Title: Comparing Standard Care Approaches for Greater Trochanteric Pain Syndrome in General Practice: A Randomised Clinical Trial

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Experimental Protocol

Background

Lateral hip pain or greater trochanteric pain syndrome (GTPS) is a common pain condition presenting on the outside of the hip. GTPS most commonly affects middle-aged women, with a prevalence of 15% in women aged 50-70 (1). The cause of this condition is tendinopathy of the gluteal tendons with or without involvement of the trochanteric bursa, resulting in pain while walking, sitting, stair climbing and lying on the side (2–4). Hence, GTPS interferes with many daily activities and affects quality of life to a degree similar to that of late-stage hip osteoarthritis (4). A quarter of GTPS patients will experience sick leave due to pain, and the prognosis is poor with 63% of patients in primary care still reporting pain at 5-year follow-up after various treatments, including pain medication, corticosteroid injections, physiotherapy, surgery, etc. (5).

Many GTPS patients will seek first-line care from their general practitioner. In general practice, GTPS covers 10-20% of patients presenting with hip pain, and 35% of the patients are treated by their general practitioner alone (5). In some cases, patients will be referred to a physiotherapist, private rheumatology or orthopaedic practice. At present, there is no protocol for the treatment of GTPS in primary care, and there is a lack of evidence on which treatment approach is the most effective. A wide range of treatment modalities are currently being used, such as wait-and-see, exercises, and corticosteroid injections (CSI). In rheumatology practice CSI is the standard treatment and as a monotherapy it has been shown to provide short-term symptom relief, with superior outcomes compared with exercise and shockwave therapy after one month, but not after 15 months (6). The primarily short term effect of CSI monotherapy has been confirmed in several studies (7–10), while evidence from other tendinopathies suggests that combining CSI with exercise may improve longer term outcomes (11,12). Although CSI is widely regarded as part of standard care, its actual role in GTPS management remains unclear, including how it contributes when used alongside exercise within a combined treatment strategy.

Apart from exercises, another key aspect in the management of tendinopathy is educating the patient about the condition and load management (14). A previous trial has shown that combining education with intensive exercise programs improves outcomes and is more cost-effective compared to corticosteroid injections alone or ‘wait-and-see’ strategies (8,15). However, resource-intensive protocols requiring multiple supervised sessions are difficult to implement in routine general practice, and it remains a central unanswered question for primary care whether adding a structured and home-based exercise programme provides meaningful benefit over advice alone. These uncertainties call for a study evaluating treatment strategies relevant to primary care, with the opportunity to examine the potential contribution of CSI as part of a more intensive approach.

Purpose

The purpose of this trial is to investigate the effectiveness of patient advice, versus patient advice plus a home exercise programme, versus patient advice plus a home exercise programme and a corticosteroid injection on global improvement at 3 months in patients with GTPS.

The main hypotheses are:

1. Patient advice plus exercises plus CSI will be superior to patient advice alone.
2. Patient advice plus exercises will be superior to patient advice alone.

Litterature search

We conducted a search on November 5th, 2025, using the following search terms in a specific search base:

("Exercise Therapy"[MeSH Terms] OR "exercise*"[Title/Abstract] OR "Physical Therapy Modalities"[MeSH Terms] OR "physiotherap*"[Title/Abstract] OR "rehabilitation"[Title/Abstract] OR "Patient Education as Topic"[MeSH Terms] OR "education"[Title/Abstract] OR "advice"[Title/Abstract] OR "Conservative Treatment"[MeSH Terms] OR "Injections"[Title/Abstract] OR "Glucocorticoids"[MeSH Terms] OR "corticosteroid*"[Title/Abstract] OR "cortisone"[Title/Abstract] OR "corticosteroid injections"[Title/Abstract] OR "injections, intra articular"[MeSH Terms]) AND ("greater trochanteric pain syndrome"[Title/Abstract] OR "gluteal tendinopathy"[Title/Abstract] OR "lateral hip pain"[Title/Abstract] OR "trochanteric bursitis"[Title/Abstract] OR "Hip Pain"[Title/Abstract]) AND ("adult"[MeSH Terms] AND 20105/01/01:2025/12/31[Date - Publication])

This gave us 211 hits to be screened. After screening and full-text reading, 16 of them was included to form the bases of the current study (9,15–29).

Subjects

For this study, we plan to recruit 192 patients. Participants will be recruited from Bispebjerg sports medicine department, general practice clinics, private rheumatology/orthopaedic clinics, social media, and advertising at social events. Any patient who presents with self-reported lateral hip pain will be considered for inclusion.

The following inclusion and exclusion criteria will be used:

Inclusion

1. 35+ years of age .
2. Self-reported lateral hip pain for at least 12 weeks, with an average intensity (when pain is present) of at least 4/10 over the past week on a numeric rating scale (NRS, 0–10; 0 = no hip pain, 10 = worst imaginable hip pain).
3. Access to a computer, smartphone, or tablet with an internet connection.
4. Tenderness on palpation of the greater trochanter AND at least one of the following:
    a. Reproduction of lateral hip pain with a 30-sec single-leg stance test.
    b. Reproduction of lateral hip pain with FADER-R.
5. Ability to speak and understand Danish (written and oral).

Exclusion

1. CSI in the affected hip within the last 6 months.
2. History of systemic inflammatory diseases, e.g., rheumatoid arthritis, spondylarthritis.
3. Weekly intake of oral glucocorticoids.

4. Individuals with diabetes characterised by unstable or inadequately controlled blood glucose levels (e.g., due to recent medication adjustments or unstable pharmacological management) will be excluded.
5. Received any treatment by a healthcare professional for GTPS within the previous 12 weeks or made any substantial changes to usual self-management of the condition in the last 4 weeks (eg, started performing stretching, made a substantial decrease in physical activity level).
6. History of prior hip or lumbar back surgery.
7. Current low back pain (>5 NRS) or episodes of low back pain within the last 3 months that have caused sick leave and/or treatment by a health professional.
8. Physical or mental disabilities that make it impossible to understand and perform exercises and complete questionnaires.
9. Current or planned pregnancy or breastfeeding.
10. Rupture of gluteal tendon identified on ultrasound.

Design and Methods

The trial is designed as a pragmatic effectiveness multi-center three-armed parallel group randomized trial with an allocation ratio of 1:1:1. The primary comparisons focus on patient advice versus the two more intensive strategies, as this reflects the most relevant clinical decision in primary care. The trial will adhere to the CONSORT statement (30) and will be pre-registered with ClinicalTrials.org and approved by the ethics committee before commencement. Participants will be randomly allocated to one of three arms after inclusion using REDCap's randomization module. The randomization procedure, including preparation of the allocation sequence, will be performed by a colleague not otherwise involved in the project to ensure allocation concealment. The randomization will be stratified by recruitment site to ensure a balanced distribution of site-specific factors across the treatment arms. The allocation will remain concealed from those responsible for including participants to minimize risk of bias.

Intervention components

We have developed the interventions for this trial using the approach of the MRC Framework of Complex Interventions (31), which recommends stepwise development of interventions and testing of feasibility before applying them to a trial. All interventions are based on current standard practice in Denmark and will be delivered by a trained physiotherapist with specialization in musculoskeletal conditions. We will ask all participants not to seek other treatments for their GTPS symptoms during the trial. The three intervention groups will be:

1. Patient advice
   This group will receive a patient information leaflet.
2. Patient advice + exercises
   This group will receive a patient information leaflet in combination with a home exercise program as an add-on treatment.
3. Patient advice + exercises + CSI

This group will receive a patient information leaflet in combination with a home exercise program and CSI as add-on treatments.

Patient information leaflet (patient advice)

The patient information leaflet is based on an existing leaflet from another recent RCT (the LEAP-trial) (8), which has been translated into Danish and adapted by clinicians and GTPS patients to fit a Danish context as part of our pilot work. The leaflet is attached as Appendix 1. The content describes the GTPS condition and emphasizes self-management of GTPS with regard to load management (e.g. how much activity they do over the course of a week). The leaflet is handed out at baseline with oral information that summarizes the key points.

Home-exercise program (exercises)

The exercise protocol was developed through our pilot work and is based on a compilation of existing literature, expert opinions, and feedback from patients with GTPS (*paper in preparation*). The exercise program includes exercises for GTPS that are considered effective and easy for patients to perform at home with no supervision, regardless of their previous training experience and will require a minimum of equipment. The exercise program consists of three body-weighted strength exercises (Hip Bridge, Hip Abduction and Squat) that are to be performed three times a week. For a full description of the exercise program, see appendix 2 ('Træningsprotokol'). The corticosteroid injection can cause a flare-up in pain with a duration of up to 48 hours (32). Participants will be instructed to begin the exercises the day after their injection or as soon as possible after a potential flare-up has settled. Compliance with exercises is measured using a training diary that the participants must fill out during the study period (see appendix 3 'Træningsdagbog'). At baseline, the patients will receive written material (see appendix 4) with instructions and pictures, access to the online exercise program and have the training diary provided. They will also receive a brief standardized verbal introduction to the exercise program (approximately 10 minutes), where the physiotherapist will orally explain the key exercises, proper technique, and progression principles based on the written materials. Participants will be allowed to ask clarifying questions. This brief instruction format is designed to be feasible within the time constraints of busy general practice settings. They will be told to perform the exercise until they achieve their Patient Acceptable Symptom State (PASS) (please see "Outcomes"-section for elaboration) plus an additional 4 weeks. Links for online instruction videos can be found at: https://www.almenmedicin.aau.dk/forskning/center-for-musculoskeletal-health/traeningsvideoer-til-udvendige-hoftesmerter-gtps.

Ultrasound-guided corticosteroid injection

Patients allocated to CSI will receive an ultrasound-guided injection with 1 ml Triamcinolone 40mg/ml and 1 ml Lidocaine 10mg/ml right over the insertion of the gluteal tendons on the greater trochanter of the hip at inclusion, no later than 7 days from baseline. The skin is cleaned with chlorhexidine alcohol 0.5%. Corticosteroid injections will be administered by the collaborating rheumatologists at Bispebjerg Sports Medicine Department and ReumaNord in Aalborg. At the 6-week appointment the injection can be repeated if self-reported pain persists (>4 on NRS (0-10) scale).

Examinations

All participants will attend three physical visits at one of the study sites (Institute for Sports Medicine at Bispebjerg Hospital or the Centre for General Practice in Aalborg). These visits are scheduled at baseline, 6 weeks, and 3 months and is estimated to take 1-1,5 hours for baseline and 3 months, and 30 minutes for the 6 week visit. Written informed consent will be obtained at the baseline visit, followed by anassessment including a clinical and ultrasound examination of the hip to assess tendon and bursal pathology and exclude rupture, as well as collection of baseline patient-reported outcomes (PROMs) via REDCap. Baseline data will also include general demographic characteristics and anthropometric measures, along with clinical information related to the participant's hip pain and prior healthcare contacts. For participants with bilateral symptoms, the most painful hip at inclusion will be designated as the study hip for all subsequent assessments. Participants allocated to receive a corticosteroid injection (CSI) will receive it at baseline or within 10 days under ultrasound guidance. Participants in the exercise intervention groups will be provided with a training diary to record adherence throughout the intervention period. A follow-up phone call will be made one week after baseline to clarify any questions regarding the assigned intervention.

At the 6-week in-person visit, exercise adherence will be reviewed, motivation and guidance provided as needed, and, for CSI participants, a repeat ultrasound-guided injection may be offered if pain remains significant (NRS >4). Additional ultrasound data will be collected for those receiving a repeat injection to confirm accurate placement and to evaluate local tissue status.

At the 3-month follow-up, participants will undergo a clinical assessment and ultrasound examination identical to baseline. PROMs will again be collected electronically and completed training diaries will be reviewed for adherence. Health economic data, including patient-reported costs and productivity, will also be collected on this visit.

Data collection points and follow-up activities are as follows:

- Baseline (Day 0): Delivery of intervention components (leaflet, exercise program, and/or CSI), baseline demographics and questionnaires, and instruction on exercise diary.
- 1 week: Follow-up phone call to address questions and ensure correct understanding of the intervention.
- 6 weeks: In-person visit to review exercise adherence, provide motivation, and, if applicable, repeat CSI.
- 1 month (electronic questionnaire): Collection of secondary and exploratory outcomes.
- 2 months (electronic questionnaire): Collection of secondary and exploratory outcomes.
- 3 months (primary outcome timepoint): Assessment of primary and all secondary outcomes; collection of health economic data.
- 6 months (electronic questionnaire): Follow-up on secondary and exploratory outcomes.
- 12 months (electronic questionnaire): Final follow-up on secondary and exploratory outcomes.

Outcomes

The outcomes for this study were selected to align with the 2020 core outcome set for gluteal tendinopathy (33), and to reflect measures commonly used in previous studies of similar patient populations.

Primary outcome

The primary outcome measure is Global Rating of Change Score (GROC), which is a 7-point numerical rating scale anchored by 'very much worse' and 'very much better', on which participants rate their perceived overall change in their hip condition from baseline to the respective follow-up (34). Participants will be asked: "How is your lateral hip pain now compared with when you first came in for treatment in this project?" The scale includes seven response categories ('very much worse', 'much worse', 'a little worse', 'no change', 'a little better', 'much better', and 'very much better'). Participants will be dichotomised as improved if they report being 'much better' or ' very much better', and as not improved if they select any of the remaining categories. The GROC scale has previously been shown to be clinically relevant for interpreting meaningful improvements from the patient perspective (35).

Secondary outcomes

The key secondary outcome is self-reported average hip pain over the previous week, measured using an 11-point Pain Numeric Rating Scale (NRS) with terminal descriptors of 0 = 'no pain' and 10 = 'worst pain imaginable'. The minimal clinically important difference (MCID) for the NRS is -1.5 points for musculoskeletal disorders (36). Other secondary outcomes include:

Pain:

- Self-reported percentage of time pain has been present during the last week.
- Self-reported worst experienced night pain during the last week (0-10 NRS).

Function and disability:

- Self-reported disability measured by Victorian Institute of Sports Assessment for gluteal tendons (VISA-G) (40). This is a validated patient specific self-reported tool for evaluating disability in patients with gluteal tendinopathy. It contains eight items addressing current hip related pain and function. Scores range from 0 to 100 with higher scores indicating higher function and less pain. We will use a Danish validated version of the questionnaire (41).
- Functional level measured by Patient Specific Functional Scale (PSFS) (42). This is a self-reported measure designed to assess functional level in patients with musculoskeletal disorders. Patients are asked to choose three activities they are having difficulties performing because of their condition and rate these on a 0-10 scale (0 = unable to perform activity, 10 = able to perform at the same level as before the injury or problem). A total score is calculated by the sum of all scores divided by the number of activities rated. A higher total score indicates better function.

Psychological measures:

- Pain self-efficacy measured by Pain Self-Efficacy Questionnaire (PSEQ) (43). This is a self-reported measure used to assess how confident patients are in performing activities while in pain. The outcome is a score of 0 to 60, with higher score indicating higher self-efficacy. PSEQ was used in previous trials investigating lower limb tendinopathies (8,38). We will use a Danish validated version (44).

Quality of Life:

- Quality of life will be measured using the five-level version of the EQ5D (EQ5D-5L) (22). This is a standardized instrument to assess health-related quality of life.

Physical activity:

- Physical activity measured by IPAQ (45).

Symptom satisfaction:

- Self-evaluated symptom satisfaction measured by Patient Acceptable Symptom State (PASS). PASS has been defined as the highest level of symptom beyond which patients consider themselves well (37). PASS has been used in other studies of musculoskeletal disorder to determine self-evaluated satisfactory(38,39). We will identify PASS by asking participants to answer yes/no to the question "Is your lateral hip pain at an acceptable level that does not require any further treatment?" When participants reach PASS, it is not necessarily equal to complete recovery, but it reflects they are satisfied with their current state despite they might still have symptoms. Participants will be asked to report as soon as they experience PASS, and the date will be noted. Furthermore, participants will be asked about their PASS status during follow-up. After the participants in the exercise intervention groups reports a PASS, they will be instructed to continue performing the exercises as prescribed for an additional 4 weeks.

<u>Cost-effectiveness outcomes</u>

We will conduct a health economic evaluation related to the enrolled patients following international guidelines (46,47). Using tools like EuroQol Health Outcome EQ-5D-5L and Danish quality-adjusted life-year (QALY) weights, we will measure health benefits gained over one year (48,49). QALYs will be calculated from participant-completed EQ-5D-5L questionnaires at baseline and at 1, 2, 3, 6, and 12 months. Responses will be converted into health utility scores using Danish population preference weights. Healthcare utilization, including contacts with general practitioners, specialists, physiotherapists, hospital visits, diagnostic procedures, and medication use, will be captured via structured patient-reported questionnaires at each follow-up. To reduce recall bias, medication use will be reported for the week preceding each follow-up, while other healthcare contacts will be reported for the preceding month. Productivity losses, including sick leave and reduced work or daily activity, will be self-reported, along with out-of-pocket expenses and other condition-related costs such as travel and equipment. Intervention costs will be calculated using standard reimbursement rates for each treatment component. Total costs over the one-year follow-up will be summarized at both the societal level, encompassing all reported costs, and the healthcare system level, including healthcare-

related costs only. Discounting of costs and QALYs is not required due to the one-year follow-up period.

Study Sites

The trial will be conducted at two main study sites: the Institute for Sports Medicine at Bispebjerg Hospital (Copenhagen) and the Research Unit for General Practice in Aalborg. These sites will conduct all baseline and 3-month follow-up controls, including clinical examinations and ultrasound scans. Corticosteroid injections will be administered by the project's collaborating rheumatologists at their respective clinical sites, including Bispebjerg Sports Medicine Department and a private rheumatology clinic in Aalborg (ReumaNord). This arrangement ensures that injections can be provided within our time frame of 7 days after baseline assessment. General practices, private rheumatology, and orthopedic clinics in the Capital Region, North Denmark Region, and Central Denmark Region will assist with patient recruitment by identifying and referring eligible participants.

Recruitment

Participants will primarily be recruited through general practice clinics to reflect the typical patient group presenting in primary care with GTPS. Additional recruitment will take place via collaborating rheumatology and orthopaedic clinics, and through social-media advertisements. Recruitment will be continuously monitored throughout the inclusion period, and predefined contingency strategies will be applied if monthly inclusion targets are not met.

<u>Recruitment of clinics</u>

To recruit general practice clinics, an open invitation will be posted on regional newsletters for healthcare professionals. General practitioners who have already shown interest in the work of the research group by participating in our feasibility and pilot work will be invited directly by email. If more clinics are needed, they will be approached directly by visiting the clinics in person or by mail. Furthermore, we will send out invitations through relevant newsletters for general practitioners. Information material about the trial will be delivered at the visit or by mail. Follow-up phone calls will be made one week after the initial contact to encourage the clinic to accept the invitation after they have had time to consider. All clinics are offered a 15–30-minute presentation about the project at their own clinic.

<u>Recruitment of participants</u>

Participant recruitment will be carried out though two pathways:

(1) Patients presenting with lateral hip pain at general practice clinics, rheumatology practices or Bispebjerg Sports Medicine Department will be informed about the trial by their physician. If the patient expresses interest in receiving further information, the physician will ask for verbal permission to share the patient's name and telephone number with the research team. Upon receiving permission, the physician will forward the patient's contact details to the project manager. The project manager will then contact the patient, who will receive further information about the study, will have the opportunity to ask questions, and will undergo an

initial eligibility screening. The written participant information (Appendix XX) will subsequently be sent to the patient by email.

(2) Social media advertisements will invite all adults with lateral hip pain to contact the research team directly via email or telephone. Commenting on posts and tagging of individuals will be disabled wherever this is technically possible. If it is not technically feasible to disable commenting or tagging on certain platforms or within specific groups, activity on the posts will be monitored closely by the research team, and any comments or posts that could lead to the exposure of individuals' health information or other private matters will be removed as soon as possible. Potential participants will be encouraged to contact the research team via email or telephone if they wish to receive further information about the study. This procedure is implemented to protect participants' privacy and to minimise the risk of public disclosure of personal health information in connection with recruitment to the research project, in accordance with the principles outlined in the Danish Committee Act (§1, subsection 1). Individuals who contact the research team will receive the written participant information by email. A telephone call with the project manager will subsequently be arranged to provide further information about the study, allow for questions and clarification, and conduct an initial eligibility screening.

Information procedure and informed consent

Following the initial telephone screening, potentially eligible individuals will be invited to attend an in-person information meeting at the study site. Prior to the meeting, they will receive the written participant information, which will be provided no later than 48 hours in advance of the scheduled information meeting to allow sufficient time for consideration. The information meeting will take place in a private consultation room at the study site to ensure that the conversation can be conducted in a confidential and undisturbed setting. The meeting will be conducted by a member of the research team with a relevant healthcare background (e.g. physician or physiotherapist) who has been formally delegated this responsibility by the principal investigator. During the information meeting, the study procedures, potential benefits and risks, and the voluntary nature of participation will be explained in detail. Potential participants will have the opportunity to ask questions and discuss any aspects of the study. All potential participants will be offered a minimum consideration period of 24 hours following the information meeting before deciding whether to participate. This reflection period is the standard procedure. However, if a potential participant, on their own initiative, expresses a clear wish to provide consent during the information meeting, they may do so. In such cases, it will be ensured that the decision is made voluntarily. Written informed consent will in all cases be obtained before any study-related procedures are initiated. All individuals responsible for conducting information meetings and obtaining informed consent will be listed in the study delegation log at the relevant study sites. A written delegation agreement will be established at each site.

Monitoring and contingency plan

The number of patients included will be closely monitored throughout the trial. In case fewer than our predefined number of 17 patients are included in any given month we till send out reminders to

the clinics and expand social-media recruitment campaigns. If fewer than 10 patients are included from general practice in any given month, additional general practices will be recruited.

Risks, Side Effects and Adverse Events

Adverse events will be graded on a scale of 1 to 5 according to the Common Terminology Criteria for Adverse Events v5.0. A medical doctor specializing in rheumatology or general medicine will evaluate and grade these events, determining whether withdrawal from the trial is necessary.

The trial poses minimal risks to participants, with expected adverse events after corticosteroid injection (CSI) including risk of local irritation, infection (risk 1:20.000), or transient local pain lasting over 48 hours post-injection. Studies have reported mostly mild adverse events after CSI in the lateral hip, with no severe adverse events related to the drug observed (6–8,38). In some cases (approximately 10%), corticosteroid injection may cause euphoria oral facial flushing, which usually resolves within few days. Rarely, corticosteroids may lead to fat cell shrinkage, resulting in a light and sunken area, typically of cosmetic significance and without discomfort. Contraindications such as local wounds, infections, or insulin-dependent diabetes will be checked before injection, along with relative contraindications like anticoagulant treatment (50).

Expected adverse events after exercise may include delayed onset muscle soreness and increased pain related to GTPS. Exercise-related adverse events will be defined as delayed-onset muscle soreness or exacerbation of GTPS symptoms rated ≥5 NRS lasting more than 24 hours. If graded as mild (grade 1), participants may skip one or two training sessions without assessment. However, if the adverse event recurs, assessment by a medical doctor is necessary before resuming the trial. Participants will be instructed to report any adverse events occurring during the trial, which will be recorded and monitored. Severe adverse events (grade 3–5) will be reported to the Ethics Committee of Capital Denmark Region within 7 days. All adverse events will be documented for future trial reporting.

Statistics

Sample size

The sample size calculation and statistical analysis plan are based on results from the LEAP-trial (8). The calculation was based on Dunnett's test to adjust for the two planned comparisons against the control group. A success rate of 35% was assumed in the control group, 65% in the education plus exercise group, and 75% in the education, exercise, and corticosteroid injection group. The sample size is determined by the comparison yielding the smallest expected difference (control vs. education plus exercise). Allowing for a familywise type I error rate of 0.05 and a power of 85%, this comparison requires 54 analysable participants per group. After accounting for an anticipated 15% loss to follow up, 64 participants per group must be enrolled, resulting in a total sample of 192 participants.

Statistical analysis

All statistical analyses will be performed by a blinded member of the project group according to a pre-established analysis plan using the intention-to-treat principle. Reporting will adhere to CONSORT guidelines. This plan is written in consultation with a statistician and will be published

before inclusion of the first participant. SPSS software (IBM Corporation, Armonk, NY, USA) and STATA will be used as statistical software. Imputation will be performed separately within each treatment group. Missing baseline variables will be imputed using single mean imputation. Estimates from 10 imputed datasets will be combined using Rubin's rules.

Primary analysis

The primary analysis will investigate the between-group difference in the proportion of participants reporting improvement on the GROC at 3 months, defined as selecting 'much better' or 'very much better' (GROC categories 6–7) versus any of the remaining categories (GROC categories 1–5). Between-group differences will be estimated using binomial regression models with a log link to calculate risk ratios with 95% confidence intervals, adjusting for baseline GROC value and study site. Comparisons between the two intervention groups are considered exploratory and will be presented descriptively.

Secondary analyses

Continuous secondary outcomes, including NRS pain, VISA-G, PSFS, PSEQ, EQ-5D-5L, and IPAQ, will be analysed using linear mixed-effects models with random intercepts and slopes for each participant. Fixed effects will include time (6 weeks, 1, 2, 3, 6, and 12 months), group allocation, baseline value, the interaction between time and group, and recruitment site. Data normality will be assessed using Q-Q plots and histograms.

Dichotomous secondary outcomes, including Patient Acceptable Symptom State (PASS) and deterioration of function or pain (e.g., decrease in VISA-G ≥ MCID or change from PASS to no longer achieving PASS), will be analysed using binomial regression models with a log link to estimate risk ratios and with an identity link to estimate risk differences, adjusting for baseline value and study site, and numbers needed to treat (NNT) will be derived from these regression-adjusted risk differences. Time-to-event analyses for achieving PASS will be conducted using Kaplan-Meier survival curves and Cox regression, considering only the time to first PASS achieved. Sensitivity analyses will include per-protocol analyses and best-/worst-case scenarios to assess the robustness of findings under different assumptions for missing data.

Blinding

The person responsible for performing the statistical analyses will remain blinded to the coding until after the analyses have been performed and only the person delivering the interventions will know which intervention is linked to which group number (group 1, 2 or 3).

Pragmatic considerations

The trial protocol has been assessed using the PRECIS-2 (51) framework to clarify the pragmatic versus explanatory aspects of the design. Each domain was scored on a 1–5 scale (1 = very explanatory, 5 = very pragmatic). The trial is positioned largely at the pragmatic end of the PRECIS-2 spectrum, reflecting a design that closely mirrors real-world clinical practice while maintaining methodological feasibility. Core features such as broadly representative recruitment, flexible intervention

delivery, and patient-managed adherence have been prioritized to maximize generalizability. A table with an overview of the scores and rationale can be found in appendix 5

Ethical Considerations

The project staff will inform the patients orally about the trial at their first visit. Participants will receive written information about the trial via email after the telephone screening (see appendix 6). Written consent will be obtained at the baseline visit. Participants can withdraw their consent at any point during the trial with no obligation to provide a reason. All interventions used in this study are part of standard practice in Danish general practice and are associated with minimal risk. Participation in the trial does not expose participants to untested or experimental treatments, as all intervention components reflect current practice. GTPS in general practice has been an overlooked research area, and there is a lack of solid evidence of the actual effect of the current treatments. By conducting this trial, we may be able to provide guidelines that will encourage effective treatment and spare treatments that are not effective. Participants in this trial will suffer from no more adverse events or risks than patients do from current treatments. It is expected that both future patients and a large proportion of the trial participants will experience therapeutic benefits from the trial. The benefits highly outweigh the disadvantages of conducting this trial, and the completion is considered fully justified from an ethical point of view. Irrespective of the results, the trial will inform clinical practice and give GTPS patients and clinicians much-needed guidance in the management of this painful condition.

Patient and end-user involvement

We will involve participants from each group in the future interpretation of the results. Their insights will also be integrated into the dissemination of the trial results through reports and conference presentations. Specifically, following the collection of primary outcomes, we will invite randomly selected participants from each group to participate. In the event of a participant turning down the offer, we will randomly select a replacement participant from the same group**.** Furthermore, we plan to invite a group of general practitioners to aid us in interpreting the clinical perspective of the results and how to implement them into practice.

Insurance

The subjects are covered by the Danish Patient Compensation Association (Patienterstatningen).

Personal Data

The trial complies with the General Data Protection Regulation and the Data Protection Act. All data included in the project are collected directly from participants through study procedures and questionnaires. The project does not involve access to or extraction of information from participants' medical records. Electronic data will be collected and stored electronically on secure servers in REDCap. Personal data will not be distributed to other countries. Data are stored in accordance with the stipulations in the General Data Protection Regulation and the Danish Data Protection Act. The trial manager, the project group members, and relevant regulatory authorities will have access to the data for monitoring and auditing purposes in accordance with Good Clinical Practice (GCP) guidelines.

Bispebjerg Hospital and the Research Unit for General Practice in Aalborg act as joint data controllers for the processing of personal data in accordance with the General Data Protection Regulation. Responsibilities for data handling, security, and retention will be defined in a formal data processing agreement between the parties.

Project Economy

The project has received initial funding from The Danish Rheumatism Association (200.000 DKK for project management salary), 'Fonden for Faglig Udvikling i Speciallægepraksis' (769.328 DKK), and 'PLU Fonden' (82.907 DKK). These funds have primarily supported previous phases of our research programme, including preparatory work, development of the home exercise programme, and patient information materials.

For the current clinical trial, we have received an additional grant of 1.134.000 DKK from The Danish Rheumatism Association to support project management salary and trial-related expenses. The clinical trial is conducted with Bispebjerg Hospital as the primary responsible institution. Research funding for the project is administered through the relevant host institutions depending on the specific grant. At present, salary funding for the PhD student is administered by Aalborg University, which disburses salary according to its institutional procedures. The researchers involved in the project have no personal financial relationships with the funding bodies or other financial interests related to the trial.

We are currently in the process of securing additional funding to cover the remaining project costs, including salaries, data collection, analysis, and dissemination. Should further funding be obtained or changes occur in the financial framework of the project, the Regional Committee on Health Research Ethics will be notified and the participant information materials will be updated accordingly.

Compensation to Subjects

The subjects will not receive compensation for their participation in the experiment.

Publishing of Results

The project protocol will be registered in www.clinicaltrials.gov before the inclusion of the first participant and the results will also be registered in this platform. Results from the trial will be published in international peer-reviewed journals and in Danish journals, e.g., 'Ugeskrift for Læger' and 'Månedsskrift for Almen Praksis'. Any positive, negative, or inconclusive results will be published. The planned order of authors is: Malene Kjær Bruun, Finn Johannsen, Henrik Riel, Michael Skovdal Rathleff, Bill Vicenzino, Jens Lykkegaard Olesen. If the leaflet and exercise program are found to be effective, we plan to integrate these into www.sundhed.dk to ensure easy accessibility for all relevant stakeholders, i.e., patients, private practice doctors, general practitioners, and junior doctors.

Time Schedule

The project is planned to start in January after approval by the committee and will be completed by December 2028. The timeline is contingent upon ethical approvals and the successful acquisition of full project funding.

Guidelines for Oral Information and Informed Consent

When potential subjects address the contact person, the following will be communicated:

- Participation in the research project is entirely voluntary. It can only take place after the individual has received both written and oral information about the project and has signed the informed consent form.
- Consent may be withdrawn at any time, either verbally, in writing, or through any other clear expression. Withdrawal of consent will not affect the person's right to current or future healthcare or any other legal rights.
- The potential participant may bring a family member, friend, or another person of their choice to the information meeting.
- The potential participant has the right to take time for consideration before signing the consent form.
- Any information about the participant's health, private circumstances, or other confidential matters obtained in connection with the project will be treated as strictly confidential.
- The processing of personal data, including information from blood or tissue samples, will be conducted in accordance with the General Data Protection Regulation (GDPR), the Danish Data Protection Act, and the Danish Health Act. The data controller of the study will provide detailed information about the participant's rights under these data protection regulations.
- Participants are entitled to request access to the study protocol under the Danish Access to Public Administration Files Act. This means they may review documents related to the organisation of the study, except for sections containing trade secrets or confidential information about others.
- Participants have the right to file a complaint and to claim compensation under the Danish Act on Complaints and Compensation within the Health Service. In the event of injury during the study, participants may contact the Danish Patient Compensation Association.
- Further information is available at www.patienterstatningen.dk.

The initial consultation

When potential participants attend the initial consultation, the following will be communicated before final inclusion and any clinical testing:

- The purpose and conduct of the trial are presented, with the "Information for Participants"/"Deltagerinformation", previously sent to the participant, as the starting point for the conversation.

- The participant is asked whether they have read the “Information for Participants”/“Deltagerinformation.” If not, they will be given an appropriate amount of time to read it.
- Once it is confirmed that the participant has read the information, they are invited to ask any questions about the study.
- It is reiterated that participation is voluntary and that the participant may withdraw their consent at any time without consequences.
- If the potential participant needs more time to consider participation, they are informed of their right to take additional time. In this case, inclusion is postponed, and a new consultation will be scheduled when the participant indicates (by phone or email) that they have had sufficient time to consider participation.

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