Trials

STUDY PROTOCOL

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Efficacy of a home-based stretching programme on fibromyalgia symptoms: study protocol for a randomised controlled trial

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Abstract

Background This protocol was developed to describe the design of a randomised controlled trial that will examine the clinical efficacy of a 6-week, novel, home-based stretching programme compared with usual care on the effect of symptoms experienced by patients with fibromyalgia. The hypothesis is that the total score of the Fibromyalgia Impact Questionnaire (FIQ-R) and other fibromyalgia symptoms will improve 6 weeks following the stretching intervention compared with usual care.

Methods Fifty-eight adults under 65 years of age diagnosed with fibromyalgia will be recruited for this study. Participants will be randomised into an intervention group and a control group (waitlist). Randomisation will be stratified by sex. The intervention group will perform 6 weeks of daily stretching exercises for 6 min—a day. The control group will maintain usual care. A mHealth app will support stretching adherence. The primary outcome will be the total score of the Revised Fibromyalgia Impact Questionnaire (FIQ-R). The secondary outcomes include regional and widespread pain sensitivity, range of motion, quality of life (SF-36), mental and physical functioning and adherence. Evaluations will be performed at baseline, following 6 weeks of daily stretches (primary endpoint) and 6 months after the termination of the intervention period (secondary endpoint).

Discussion By investigating the clinical efficacy of a 6-week, novel, home-based stretching programme, we hope to provide applicable and generalisable knowledge about the efficacy of stretching exercises that can potentially help ease the burden of symptoms experienced by patients with fibromyalgia.

Trial registration NTC, NCT06487741. Registered on 24 June 2024.

Keywords Randomised controlled trial, Fibromyalgia, Physical therapy modalities, Muscle stretching exercises, Exercise adherence

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Background

Fibromyalgia (FM) is a complicated pain syndrome characterised by chronic widespread pain and generalised hyperalgesia [1]. Pain is considered the defining feature of FM [2]. In addition to pain, other prevalent symptoms include fatigue, insomnia and muscle weakness [3]. FM patients are sensitive to physical activity and often suffer from systemic symptoms such as cognitive dysfunction, sleep disturbances, muscle tightness and emotional distress such as anxiety and depression [4]. The pathophysiological causal factors of FM are not

yet well known, but sensitisation is considered the main driver of FM [3, 4]. Accurately diagnosing FM can be challenging as FM is mostly considered a diagnosis of exclusion [5]. FM encompasses a subgroup of individuals with chronic widespread pain [6, 7]. However, the American College of Rheumatology (ACR) 2016 diagnostic criteria can support clinicians in making the diagnosis when symptoms exceed the ACR diagnostic threshold [8].

The current treatment for fibromyalgia is based on symptom management and includes both pharmacological and non-pharmacological interventions [9]. Pharmacological treatment alone is often inadequate. Hence, multidisciplinary treatment programmes are advocated for patients with FM [3, 9, 10]. Current recommendations include individualised graded physical exercise that may be complemented with cognitive behavioural therapies [9], and emerging research offers promising insights into the efficacy of health education programmes [11]. In addition, a range of complementary treatments such as yoga and tai chi, virtual reality distraction therapy, acupuncture and massage therapy are employed to alleviate the burden of FM despite limited supporting evidence [12].

Graded physical exercises are recommended, given their positive effects on pain, physical function and well-being, availability, and low cost [9]. However, the ability of patients to participate in exercise programmes is often impeded by the level of pain or fatigue [4]. In addition, exercise-induced worsening of symptoms is a well-known sequelae of initiating physical exercise interventions for people with FM [10]. Therefore, adherence is challenged, and patients often refrain from physical activity for fear of worsening symptoms [13]. In summary, despite advancements in research and the development of new therapy options, many patients still face challenges with respect to treatment efficacy. Therefore, further studies are needed to examine the efficacy of other exercise modalities that may improve the impact of FM symptoms.

Current evidence suggests that stretching exercises may have a positive effect on pain, depression, physical and mental functioning and quality of life in people with FM [14, 15]. However, the certainty of the evidence is low due to issues like high risk of bias, poorly prescribed protocols and small sample sizes [15, 16]. The primary objective of the RCT is to investigate the clinical efficacy of a 6-week, novel, home-based stretching intervention compared with usual care on the symptoms experienced by patients with FM. We hypothesise that the primary outcome, the Fibromyalgia Impact Questionnaire (FIQ-R) total score, and other FM symptoms improve within 6 weeks following the stretching intervention.

Methods/design

This is a study protocol for a randomised controlled trial designed to study the effects of 6 weeks of daily stretching exercises on the impact of symptoms experienced by patients with FM. The trial will be conducted in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement (SPIRIT) [17]. The trial is approved by The North Denmark Region Committee on Health Research Ethics (N-20240035), reported to the Danish Data Protection Agency, and registered at ClinicalTrials.gov (Trial registration number NCT06487741). Participants will provide written informed consent before allocation to treatment groups, and they will be randomised into an intervention or control group (waitlist) following baseline measures. Counterbalanced block randomisation will be performed on a 1:1 ratio stratified by sex. Block sizes of 4–6 will be used. Randomisation will be performed using a computer-generated random number sequence (https://www.randomizer.org/). Outcomes will be measured immediately before (baseline), after 6 weeks of stretching exercise (primary endpoint) and 6 months after the termination of the intervention period (secondary endpoint) (Fig. 1). This approach allows for the assessment of the short-term effects of intervention and any residual effects. Before the baseline measures, the participants are familiarised with the experimental procedures and devices used. Figure 2 shows a schematic diagram of the progress of the various stages of the trial.

Study setting

The study will take place at the University College of Northern Denmark research laboratory. Selma Lagerløfs Vej 2, 9220 Aalborg East, Denmark. The stretching intervention is carried out in the participant's home. No additional infrastructure or relevant features are necessary for the stretching intervention.

Participants

Inclusion criteria

Participants are included if they are aged 18 to 65 years. Eligibility criteria require individuals to have been diagnosed with FM in accordance with the ACR diagnostic criteria [18]. In addition, individuals diagnosed with chronic non-malignant pain or individuals diagnosed with chronic widespread pain (including fibromyalgia syndrome) are also included when they meet the ACR 2016 diagnostic criteria.

Exclusion criteria

The exclusion criteria are non-controlled systemic disorders (such as hypertension, diabetes and coronary insufficiency), neurological conditions that impair alertness or

	STUDY PERIOD			
	Enrolment	**Baseline assessment and allocation**	**Post-allocation**	
TIMEPOINT**	***-t_1***	**0**	***t_1: primary endpoint***	***t_2: secondary endpoint***
ENROLMENT:				
Eligibility screening	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS:				
Stretching		→	→	
Usual care (waitlist)		→	→ ·····	
ASSESSMENTS:				
Demographics and patient characteristics	X			
Current pharmacological therapies		X	X	X
Primary outcome				
FIQ-R		X	X	X
Secondary outcomes				
SF-36		X	X	X
IPAQ		X	X	X
ROM		X	X	
PPT		X	X	
Adherence		↔	↔ X	

Fig. 1 SPIRIT diagram for trial stages of enrollment, intervention, and assessment. FIQ-R, the Revised Fibromyalgia Impact Questionnaire; SF-36, the Short Form-36; IPAQ, The International Physical Activity Questionnaire; ROM, Passive knee extension range of motion; PPT, pressure pain thresholds

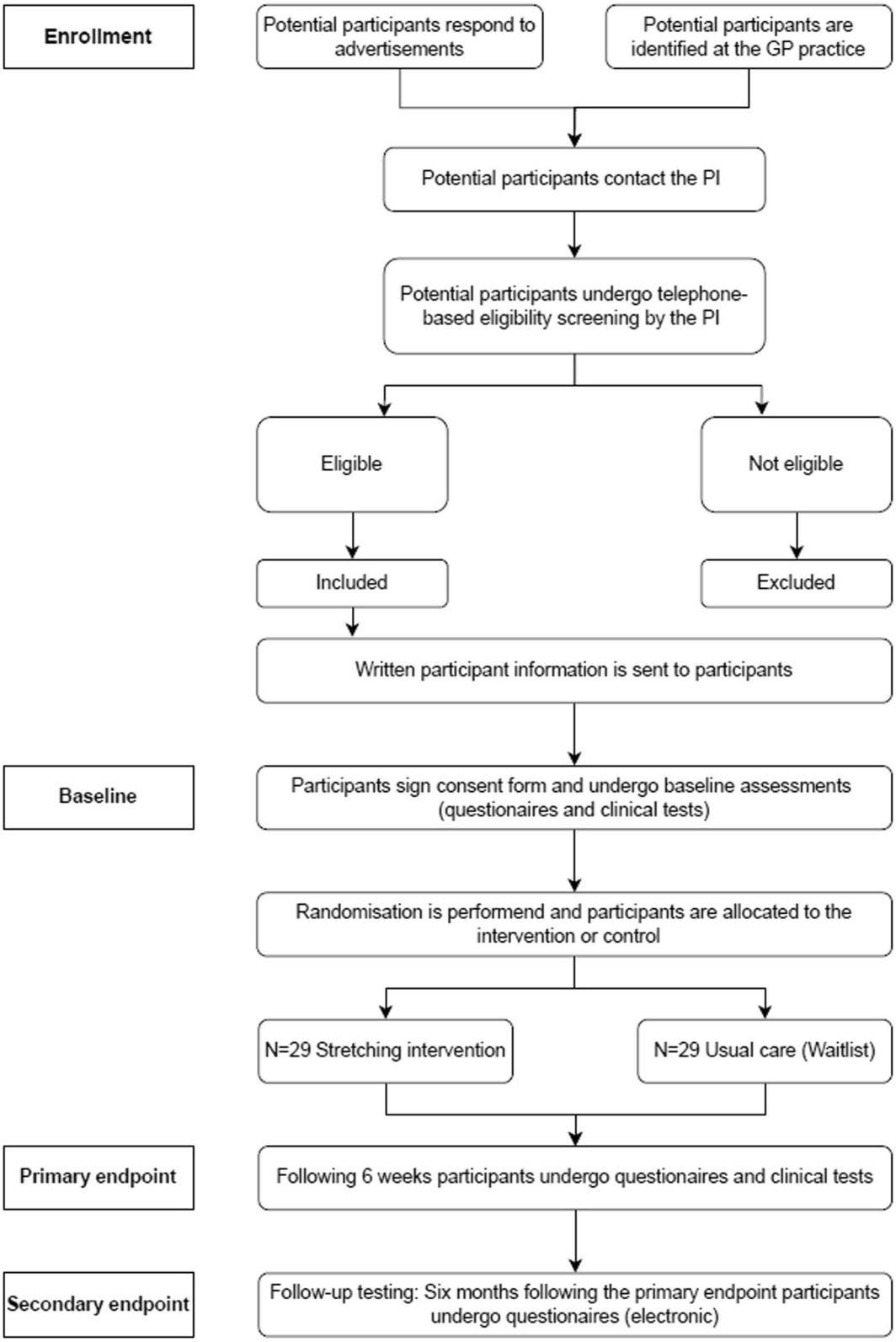

Fig. 2 Study procedure flow chart

comprehension, musculoskeletal conditions that could compromise assessments (such as nerve root compression or knee joint inflammation), relevant joint disorders (such as severe arthritis, arthroplasty of the hip or knee, and rheumatoid arthritis), and recent changes in therapy for fibromyalgia (i.e. within 4 weeks of baseline).

Intervention group

The intervention comprises 6 weeks of daily static stretching exercises (6 min. a day) in accordance with the recommendation of the American College of Sports Medicine [19]. The intervention is self-administered and consists of two bouts of 30-s bilateral static stretches of the knee flexors, hip abductors, and shoulder elevators. The participants are instructed to apply tension to the point of a stretching sensation, holding the stretch for 30 s. A minimum of 30 s of rest between bouts is maintained. The participants are individually instructed in the stretching procedures by the principal investigator (MPS). The Template for Intervention Description and Replication (TIDieR) Checklist for reporting interventions describes the intervention (Table 1) [20]. Adherence to the stretching protocol is supported by a mHealth app (My Physiotherapist, DigiFys, Viborg, Denmark), where the participants are asked to keep a log of the dates when they perform the stretching exercises [21]. The mHealth app also supports video instructions for stretching procedures. MPS will contact each study participant weekly throughout the trial via the mHealth app. Participants will be encouraged to maintain their daily routine but refrain from changing their current pharmacological treatment or initiating new physical exercise practices during the study.

Control group

The control group (waitlist) receives usual care, and no change in treatment is made. Participants will be encouraged to maintain their daily routine but refrain from changing their current pharmacological treatment or initiating new physical exercise practices during the study. MPS will contact each study participant via e-mail weekly throughout the trial. Also, participants in the control group are requested not to begin stretching exercises independently during participation. Instead, participants in the control group are informed that they will be invited to receive the intervention upon completion of the study (primary endpoint).

Outcomes

Descriptive characteristics

The following descriptive characteristics will be collected: sex, age, body weight, height, first onset of symptoms, year of diagnosis and current pharmacological therapies such as low-dose naltrexone, tricyclic compounds, gabapentinoids and serotonin-norepinephrine reuptake inhibitors, and pain medications such as tramadol, NSAID and paracetamol.

Primary outcome measures

The primary outcome measure is the Danish version of the Revised Fibromyalgia Impact Questionnaire (FIQ-R) total score [22]. The FIQ-R is a multidimensional questionnaire that measures the participant's self-rated overall fibromyalgia severity. The FIQ-R is the most widely used FM-specific patient-reported outcome measure to assess the full spectrum of FM-related problems and their response to therapy [23]. The FIQ-R demonstrates good reliability and validity and has sound psychometric properties [22–25]. The FIQ-R consists of 21 questions (items) linked into three domains (function, overall severity, and symptoms). Each item is standardised on a scale ranging from 0 to 10, with lower scores indicating greater improvement or less negative impact. The FIQ-R total score ranges from 0–100, with higher scores indicating a more significant impact of symptoms [24]. A change in the FIQ-R total score of approximately 14%, or 8.1 in absolute value, is considered a minimal clinically important difference (MCID) [26]. Subscores for the three FIQ-R domains will be used as secondary outcomes.

Secondary outcome measures

Health-Related Quality of life (HRQL)

HRQL is assessed using the Danish version of the Short Form-36 (SF-36) questionnaire, a reliable and valid questionnaire assessing HRQL within the physical and mental health domains [27].

Self-reported physical activity

The International Physical Activity Questionnaire (IPAQ) short form is used to assess the participants' perceived physical activity levels. The IPAQ short form is a 9-item self-report measure of the perceived time spent engaged in vigorous activities, moderate-intensity activities, walking and sitting during the previous 7 days [28]. The IPAQ short form has demonstrated acceptable reliability and validity [29].

Range of motion

Passive knee extension range of motion is assessed before the start of the study (baseline) and after 6 weeks (primary endpoint) using the Biodex System 4 Pro isokinetic dynamometer (Biodex Medical Systems, Shirley, New York, USA). The Biodex system has excellent reliability and validity [30–32]. The participants are seated and fixed to the chair with a hip flexion angle of 100° and a knee extension angle of 90°. The dynamometer lever

Table 1 Intervention delivery described using the TIDieR guidelines

	BRIEF NAME	
1	Provide the name or a phrase that describes the intervention	Six weeks app supported static stretching of the knee flexors, hip abductors and shoulder elevators
	WHY	
2	Describe any rationale, theory, or goal of the elements essential to the intervention	Previous studies have found that regular stretching exercises have positive effects on pain, physical and mental functioning, depression, and quality of life in adults with fibromyalgia
	WHAT	
3	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL)	A mHealth app (My Physiotherapist) supports adherence to the home-based stretching programme. The app also supports video instructions on the stretching procedures
4	Procedures: Describe each of the methods, activities, and/or processes used in the intervention, including any enabling or support activities	The intervention includes self-administered static stretching of the knee flexors, hip abductors and shoulder elevators Knee flexors: Participants are to perform static stretching of the knee flexors in a seated position. The participant sits upright on the floor with one leg straight. The sole of the other foot is placed on the inside of the outstretched leg. The participant leans slightly forward and tries to touch their toes while maintaining full knee extension. A modification of the exercise is used when necessary. For the modified stretch, the participant is standing, placing the heel of the stretching leg on an elevated surface, approximately knee to waist high, with the knee fully extended. The participant then flexes forward at the hip Hip abductors: Participants are to perform static stretching of the hip abductors seated on the floor with both legs extended out in front. The participant bends the left leg at the knee until it touches the chest. The back is kept straight, with the left foot crossed over the right leg, while both hands hug the left knee to the chest. The participant then twists the body toward the left knee. The participant can then pull the left knee to increase the stretch. A modification of the exercise is used when necessary. For the modified stretch, the participants lie on their back, cross one leg over the opposite knee and gently pull the knee towards the chest Shoulder elevators: Participants are to perform static stretching of the shoulder elevators in a seated position. The participant sits upright. The participant performs a slight cervical retraction followed by a cervical lateral flexion towards the opposite shoulder The participants are requested to log the daily stretching exercises using the mHealth app. The principal investigator (MPS) will contact each study participant weekly throughout the trial via the mHealth app to monitor adverse responses to the intervention and provide real-time feedback
	WHO PROVIDED	
5	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given	A physiotherapist (MPS) provides intervention instructions
	HOW	
6	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group	Intervention instructions are delivered face-to-face by a physiotherapist and are bolstered by video instructions on the mHealth app. The app supports direct message contact between the participant and the principal investigator for Q&A during the study
	WHERE	

Table 1 (continued)

	BRIEF NAME	
7	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	Intervention instructions are performed in the University College of Northern Denmark research laboratory. Selma Lagerløfs Vej 2, 9220 Aalborg East The stretching intervention is carried out in the participant's home. No infrastructure or relevant features are necessary to carry out the stretching intervention
	WHEN and HOW MUCH	
8	Describe the number of times the intervention was delivered and over what period of time, including the number of sessions, their schedule, and their duration, intensity or dose	The self-administered stretching programme consists of two bouts of 30-s bilateral static stretches of the knee flexors, the hip abductors and elevators of the shoulder 7 days a week for 6 weeks. The participants are instructed to apply tension to the point of a stretching sensation, holding the stretch for 30 s with a minimum of 30 s of rest between bouts

arm passively extends the knee at an angular velocity of 5°/s. [33]. The combined trunk and hip position ensures that tension is placed primarily on the muscle–tendon unit of the knee flexors to ensure that participants cannot straighten the knee during the testing procedure [34]. The participants are instructed to stop the lever arm by pressing a stop button when the sensation changes from stretch to pain. For each measurement, the test is performed once.

Pain sensitivity

Pain sensitivity expressed as pressure pain thresholds are assessed before the start of the study (baseline) and after 6 weeks (primary endpoint) using a handheld electronic pressure algometer with a probe size of 1 cm^2 and (Algometer Type 2, SBMEDIC, Hörby, Sweden). Pressure algometry is considered a reliable method for pain assessment [35]. The rate of pressure increase is applied perpendicular to the tissue and kept at 30 kPa/s. The first time the sensation of pressure is perceived as painful, the participant presses a button, stopping the stimulation. The pressure value at this time point defines the pressure pain threshold. Pressure pain thresholds are assessed at two sites (m. tibialis anterior and m. trapezius), located and marked using the SENIAM guidelines for placing electrodes in EMG studies as inspiration [36]. The tibialis anterior site is located at 1/3 on the line connecting the tip of the fibula and the tip of the medial malleolus. The trapezius site will be located at the left upper trapezius muscle, 10 cm from the acromion in direct line with the seventh cervical vertebra. The pressure pain thresholds are assessed three times at each site, alternatingly, with 20-s intervals between assessments. Mean values are used for the analysis.

All outcome measurements are made at independent time points, not following a stretching protocol.

Adherence

Adherence to the intervention is evaluated by the number of days stretching is performed using the self-reported data from the mHealth app.

Sample size calculation

The sample size for this study was informed by data from our previous feasibility study that used a similar home-based stretching intervention [37]. The sample size was calculated using repeated-measures analysis of variance for a design with a 2-level within-subject factor and a 2-level between-subject factor. The mean baseline FIQ-R total score was set at 56.5, and the covariance matrix for repeated measurements, assumed to be constant across both groups, was set to [276,209/209,211]. With an alpha level of 0.05, assuming no change in the score in the control group and a minimal clinically relevant score change of 14% in the intervention group, 24 patients per group are required to achieve a power of 0.9. Additionally, considering a 20% loss to follow-up, the final total sample size needed is 58 (29 in each group).

Recruitment

Individuals diagnosed with FM are recruited through the Danish Fibromyalgia & Pain Association and general practitioners in the North Denmark Region. Individuals diagnosed with chronic non-malignant pain or chronic widespread pain (including fibromyalgia syndrome) who meet the ACR 2016 diagnostic criteria are recruited through their general practitioners only.

Active recruitment via social media will be an additional strategy to recruit individuals diagnosed with FM to reduce the risk of selection bias (e.g. over-representing individuals with similar health-seeking behaviour). Individuals interested in the study will contact MPS by phone or e-mail. Information about the study and screening for eligibility after verbal consent is carried out by phone. If the screening criteria are met and the individual is interested in participating in the study, an appointment is scheduled. Potential participants will receive the participant information via e-mail, allowing time to read the information before the appointment.

Blinding

The participants are blinded to the results of the pressure pain threshold measurements. The participants and the outcome assessor (MPS) are blinded to the range of motion measurement results. MPS is blinded to the outcome of the FIQ-R, SF-36 and IPAQ questionnaires. Owing to the specific nature of the intervention, blinding participants and the care provider (MPS) from treatment allocation is deemed unfeasible.

Participant adherence to the intervention, adverse events and concomitant care

The mHealth app is used to support adherence to the stretching protocol. Participants are instructed to log the dates they perform the stretching exercises using the mHealth app. MPS contacts each participant weekly throughout the trial via the mHealth app, monitors adverse responses to the intervention and provides real-time feedback. Serious adverse events will be reported to the North Denmark Region Committee on Health Research Ethics in accordance with the Danish Committee Act. Stretching exercises are considered safe [38]; hence, no adverse events are expected; however, possible harms (e.g. soreness or injuries) are monitored using baseline values to oversee the condition of all participants during the trial.

Statistical analysis

Data management and analyses are performed using SPSS 30 (SPSS Inc., Chicago, IL, USA). Data are analysed using descriptive and inferential statistics. Continuous variables are presented with mean ± SD and 95% CIs. An intention-to-treat analysis will be used to assess the response to the intervention, with the baseline evaluation carried forward when necessary (missing data imputation). The primary and secondary outcomes will also be analysed per protocol, in which only participants who present an adherence >= 70% will be included. Variables are tested for normality using the visual inspection of histograms and an inspection of Q-Q plots and complemented by a test of deviation from normality (Shapiro–Wilk test). Parameters that do not meet the assumption of sphericity are corrected using the Greenhouse–Geisser adjustment. The intragroup and intergroup comparisons will be carried out using Two-Way Repeated Measures Analyses of Variance (RAM ANOVA). In case of significant factors or interactions in the RM-ANOVAs, Bonferroni corrected post hoc paired comparisons of pairs of each independent factor are performed. Effect size estimates are calculated using partial eta squared (η_p^2) for ANOVA and were interpreted as small (ES 0.01), moderate (ES 0.06), and large (ES 0.14) [39]. An alpha level of 0.05 is defined for the statistical significance of all tests.

Patient and public involvement

The main research question was informed by previous research. In the early planning stages, the RCT protocol was assessed by the Center for General Practice, Aalborg University user panel on the 21st of September, 2023. The user panel comprised 20 representatives from various patient associations in the North Denmark Region. The user panel provided feedback on the research protocol and participants' information material and assessed the burden of the intervention. On the 14th of March 2024, the RCT protocol was evaluated by the Center for General Practice, Aalborg University practice network. The practice network comprised eight general practitioners from eight different general practices in the North Denmark Region. The practice network provided feedback on the recruitment strategy, the definition of the inclusion and exclusion criteria, and the choice of outcome measures.

Furthermore, a feasibility and acceptability trial involving twelve participants diagnosed with fibromyalgia was conducted in the first half of 2024 in collaboration with the Danish Fibromyalgia & Pain Association [37]. The purpose of the study was to evaluate the feasibility and acceptability of the intervention and inform the RCT study protocol, participant information and sample size calculation.

Discussion

Current evidence shows that stretching exercises may have a positive effect on pain, depression, and quality of life in people with fibromyalgia [14, 40]. However, the certainty of the evidence is low due to the risk of bias, poorly prescribed protocols and a small number of study populations [15, 16]. This is the first study to examine the effect of a home-based stretching intervention that comprises daily static stretches on fibromyalgia symptoms compared with usual care.

To reduce the risk of selection bias (e.g. over-representing individuals with similar health-seeking behaviour) individuals diagnosed with FM are recruited through the Danish Fibromyalgia & Pain Association and general practitioners in the North Denmark Region along with active recruitment via social media. In addition, individuals diagnosed with chronic non-malignant pain or chronic widespread pain (including fibromyalgia syndrome) who meet the ACR 2016 diagnostic criteria are recruited through their general practitioners only.

Adherence to exercise is a known challenge in patients with FM [13]. Consequently, the use of an mHealth app allows for remote and personalised support to increase adherence to the intervention and daily monitoring of potential harms during the trial.

Stretching exercises show promising positive effects on the severity of FM symptoms and are simple to implement, affordable and generally well tolerated. However, further studies need to be carried out to advance our understanding of the benefit of stretching exercises on FM symptoms to enable the adaptation of interventions for diverse patient populations [40]. This study will add to the present-day understanding of the efficacy of stretching exercises on FM symptoms. Moreover, the knowledge generated by this study may directly impact the evidence towards developing targeted interventions and self-management of therapeutic resources to decrease the burden of FM. If shown to be effective, this intervention could readily be applied in both primary and secondary sectors because of its low cost, convenience, and simplicity.

Ethics and dissemination

The project complies with the relevant national regulations and institutional policies and will be performed following the tenets of the Helsinki Declaration. The trial is reported to the Danish Data Protection Agency, registered at ClinicalTrials.gov (trial registration number NCT06487741), and approved by the Committee on

Health Research Ethics in The North Denmark Region (N-20240035). The participants will be informed of the study objectives, risks, and benefits and must provide written informed consent before participation. Participants can stop participation at any time without giving an explanation. The study findings will be disseminated via peer-reviewed journals, national and international conferences, and media releases. The results will be submitted to scientific journals for publication, irrespective of the study findings.

Data statement section

According to the EU Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, General Data Protection Regulation (GDPR), data will be stored in a secure web-based database (UCNemDok) with restricted access and ID code. Each participant will be assigned a unique identification number, which is the only identifier. Source documents, including dates and participant IDs, will be scanned and saved as electronic copies, and the paper material will be destroyed. Participant data from the Biodex system will be transferred using an encrypted Universal Serial Bus (USB) stick. Data will be stored for 5 years after the termination of the trial. MPS will have access to all trial data.

Trial status

The protocol version number and date: Version number 1, 06/24/2024.

Recruitment: Recruitment started on October 24th, 2024. The anticipated recruitment completion is in August 2026.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08776-z.

Supplementary Material 1.

Acknowledgements
Not applicable.

Authors' contributions
MPS is the Chief Investigator; he conceived the study and led the proposal and protocol development. SPM, JLT and AR contributed to the study design and to the development of the proposal. All authors read and approved the final manuscript.

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Data availability
The full trial protocol and informed consent materials are available at any reasonable request to the corresponding author. The final trial dataset and the code for statistical analysis will be accessible by non-commercial partners upon request.

Declarations

Ethics approval and consent to participate
The trial is approved by The North Denmark Region Committee on Health Research Ethics (N-20240035), reported to the Danish Data Protection Agency, and registered at ClinicalTrials.gov (Trial registration number NCT06487741). The participants will provide written informed consent before allocation.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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