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# Proof of concept of prehabilitation: a combination of education and behavioural change, to promote physical activity in people with fibromyalgia

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## ABSTRACT

**Objectives** To establish proof of concept of a prehabilitation intervention, a combination of education and behavioural change, preceding a physical activity programme in people with fibromyalgia (FM).

**Settings** Open-label, feasibility clinical trial.

**Participants** Eleven people with FM (10 women).

**Interventions** The prehabilitation intervention consisted of 4 weeks, 1 weekly session (~1 to 1.5 hours), aimed to increase self-efficacy and understand why and how to engage in a gentle and self-paced physical activity programme (6 weeks of walking with telephone support).

**Primary and secondary outcome measures** Primary outcome was the acceptability and credibility of the intervention by means of the Credibility/Expectancy Questionnaire. Secondary outcomes comprised scales to measure FM severity, specific symptoms and sedentary behaviour. An exit interview was conducted to identify the strengths and weaknesses and barriers to the intervention.

**Results** One participant dropped out due to finding the walking programme excessively stressful. Participants expected the intervention would improve their symptoms by 22%–38% but resulted in 5%–26% improvements. Participants would be confident in recommending this intervention to a friend who experiences similar problems. The interviews suggested that the fluctuation of symptoms should be considered as an outcome and that the prehabilitation intervention should accomodate these fluctuation. Additional suggestions were to incorporate initial interviews (patient-centred approach), to tailor the programmes to individuals' priorities and to offer a variety of physical activity programmes to improve motivation.

**Conclusions** This feasibility study demonstrated that our novel approach is acceptable to people with FM. Future interventions should pay attention to flexibility, symptoms fluctuation and patients support.

**Trial registration number** NCT03764397.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Physical exercise is a first-line treatment in the management of fibromyalgia, however, adherence to exercise is often low.
⇒ In this feasibility study, we designed a novel prehabilitation intervention to promote physical activity in fibromyalgia.
⇒ A mixed-method approach was conducted to obtain quantitative and qualitative information regarding the acceptability and credibility of the intervention, and changes in fibromyalgia severity, specific symptoms and sedentary behaviour.
⇒ The knowledge gained form this proof-of-concept study will inform the design of future randomised controlled trials.

## INTRODUCTION

Fibromyalgia (FM) is a common condition, with a prevalence of around 2% in Europe, and is around nine times more prevalent among women than men.[1] The diagnostic criteria for FM include the presence of chronic widespread pain, fatigue, sleep dysfunction and cognitive problems,[2 3] however, people with FM often have multiple other symptoms.[4] Fatigue is often the most common symptom[5] and it represents the main complaint for one out of four people with FM.[6] Pain and fatigue, together with other symptoms, represent a serious burden to people and can result in significant disability.[7] In addition to higher economic costs for the healthcare system (in Europe, up to € 7580 per patient annually),[8] the greatest issue caused by chronic pain in FM is its negative impact on quality of live, which may account for increased mortality.[4 9 10]

There is no cure for FM and so adaptation is the main aim of therapy. The European Authorities have not approved any pharmacological treatment for FM,[11] therefore, non-pharmacological approaches are the mainstay of treatment. Recent research has comprehensively demonstrated that more time engaged in physical activity is related to reduced symptoms and improved quality of life in FM.[12–18] Thus, it is not surprising that

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the current recommendations for the management of FM highlight the benefits of engaging in physical exercise.[19 20]

Although the level of evidence for the effectiveness of physical exercise in this disease was appraised as 'strong for' by the European League Against Rheumatism,[20] adherence to exercise programmes is often challenging[21] and rather low.[22 23] Behavioural barriers such as fear of movement, catastrophising, depression or low self-efficacy have been shown to reduce physical activity in people with FM.[24–26] As a result, avoidance of physical activity may then lead to physical and mental deconditioning[27] and can trigger a vicious circle of inactivity as a result of increasing pain and fear.[28] Promisingly, educational interventions tackling fear of movement and avoidance behaviour towards physical activity seem effective in increasing physical functioning in people with FM.[29–31] In view of this, interventions focused on developing positive attitudes rather than reducing pain symptoms appear more effective in promoting walking activities in women with FM.[32] These findings strengthen the hypothesis that the provision of a behavioural change intervention, as an adjuvant therapy, before a physical activity programme (ie, prehabilitation) would not only increase the effectiveness of the physical activity programme but also the adherence to the programme. Despite its potential, there is still sparse knowledge and a lack of consensus on how to design and implement an effective prehabilitation intervention in people with FM.[31]

Therefore, this study aimed to establish proof-of-concept of a novel 4-week prehabilitation, behavioural change intervention, focused on improving self-management skills and understanding of the benefits of physical activity, to increase engagement and effectiveness of a subsequent physical activity programme. As a main contribution to the existing knowledge, this study attempted to identify the strengths, weaknesses and barriers of the prehabilitation combining a quantitative (scales) and qualitative (interviews) approach.

## METHODS

### Study design

This is an open-label, feasibility clinical trial involving a single group assignment. The protocol was registered in ClinicalTrials.gov (Identifier: NCT03764397; link: https://clinicaltrials.gov/ct2/show/NCT03764397). FM patients received a 4-week prehabilitation, behavioural change intervention, focused on improving self-management skills and understanding of the benefits of physical activity, to increase engagement and effectiveness of a subsequent, 6-week physical activity programme (figure 1). Participants reported their thoughts and feelings, main barriers to, and strengths and weaknesses of the intervention. Participants also reported changes in FM severity, specific symptoms and sedentary behaviour by means of scales and an exit interview.

### Participants

Participants for this feasibility study were recruited from a local FM patient support group in Belfast, namely, the Fibromyalgia Support Northern Ireland (FMSNI). The chair of the group distributed an email from the research team to members with FM to inform them of the study. At an information session in the patient support group setting, the research team presented detailed information to those interested in participating in the study. Those people who were willing to participate in the study received a patient information sheet and a consent form.

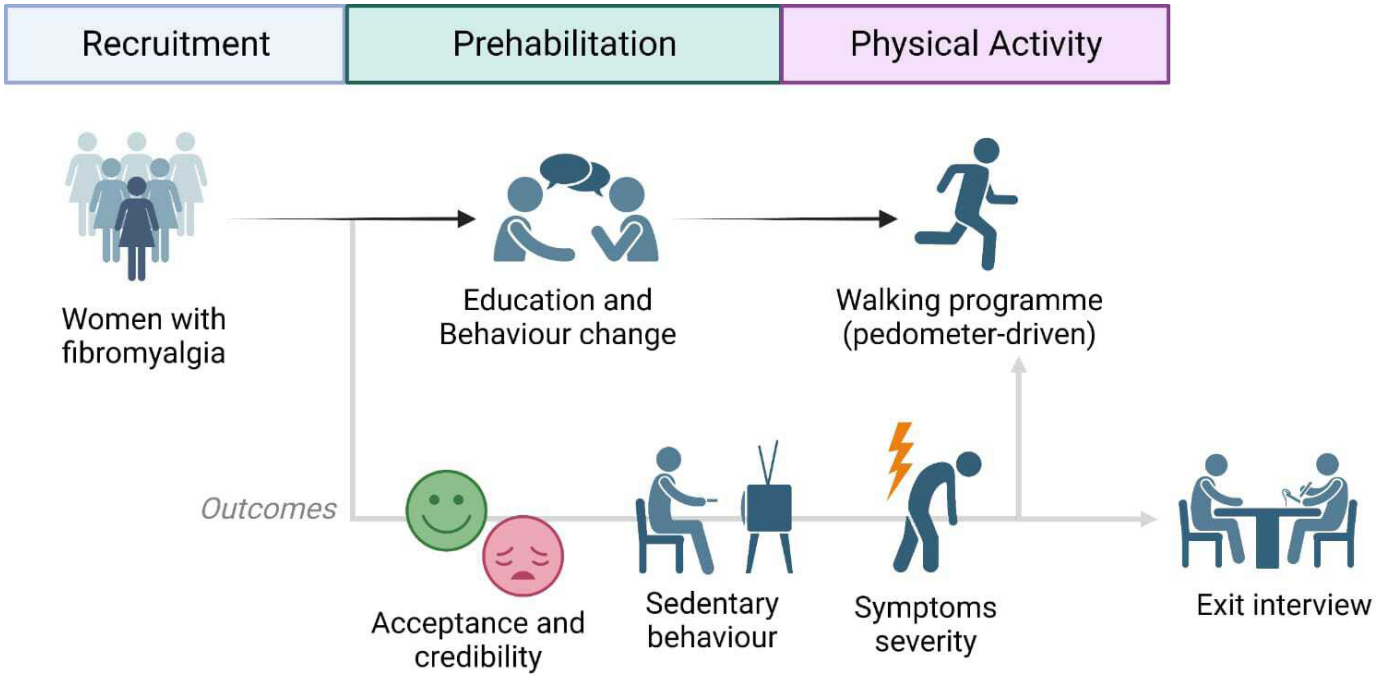


**Figure 1** Study design.



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After a cooling off period of 1 week, the participants were invited to attend a screening and baseline-related assessments meeting. Before such assessment, the participants returned their signed informed consent form to the research team. The aimed sample size was 12 people with FM. All the meetings took place in the setting of the patient support group.

Inclusion criteria for participating were (1) a clinical diagnosis of FM and (2) fulfil the corroboration conducted by the research team that is, the modified 2011 preliminary FM criteria questionnaire.[33] Participants were required to satisfy the 'Widespread Pain Index' (WPI) and 'Symptom Severity Scale' (SS) as follows, either WPI≥7 and the SS≥5, or the WPI is 3–6 and the SS≥9. Potential participants were excluded if they (1) were younger than 16 years old, (2) were not able to communicate in English, (3) could not mobilise independently/unaided, (4) had any medical condition that would make exercise participation unsafe (eg, heart disease, stroke, respiratory disease, severe mobility problems, severe arthritis or inflammatory joint disease), (5) were engaged in ongoing litigation involving FM, (6) were currently under active treatment by a physiotherapist or involved in any other research studies or (7) were pregnant. Moreover, participants filled out the Physical Activity Readiness Questionnaire, which is a widely used and valid questionnaire to uncover any heart, circulatory, balance, medication, emotional and joint problems that could make participation in the self-managed walking programme unadvisable for potential participants.[34]

## Intervention

The 4-week prehabilitation intervention, a combination of education and behavioural change, consisted of one session (approximately 1–1.5 hours) per week. This intervention involved a mixture of interactive and didactic sessions, facilitated by a physiotherapist and a sports scientist. The sessions focused on education and skills training in: exercise/physical activity, symptom flares, pacing, causes of symptoms in FM (eg, pain and fatigue) and their management. Participants were taught how to set goals based on the principle (specific, meaningful, adaptable, realistic and timely goals) and were encouraged to base their goals on what was valuable or meaningful to them. Participants identified a 'committed action' linked to their goal, which was revisited throughout the programme. The principles of third wave cognitive–behavioural therapy/acceptance and commitment therapy (CBT-ACT) were used to address maladaptive thought processes such as catastrophising. Stress management and the skills of relaxation were also covered in the prehabilitation programme. Participants were advised on the use of pedometers to monitor physical activity. The purpose of the initial prehabilitation programme was to gain participant 'buy-in' to the programme, to assist participants engage with exercise, to help participants overcome barriers to exercise and improve self-efficacy for exercise. The prehabilitation phase enabled participants to understand why and how to perform gentle self-paced exercise.

After the prehabilitation programme, participants were supported to engage in gentle, self-paced physical activity for 6 weeks, that is, a simple pedometer-driven walking programme with weekly telephone support. The research team contacted each participant using WhatsApp messages every week to discuss progress, to document mean daily step count and to discuss a new physical activity target (step count) for the subsequent week.

## Patient and public involvement (PPI)

The study was discussed with our PPI member from the FMSNI who was supportive of the study. The PPI member reviewed the protocol and participant-facing documents and facilitated recruitment through the support group.

## Outcomes and measurements

### Acceptability and credibility (primary outcome)

The acceptability and credibility of the prehabilitation intervention were determined by means of the Credibility/Expectancy Questionnaire (CEQ).[35] The scale includes six questions which measure how much the participant believes, right now, that the therapy they are receiving will help to reduce symptoms and includes two aspects (1) what one thinks will happen (credibility) and (2) what one feels will happen (expectancy). The CEQ combines two rating scales; one from 1 (not at all) to 9 (very much), and another from 0 to 100% (to rate how much improvements they think and feel will occur). Psychometric properties indicate that this questionnaire derives the two predicted factors (cognitively based credibility and relatively more affectively based expectancy) and that these factors are stable across different populations. Furthermore, the questionnaire demonstrated high internal consistency within each factor and good test–retest reliability.[36] Additional primary outcomes were: the number of sessions attended (≥75%), the number of drop-outs (≤20%), reasons for early withdrawal and the number of questionnaires completed and returned (>80%).

### Secondary outcomes

FM severity was assessed using the Revised FM Impact Questionnaire (FIQR).[37] The FIQR is a self-administered questionnaire, comprising of 21 individual questions with a rating scale of 0–10.[37] The FIQR total score range is from 0 to 100, with a higher score indicating greater impact of the condition on the person's life. Pain was assessed by the 'pain rating' question from the FIQR,[37] which was used to assess perceived pain intensity (on a 0–10 Numeric Rating Scale (NRS)) in the context of the past 7 days. Sedentary behaviour was measured using the Sedentary Behaviour Questionnaire (SBQ).[38] The SBQ was used to assess the time (minutes per day) spent on various sedentary behaviours; for example, television viewing, studying or playing video games. The questions were asked for a usual weekday and weekend day separately. Responses



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for a usual weekday were multiplied by five and weekend by two. To compute a subjective assessment of sedentary behaviour (min/week), the sedentary time of week and weekend was summed. Specific symptoms screened using the Pain NRS.[39 40] Participants were asked to rate on a 0–10 Likert scale their levels of pain, energy, sleep, depression and anxiety.

### Exit interview

The aim of the exit interview was to identify the strengths, weaknesses and barriers of the prehabilitation programme including: Experiences of taking part in the trial, how they find the intervention and suggestions for improvements. Interviews were planned to length 30–60 min, including five main questions: 'Tell me about your experiences of taking part in the trial', 'How did you find the intervention?', 'What parts of the intervention did you like?', 'What aspects of the trial could have been better?', 'What parts of the intervention did you find difficult?' and 'Is there any way we could have supported you to adhere to the exercise programme better?'. Participants were encouraged to expand their answers with probe ('why?', 'can you tell me more?').

## Data analysis

As this was a proof-of-concept study, the main and secondary outcomes were analysed using descriptive statistics (means and SD). Exit interview data analysis was based on Braun and Clarke's reflexive thematic analysis approach.[41] Analysis consisted of familiarisation of the data by reading and rereading the transcripts of the interview by members of the research team. The data were then coded and initial themes were generated. Initial themes were discussed with the whole research team where themes were reviewed and refined, a number of team meeting were held where themes were refined and defined.

## RESULTS

### Feasibility, acceptability and outcome assessments

Eleven participants (10 women) were recruited to this study, and nine (80%) attended at least three education sessions. Two participants dropped out, one due to lack of time and another due to finding the self-paced walking programme excessively stressful. Six participants (55%) completed all questionnaires at all the time points (ie, at baseline, after the behaviour change programme and after the self-paced walking programme). The CEQ (table 1) indicated that the prehabilitation intervention was logical and that the participants would be confident in recommending this intervention to a friend who experiences similar problems. Participants found the intervention logical, reported they thought that the intervention would improve their symptoms by from 22% to 38% and they would be somewhat confident in recommending the programme to a friend (6 out of 10). Results for the fibromyalgia severity (FIQR), specific symptoms (NRS, 0–10) and sedentary behaviour (SBQ) are presented in table 2. Improvements in FIQR ranged from 3% (FM function) to 13% (FM Symptoms). NRS found energy (26%) as the main benefit from the intervention, followed by sleep, depression and pain (12%–15%), with anxiety being the least impacted symptom (5%). Sedentary time during the week was reduced by 14% (around 80 min/week), with no impact on weekend time (table 2).

**Table 1** The acceptability and credibility of the prehabilitation behavioural change intervention by means of the Credibility/Expectancy Questionnaire (n=5)

| | |
|---|---|
| Credibility (thoughts) | |
| How logical does the intervention offered to you seem?* | 6.2 (2.3) |
| How successfully do you think this intervention will be in reducing your symptoms?* | 5.6 (2.1) |
| How confident would you be in recommending this programme to a friend?* | 6.0 (1.6) |
| How much improvement (%) in your symptoms do you think will occur?† | 30.0 (8.2) |
| Expectancy (feelings) | |
| How much do you really feel that intervention will help you to reduce your symptoms?* | 5.4 (1.2) |
| How much improvement (%) in your symptoms do you really feel will occur?† | 27.5 (9.6) |

Data are means and SD, M (SD).
*Items rated from 1 (not at all) to 9 (very much).
†Items rated from 0% to 100%.

## Exit interview

### Experiences of taking part in the trial

Participants highlighted that symptoms of FM fluctuate, even within short periods of time, but they felt that the questionnaires in the study were not able to capture this variation in symptoms. For example, with respect to the question in the FIQR 'Can you brush your hair?'

> Participant 1 (P1) stated *I can brush my hair. But when I'm really tired, I can't brush … it just depends.*

Thus, to include only one time point for evaluating outcomes may not accurately reflect FM symptoms. Participants expressed the view that if an accurate picture of the symptom experience was required, people would need to be monitored for at least 1 day, but ideally more than 1 day.

> P2: *[To evaluate] a day in the life of a fibro sufferer… or even two days would be fantastic, you could see how much or how little [a person is able to do] … I know two days is not really enough to [home-in] on different situations of our illness, but it would be a start.*

Participants also reported that the response-scale of some questionnaires was excessively restricted particularly questionnaires involving dichotomous responses (eg, yes vs no).



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Table 2 Participants' symptoms and sedentary behaviour at baseline as well as after prehabilitation and physical activity programmes (n=6)

| Outcomes | Baseline | After prehabilitation | After physical activity | Change from baseline |
|---|---|---|---|---|
| Fibromyalgia severity (FIQR) | | | | |
| Function | 20.6 (7.6) | 22.6 (6.1) | 19.9 (7.1) | –3.5% |
| Overall impact | 11.5 (4.6) | 16.2 (4.5) | 12.7 (5.1) | 9.4% |
| Symptoms | 39.9 (6.2) | 39.3 (4.7) | 35.4 (6.8) | –12.7% |
| Total score | 72.0 (16.0) | 78.0 (14.8) | 68.0 (16.2) | –5.9% |
| Specific symptoms (NRS 0–10) | | | | |
| Pain | 6.7 (2.0) | 8.8 (1.2) | 6.0 (1.8) | –11.7% |
| Energy | 8.2 (1.9) | 9.5 (0.8) | 6.5 (3.4) | –26.2% |
| Sleep | 9.5 (0.8) | 7.0 (1.7) | 8.3 (2.9) | –14.5% |
| Depression | 7.0 (2.4) | 8.2 (1.3) | 6.2 (1.2) | –12.9% |
| Anxiety | 8.2 (1.6) | 8.8 (1.2) | 7.8 (1.9) | –5.1% |
| Sedentary behaviour (SBQ) | | | | |
| Sedentary time (min/weekday) | 702.5 (200.9) | 647.5 (255.0) | 617.5 (294.0) | –13.8% |
| Sedentary time (min/weekend day) | 590.0 (235.8) | 612.5 (346.3) | 587.5 (290.6) | –0.4% |

Data are means and SD, M (SD).
FIQR, Fibromyalgia Impact Questionnaire-Revisited; NRS, Numeric Rating Scale; SBQ, Sedentary Behaviour Questionnaire.

P3: *The understanding of this questionnaire is quite 'you do, or you don't'. There's no in between about, 'maybe you could or maybe you couldn't'.*

Collectively, participants perceived that using questionnaires prevented a full understanding of the complex nature of their condition. Therefore, they preferred interviews when an intervention is evaluated.

P4: *Questionnaires are about crossing boxes, FM is not that easy. However, [when we are] talking, we can understand each other.*

Another suggestion by participants was to include an open comments section in questionnaires for clarifying some responses.

P5: *It can't be just, 'how do I feel, one to ten?', you need to be able to write why.*

### Perceptions of the intervention

Participants reported that the intervention should inform participants broadly about the symptoms of FM and that their impact varies with different people. It was emphasised that this message was particularly important with respect to physical function.

P3: *[In the walking programme] my [pedometer] numbers were sky high through all of mine, but I said to [a researcher's name] I feel very reluctant about handing my sheets in because I don't want you to be putting in, 'we had a guy there who has FM, but he did 42 000 steps a day' but that was me.*

A second topic that participants would like to have included in the prehabilitation programme was information regarding the fluctuations of the condition, even within a day. For example,

P 4: *I can actually feel really good in the morning but then by lunch time I could be in bed. It's so up and down, where I think you need to take into consideration that, as well as the steps.*

Participants demanded more information focused on increased content on particular topics and inclusion of other topics of interest. For instance,

P2: *the DIMs (Dangers in me) and SIMs (Safety in me) that you talked about, I found that really useful. I think they were really good, but you should have probably just done another meeting, where we explained everything a lot more.*

Participants also requested information on communication skills in the programme.

### Suggestions for improvements

Instead of a walking programme, most of the participants suggested that they would prefer a more comprehensive and varied physical intervention.

P1: *Movement is not walking, we need to broaden the thing. Walking is never going to work for me. I can't do this. I am just a waste of time because this just does not work for me.*

P1: *Sometimes there are activities that you do that don't count in steps but they're physical. I do crochet and knitting, which doesn't obviously come up on the pedometer, but my arms are moving.*



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In order to acknowledge the fluctuations of symptoms commonly experienced by people with FM participants suggested the need for flexibility within the predefined daily goals so that they can amend their goals according to the impact of FM on a particular day.

P4: *I would do a diary for the day, based on how you feel for a day because, the way you say, it's so unpredictable.*

This suggests that on days when the burden of FM is particularly high, participants could adapt their daily target to perform reduced physical efforts such as simply attending to activities of daily living.

P6: *My day is going to be 'I'm going to get out of this bed and I'm going to go to my living room chair' and that, to me, I've done something.*

Incorporating flexibility into daily goals might increase self-efficacy and reduce stress. Participants' comments also highlight the need to reinforce their achievements, however small, and reducing the responsibility and commitment felt as research participants. This could be particularly helpful for those who try to engage in physical efforts beyond their capabilities.

P2: *Something that I can sum up and really quickly I can see, I get a sense of achievement out of it. I score highly in that [Self Efficacy] Questionnaire because I make myself do things, even if I'm sore, so I get a high sense of achievement.*

P1: *I hope it works because anything that I've done, I will put everything I have into it. I was almost in tears because I just felt, 'I have let the whole group down'.*

P3: *I always push, push, push my limitations past what I should do, I have a problem with not stopping.*

Finally,participants suggested the need for more support during the walking programme. Participants identified two possible support mechanisms: (1) a general psychological support helpline that is not only related to the walking programme and (2) a peer-support programme.

P5: *Why did I not have somebody to call at the end of the day or whenever I'm feeling absolute rubbish? Having somebody to talk to, who knows what you're going through, would make a difference.*

P2: *The way you were contacting us all individually, you could have put us all into a WhatsApp group.*

## DISCUSSION

This feasibility study has demonstrated that it is feasible to engage people with FM in a prehabilitation programme which they found useful and beneficial to them and they believed supported them to engage in the physical activity programme. Feedback from participants has provided information which will strengthen the development of such programmes for future trials. Adherence results demonstrated that people with FM would be willing to attend education sessions (80% attendance) and complete a walking physical activity programme (only two dropped out). Based on the results from the scales we could cautiously conclude that (1) the current intervention combining a prehabilitation programme before a physical activity programme was feasible and acceptable to people with FM and (2) the physical activity programme resulted in improvements in all the outcomes examined. Based on exit interviews, participants highlighted that a choice of alternative physical activities may encourage greater engagement with physical activity.

One main challenge when designing and prescribing educational and exercise programmes in FM is the different responses and experiences that people may have. This is further confounded by the fact that symptoms in FM fluctuate over the short and longer term, making recommendation on treatment effectiveness difficult.[42] Our findings support the need for adapted and flexible programmes for people with FM. Thus, reflecting earlier recommendations, both behavioural change[43] and physical activity[44] interventions for people with persistent pain must be individually tailored to people's interests, priorities, preferences and current circumstances. According to participants in this study, communication is of the utmost importance, which should foster adherence and improve outcomes.[45] Indeed, participants preferred interviews over standard questionnaires, this preference is valuable information that should be taken into account in developing future prehabilitation programmes for people with FM.

Collectively, participants preferred the behavioural change programme to the movement component. Common barriers for people with FM regarding engagement with physical activity are fear of movement and low expectations of their capabilities.[21 46] Improvements in self-efficacy[47] and perceived control[48] appear to be an effective strategy to promote exercise programmes among people with FM. A lesson from this feasibility study is the need to cope with these barriers to increase physical activity endorsement and motivation. Furthermore, based on the interviews, it seems that a more comprehensive and varied physical intervention would improve motivation. While more challenging, researchers and practitioners are now provided with evidence-based guidelines for exercise dosage and prescription in people with FM[49 50] which advise consideration of a wider range of physical activities.

Another obstacle identified by participants was the lack of support during the walking programme. In particular, they asked for more peer-support, remote support by the research team and, particularly, combined remote with face-to-face support. A good example of how to incorporate support during combined educational and exercise programmes in people with chronic pain can be found in McBeth *et al*.[51] Future prehabilitation programmes in FM should, therefore, conduct an initial patient-centred assessment (shared understanding, problems formulation and patient-defined goals) and invest time



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in providing face-to-face and/or telephone support to increase effectiveness.

It should be noted that the lessons and perspectives described in this pilot study come from a small sample size of participants. However, the information they provided contributes in a better understanding of how to promote physical activity in people with FM. There remains a paucity of evidence on successful prehabilitation programmes in FM, therefore, the information and testimonies described in this paper should help to optimise future interventions. This study contemplates and supports the active involvement of people with FM by collecting and disseminating their lived experience and knowledge to improve physical activity engagement in clinical and community settings. The use of self-reported physical activity questionnaires may overestimate the measures of moderate-to-vigorous physical activity up to 25% if compared with objective device-based methods (ie, accelerometery).[52] The use of technology in FM treatment is leading to new forms of measurement (eg, heart rate variability biofeedback to increasing stress resistance and emotional adaptability and reducing pain).[53] However, the use of devices requires extra costs and particular training to operate the software, which may limit its feasibility[54] and implementation in large-scale clinical settings. In our study, we used technology to track the physical activity volume (ie, pedometer-driven) finding no operational difficulties among participants.

## CONCLUSION

This feasibility study demonstrated that a prehabilitation, behaviour change intervention is acceptable to people with FM. The main limitations raised by participants were the lack of flexibility and support. Potential solutions included, using interviews rather than questionnaires and to consider symptoms fluctuations, to adapt the programmes to individual's priorities and symptoms on a daily-basis and to offer a variety of physical activity programmes. This feasibility study provides valuable information for the development of effective prehabilitation, behavioural change programmes for people with FM.

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