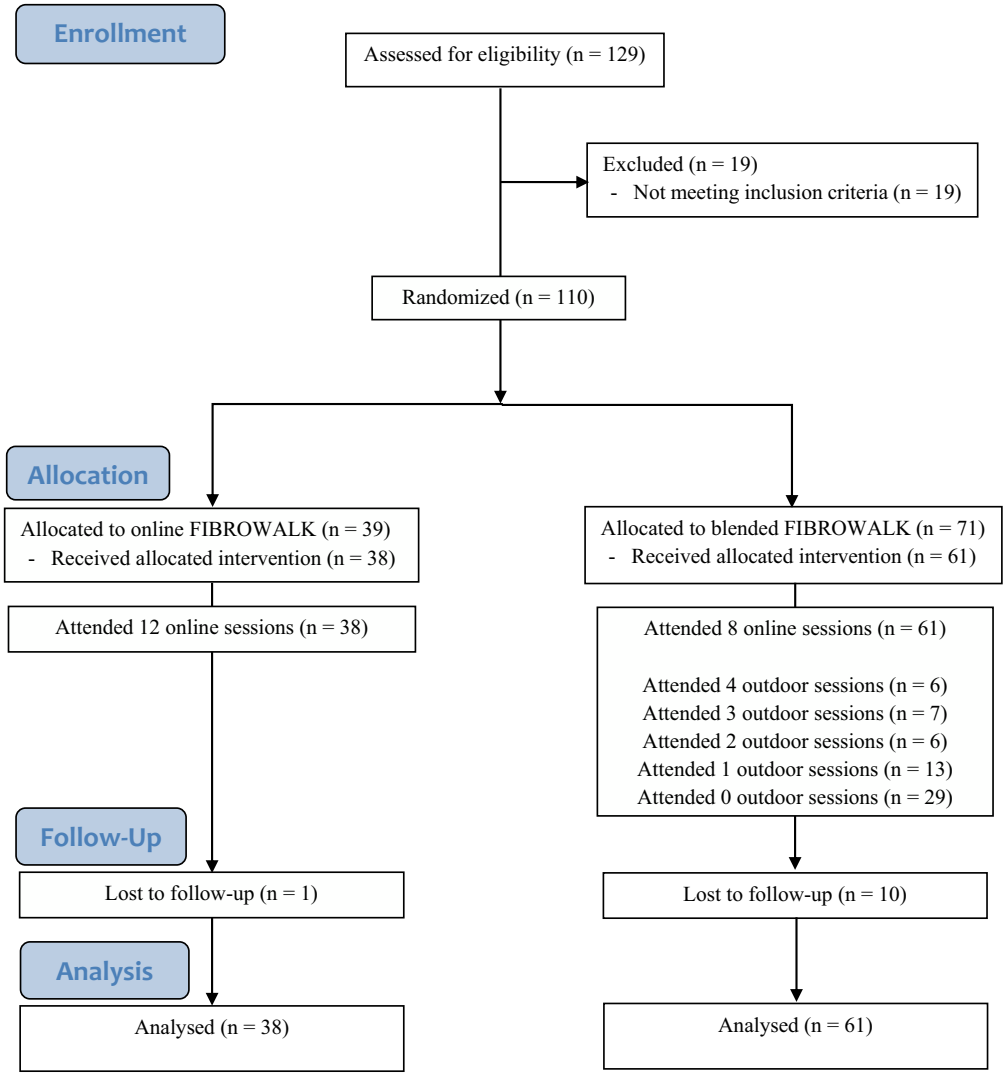

Fig. 1. Flow of participants through the trial.

Participants diagnosed with FM from the Central Sensitivity Syndromes Specialised Unit (CSSSU) at the Vall d'Hebron University Hospital (Spain) were initially screened by the main researcher (M.S.) and informed of the study. After obtaining informed consent, the participants were assigned an alphanumeric code and randomized into either the online FIBROWALK group or the blended FIBROWALK group using SPSS version 26. The participants were assessed at baseline and upon completion of the intervention (12 weeks after the beginning) through an online survey platform (REDCap). Participants in both arms continued their usual treatment, mainly pharmacological treatment tailored to each patient's symptom profile.

Adherence to the online sessions in both formats was evaluated using a weekly content test, and adherence to the outdoor sessions was evaluated using attendance logs.

Description of the treatments

Online FIBROWALK: This program comprised 12 weekly sessions, each lasting 60 min. The participants were sent via e-mail a weekly link to a 60-min video. Each video module integrated diverse components of the program, including Pain Neuroscience Education (PNE), therapeutic physical exercise, Self-management Patient Education, CBT techniques, with an emphasis on cognitive restructuring and mindfulness training. The content and structure of the program are described in detail elsewhere.[10] Additionally, the program integrated homework tasks aimed at enhancing patients' endurance and resilience through consistent challenges. To ensure that participants engaged in the program, a brief content test consisting of (<10 questions) about the session was sent via email every week.

Blended FIBROWALK: The contents are identical to those delivered in the online FIBROWALK, but sessions corresponding to weeks 2, 6, 8, and 11 were performed face-to-face in addition to online sessions. Participants freely chose to attend outdoor sessions. These sessions were carried out in a park located near the referral hospital ("Parc del Cargol") for one of the subgroups and in a beach ("Platja del Bogatell") for the other.

Study measures

Sociodemographic and clinical variables: Data on gender, age, marital status, cohabitation, educational level, and employment status were collected using an ad hoc survey. Concerning clinical variables, we asked participants about their years with an FM diagnosis, possession of a disability certificate, height, weight, and comorbidity with chronic fatigue syndrome.

The Revised Fibromyalgia Impact Questionnaire (FIQR)[14] was used to measure functional impairment. This instrument assesses three dimensions: physical dysfunction, impact of FM, and severity of symptoms. The total maximum score can be calculated by adding the three subscale scores, where a higher score indicates greater impairment (range of scores: 0–100). The Spanish version was used[15]; in our sample, it showed good internal consistency (α pre = .95; α post = .95).

The Hospital Anxiety and Depression Scale (HADS)[16] was used to measure anxiety and depressive symptoms. It comprises 14 items answered using a four-point Likert scale. An overall psychological distress score can be calculated by adding all item scores, with higher values indicating greater anxiety-depressive symptomatology (range of scores: 0–42). A Spanish version was used.[17,18] It showed adequate internal consistency in our sample (α pre = .85/.87; α post = .89/.89).

The physical functioning subscale of the Short Form-36 Health Survey (SF-PF-36)[19] was used to measure physical function. This dimension consists of ten items rated on a three-point Likert scale. The total score can be calculated by adding all item scores. Higher scores indicate higher physical functioning (range: 0–100). The Spanish version was used in this study.[20] It showed adequate internal consistency in our sample (α pre = .86; α post = .88).

The Tampa Scale for Kinesiophobia (TSK)[21] was used to measure fear of movement and pain. This scale consists of 11 items rated on a four-point Likert scale. The total score can be calculated by adding all item scores. Higher scores indicate greater fear of movement (range of scores: 11–44). The Spanish version was used.[22] It showed adequate internal consistency in our sample (α pre = .86; α post = .89).

The *Credibility/Expectancy Questionnaire (CEQ)*[23] was used to assess treatment expectancy and opinions of the interventions. It consists of six items on an 11-point Likert scale (from 0 to 10), with the pre-test part focusing on therapy credibility and expectations, and the post-test part gathering patient opinions after treatment completion. Higher scores indicate a better perception of the treatment (range of scores: 0–10). An ad-hoc Spanish version was used.[7]

Statistical analyses

Data analyses were performed using SPSS v26. Descriptive statistics for all variables were calculated and reported using means and standard deviations for continuous data, and frequencies and percentages for categorical data. Student's *t*-tests and χ^2-tests were conducted to further analyze any potential differences in sociodemographic and clinical characteristics between the online and blended FIBROWALK groups. In addition, the continuous variables were checked for normality (kurtosis ranging from −2 to +2 and skewness from −7 to +7, Kolmogorov–Smirnov's statistic with $p > 0.05$, histograms, and *Q*–*Q* plots), with no major violation noted of this assumption for parametric tests. Moreover, within-paired-samples *t*-tests were conducted to evaluate the impact of the interventions in each group on the FIQR, HADS, SF-PF, and TSK scores.

A series of one-way between-groups analyses of covariance (ANCOVA) was conducted to compare the effectiveness of both interventions. The independent variable was the type of intervention (online FIBROWALK, blended FIBROWALK), and the dependent variables consisted of total scores on the FIQR, HADS, SF-PF-36, and TSK administered after the intervention was completed. Participants' scores on the pre-intervention administration of these measures were used as covariates in each analysis. Cohen's *d* was calculated as measure of effect size using the pooled initial SD to measure differences in the initial and subsequent mean values and to correct for the estimated population ($d = 0.20$, small effect size; 0.50, moderate; and 0.80, large).[24] For this analysis, we employed a 'completers approach', which provided insight into the effectiveness of patients who reached the study endpoint. In addition, a 'per-protocol analysis' was performed including only those who completed the study and attended all online sessions in both interventions and at least two outdoor sessions of the blended format.

A Chi-Square Test for Independence was conducted to explore the relationship between the type of intervention and the proportion of 'responders'. A ≥20% reduction in the FIQR total score was considered a criterion of a clinically relevant change.[14] Student's *t*-tests and χ^2-tests were conducted to further analyze any potential differences in sociodemographic and clinical characteristics between responders and non-responders within each arm.

Results

Adherence and satisfaction

Eleven participants (10%) dropped out due to personal or family circumstances at the beginning of the intervention period. Dropout rates did not vary significantly across treatment arms ($\chi^2 = 2.54$, $p = .111$): one participant (2.56%) in the online group and ten (14.01%) in the blended group. There were no statistically significant differences in baseline characteristics between dropouts and completers in both arms ($p > .05$ in all cases). Participants who completed both interventions (38 in online FIBROWALK and 61 in blended FIBROWALK) attended all online sessions. In the blended format, 19 participants (26.76%) attended at least two sessions.

Table 2 presents the participants' scores on expectancy and opinion items for both the interventions. Overall, participants had high expectations of online FIBROWALK (CEQ total mean score = 8; SD = 1.40) and blended FIBROWALK (CEQ total mean score = 7.68; SD = 1.66), with no significant between-group differences ($p = .331$). An inspection of the items scores indicated that the online and blended FIBROWALK were expected to be logical,

Table 2
Expectancy and opinion of participants about online and blended FIBROWALK.

CEQ items	Expectations			Opinion		
	Online FIBROWALK *M* (SD)	Blended FIBROWALK *M* (SD)	*p*	Online FIBROWALK *M* (SD)	Blended FIBROWALK *M* (SD)	*p*
1. The extent to which the treatment appears logical.	8.45 (1.61)	7.87 (1.86)	.117	8.29 (1.56)	7.82 (2.29)	.269
2. The extent to which the treatment would (have) satisfy(ed) you.	8.37 (1.57)	8.05 (2.00)	.406	7.97 (1.73)	7.52 (2.63)	.353
3. The confidence with which the patient would recommend the treatment to a friend having the same problem.	8.50 (1.59)	8.11 (2.12)	.338	8.87 (1.42)	8.39 (2.32)	.243
4. The extent to which the treatment appears useful for treating other problems.	8.05 (1.80)	7.79 (1.98)	.504	8.37 (1.65)	8.16 (2.23)	.627
5. The extent to which the treatment appears useful.	7.71 (1.74)	7.51 (2.04)	.613	7.16 (2.18)	7.07 (2.57)	.854
6. The extent to which the treatment appears aversive.	3.08 (3.31)	3.23 (3.28)	.825	2.29 (3.05)	4.03 (3.50)	**.013**

Note. Statistically significant effects are shown in bold ($p < .05$). $n = 38$ for online FIBROWALK; $n = 61$ for blended FIBROWALK. CEQ = Credibility/Expectancy Questionnaire. Possible range of scores for each item: 0–10.

satisfactory, useful, recommendable, useful for treating other problems (*M* ranging between 7.71 and 8.50 for online FIBROWALK; *M* ranging between 7.51 and 8.11 for blended FIBROWALK), and non-aversive (*M* = 3.08 for online FIBROWALK; *M* = 3.23 for blended FIBROWALK), with no significant between-group differences ($p > .05$ in all cases). The per-protocol analysis showed similar results (see Table S1 in the Supplemental Material).

Overall, after the interventions were completed, participants had a good opinion of online FIBROWALK (CEQ total mean score = 8.06; SD = 1.44) and blended FIBROWALK (CEQ total mean score = 7.49; SD = 1.95), with no significant between-group differences ($p = .120$). Concretely, the CEQ item scores indicated that both the online and blended FIBROWALK were considered logical, satisfactory, useful, recommendable, useful for treating other problems (*M* ranging between 7.16 and 8.87 for online FIBROWALK; *M* ranging between 7.07 and 8.39 for blended FIBROWALK), and non-aversive (*M* = 2.29 for online FIBROWALK; *M* = 4.03 for blended FIBROWALK), with no significant differences between group scores ($p > .05$ in all cases), except for the aversiveness item ($p = .013$). The per-protocol analysis reflected that the blended FIBROWALK group perceived it as more logical, and participants were more satisfied than those in the online group. In addition, the aversiveness item score was lower and there was no statistically significant between-group difference ($p = .368$) (see Table S1 in the Supplemental Material for more details).

Changes in outcomes

Overall, paired-samples *t*-tests showed that there were statistically significant improvements in the FIQR, HADS, SF-PF, and TSK scores from baseline to post-treatment in both conditions with small-to-large effect sizes ($p < .05$ in all cases, Cohen's *d* ranged from .19 to 1.43; see Table S2 in the online Supplemental Materials for more details). However, the online FIBROWALK group did not exhibit a significantly lower average score on the HADS from baseline to post-test ($p = .052$, $d = .19$).

Table 3 shows the means and SDs of the patient-reported outcome measures at baseline and post-treatment in the online and blended FIBROWALK groups (with completers). A statistically significant between-group difference with a moderate effect size was found in the HADS scores ($p = .042$; $d = .60$), indicating that the blended FIBROWALK group had a lower level of psychological distress than the online group at the end of the intervention period. The per-protocol analysis reflected the same results (see Table S3 in the online Supplemental Materials for more details).

Among the participants, 33 (33.33%) of the total sample achieved responder status (i.e. reduction of ≥20% in FIQR scores), of which 13 (34.21%) belonged to the online group and 20 (32.79%) to the blended group. The rate of responders did not vary significantly across treatment arms ($\chi^2 = 0.02$, $p = .884$).

Tables S4 and S5 in the Supplemental Material show that there was a statistically significant difference in years of illness between responders (*M* = 9.08; SD = 7.34) and non-responders (*M* = 16.64; SD = 12.20) of the online FIBROWALK group ($p = .048$) as well as a statistically significant difference in BMI between responders (*M* = 30.80; SD = 7.70) and non-responders (*M* = 27.07; SD = 6.02) of the blended FIBROWALK group ($p = .043$). In contrast, their sociodemographic and clinical characteristics and baseline FIQR, HADS, SF-PF, and TSK scores were not significantly different ($p > .05$ in all cases).

Discussion

The results of this pilot study provide empirical support that complementary face-to-face outdoor sessions to the online multicomponent FIBROWALK program are feasible in patients with FM. Most participants were able to complete the blended FIBROWALK successfully (86%), with 52% attending at least one outdoor session. This result suggests that approximately half of the users of online FIBROWALK, which might be translated to any similar online intervention, would be able and/or interested in additionally joining in-group therapeutic sessions with other patients. Indeed, participants reported high expectancy about blended FIBROWALK. Participants initially perceived this format as logical and non-aversive and maintained that impression when asked at the end of the intervention period.

Regarding the changes in FM-related clinical outcomes, our findings revealed significant improvements in functional impairment, psychological distress, physical function, fear of movement, and fear of pain in both the online and blended groups, but not in psychological distress in the online group. Overall, these results are consistent with previous RCTs that have demonstrated the efficacy of the fully online FIBROWALK program.[9,10] Our findings suggest that both programs are similarly effective for the management of FM-related symptoms. Indeed, around the 30% of participants of both programs showed a relevant clinical reduction of FM-related functional impairment. On the one hand, responders and non-responders of the online FIBROWALK differed at baseline in the years with the FM diagnosis, showing the latter almost the double of years of illness. This result suggests that individuals with a long FM trajectory (>10 years) may not respond or may not respond rapidly to online treatment. On the other hand, responders of the blended FIBROWALK at baseline showed a mean-group BMI that falls into the category of obesity class I (BMI between 30.0 and 34.09) while non-responders could be considered overweight individuals (BMI between 25.0 and 29.99). This result suggests that

Table 3
Descriptive statistics and between-group differences for study outcomes (completers analysis).

	Online FIBROWALK ($n = 38$)	Blended FIBROWALK ($n = 61$)	Online vs blended		
	Mean (SD)	Mean (SD)	*F*	*p*	Cohen's *d* [95% CI]
FIQR			1.21	.275	.25 [−0.16, 0.66]
Baseline	68.13 (21.22)	72.33 (16.82)			
Post-Treatment	62.53 (2.53)	58.99 (1.99)			
HADS-Total			4.23	**.042**	.60 [0.19, 1.01]
Baseline	22.58 (8.66)	25.10 (7.22)			
Post-Treatment	22.21 (0.85)	19.98 (0.67)			
SF-PF			0.56	.456	0 [−0.41, 0.41]
Baseline	36.58 (21.60)	34.26 (19.72)			
Post-Treatment	43.91 (2.44)	41.58 (1.92)			
TSK			0.59	.443	.01 [−0.40, 0.42]
Baseline	28.63 (7.16)	29.64 (7.07)			
Post-Treatment	22.79 (0.99)	23.76 (0.78)			

Note. Statistically significant effects are shown in bold ($p < .05$). Adjusted means (post-treatment) are shown. There were no statistically significant between-group differences at baseline scores for any measure. FIQR: Revised Fibromyalgia Impact Questionnaire; HADS; Hospital Anxiety and Depression Scale; SF-PF: Physical Functioning component of the 36-Item Short Form Health Survey; TSK: Tampa Scale for Kinesiophobia.

obese individuals (only according to BMI) might benefit more from the outdoor component of the blended program than those with a BMI lower than 30. Future research should study the moderator role of both variables (i.e., BMI and years with FM) in the effectiveness of online/blended multicomponent interventions for FM.

Participants in the blended FIBROWALK group achieved a significantly greater improvement in psychological distress than the online group. This finding aligns with previous research emphasizing the significance of outdoor exposure and nature in enhancing the psychological aspects of chronic disease syndromes such as depression.[25] The positive effect of outdoor sessions is also likely to be influenced by their social aspects, as emphasized by Buckley et al.[26] Research has consistently demonstrated that being a part of social groups can significantly protect against depression and help alleviate existing symptoms of depression.[27]

Overall, blended FIBROWALK was feasible, satisfactory, and preliminary effective; when compared to the online version, it showed some advantage in terms of effectiveness, and satisfied the needs of a significant proportion of participants who preferred to attend in-person sessions. In our opinion, the implementation of blended interventions may optimize healthcare system resources use, and solve some of the disadvantages of online interventions reported by health professionals, such as the non-suitability for patients due to symptom severity.[28]

Recent meta-analyses suggest that blended interventions have shown a potential to promote physical activity in clinical and non-clinical populations,[29,30] quality of life in chronic conditions,[31] and treat mental disorders in adult patients.[32] However, there is no clear evidence of the superiority of these interventions compared to traditional methods. For instance, Kloek et al.[33] examined in their systematic review the effectiveness of blended interventions in patients with chronic somatic disorders compared to face-to-face and online interventions. They found few studies comparing those approaches and big heterogeneity in the blended approaches, and probably as a result of this, they found mostly inconsistent evidence for mental health outcomes and symptoms when comparing them.[33]

The present study has several limitations. First, using self-reported measures to assess intervention outcomes may have introduced a response bias. Participants might have provided skewed estimates of the assessed variables due to various factors, such as misunderstandings of scale items or social desirability. In addition, there was no long-term follow-up to assess the maintenance effects, which is crucial for evaluating the effectiveness of multicomponent treatments within real-world clinical practices, and to assess the stability of results over time. Moreover, the small sample size limited the generalisability of the findings and our ability to perform more sensibility analyses, such as controlling for the effect of the scenario of the outdoor session. In this line, four concrete sessions were chosen to be delivered in person, which might have biased the results. In addition, there were no inclusion or exclusion criteria related to accessing the online sessions, which may have led to the inclusion of patients who were unable to participate. Nevertheless, the research team was confident that almost all patients had at least the minimum means necessary to access the online content. Finally, the underrepresentation of men in this study is another limitation.

In future research, addressing these limitations is crucial. Conducting follow-up assessments will provide valuable insights into the long-term effectiveness of multicomponent treatments. Increasing the sample size will improve the study's statistical power and enhance the generalisability of the findings, while ensuring adherence to outdoor sessions will reveal potential effects that may not have been observed in this study. Ideally, a future study should allow participants to freely choose to attend in-person or online to the FIBROWALK sessions according to their needs. Additionally, designing studies that match therapy dosage between groups, such as providing additional online sessions to facilitate group interaction, will help ensure a more equitable distribution of therapy intensity.

Conclusion

The results of this pilot study contribute to a small but growing body of literature on the effectiveness of multicomponent programs for FM management in general, particularly the FIBROWALK program. We concluded that integrating outdoor sessions into an online format is feasible. In addition, blended FIBROWALK is a promising treatment option for individuals with FM, particularly for addressing psychological distress. This blended program was feasible, overall satisfactory, and preliminary effective, and is important because it has good prospects for future efficacy trials.

Author note

All procedures followed the ethical standards established in the 1964 Declaration of Helsinki and its subsequent revisions. The FIBROWALK study protocol was approved by the Ethical Committee of Clinical Investigation of Vall d'Hebron Hospi-

tal (code: PR(AG)249/2020) and registered on ClinicalTrials.gov (NCT05397080).

Ethical considerations

The FIBROWALK study protocol was approved by the Ethical Committee of Clinical Investigation of Vall d'Hebron Hospital (code: PR(AG)249/2020).

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Conflict of interest

The authors have no conflicts of interest to disclose.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.1016/j.reuma.2025.501817.

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