Title

The efficacy of a self-managed resistance training protocol versus a predetermined resistance training protocol in individuals with plantar fasciopathy during a 12-week intervention: a randomised controlled superiority trial

NCT-Number

NCT03304353

Date

November 7th 2017

1 Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym

The efficacy of a self-managed resistance training protocol versus a predetermined resistance training protocol in individuals with plantar fasciopathy during a 12-week intervention: a randomised controlled superiority trial

2a Trial identifier and registry name. If not yet registered, name of intended registry

2b All items from the World Health Organization Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	Clinicaltrials.gov (NCT03304353)
Date of registration in primary registry	October 9th 2017
Secondary identifying numbers	N-20170051
Source(s) of monetary or material support	Research Unit for General Practice in Aalborg and Aalborg University
Primary sponsor	Research Unit for General Practice in Aalborg
Secondary sponsor(s)	Aalborg University
Contact for public queries	hriel@dcm.aau.dk
Contact for scientific queries	hriel@dcm.aau.dk
Public title	The efficacy of a self-managed resistance training protocol versus a predetermined resistance training protocol in individuals with plantar fasciopathy during a 12-week intervention: a randomised controlled superiority trial
Scientific title	The efficacy of a self-managed resistance training protocol versus a predetermined resistance training protocol in individuals with plantar fasciopathy during a 12-week intervention: a randomised controlled superiority trial
Countries of recruitment	Denmark
Health condition(s) or problem(s) studied	Plantar fasciopathy
Intervention(s)	Intervention: self-managed training programme Control: predetermined training programme
Key inclusion and exclusion criteria	Inclusion criteria: History of inferior heel pain for at least 3 months before enrolment; pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia; thickness of the plantar fascia of 4.0 mm or greater; and mean heel pain of ≥ 20 mm on a 100 mm VAS during the previous week Exclusion criteria: Below 18 years of age; diabetes; history of inflammatory systemic diseases; prior heel surgery; pregnancy or; corticosteroid injection for plantar fasciopathy within the previous six months
Study type	Interventional, randomised, participant blinded, parallel assignment, superiority
Date of first enrollment	October 12th 2017

Target sample size	70
Recruitment status	Recruiting
Primary outcome(s)	Foot Health Status Questionnaire pain domain score
Key secondary outcomes	Total Foot Health Status Questionnaire score; Plantar fascia thickness; Compliance to exercise; Global Rating of Change; Patient Acceptable Symptom State; Pain Self-Efficacy Questionnaire; International Physical Activity Questionnaire

3 Date and version identifier

November 7th 2017, version 3.1

4 Sources and types of financial, material, and other support

5a Names, affiliations, and roles of protocol contributors

The project will be conducted with **HR** as primary investigator. All authors are expected to make substantial scientific contributions to the design of the study that will qualify them as authors. **HR** and **MSR** wrote the first draft of the protocol. **MBJ, BV** and **JLO** are all expected to make valuable scientific additions to the draft and will be co-authors on subsequent manuscripts based on these data. The definition of author is defined on ICMJE´s four criteria (1):

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

The expected author list is: Riel H; Jensen MB; Vicenzino B; Olesen JL; Rathleff MS

5b Name and contact information for the trial sponsor

Trial sponsor: Research Unit for General Practice in Aalborg.
Contact name: Michael Skovdal Rathleff
Address: Research Unit for General Practice in Aalborg, Fyrkildevej 7, 1., 9220 Aalborg East, Denmark
E-mail: misr@hst.aau.dk

5c Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of

the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities

Sponsor is part of the study design, data analyses and writing of the manuscript. Sponsor will ensure that the results will be submitted for publication. Sponsor is non-commercial and declares no conflict of interest.

5d Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

N/A

6a Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

Background and rationale

Plantar fasciopathy (PF) is the most commonly reported cause of severe and sharp heel pain with a lifetime prevalence of 10% (2–5). Pain is often exacerbated during the first steps in the morning and after prolonged periods of rest (6). It is one of the most prevalent musculoskeletal conditions and PF is most often seen among runners (4) and 40 to 60-year-old individuals with a low activity level and a high BMI (7). It accounts for an estimated one million patient visits per year to general practitioners in the US with similar high rates in Denmark. The majority of patients will experience pain for more than 12 months and 6% of patients will lose an average of 19 workdays because of their heel pain (8–10). Thus, PF can be debilitating to the patient and have large societal costs.

Standard care consists of gel heel inserts and stretching of the plantar fascia which are superior to placebo treatment. Despite such evidence, 40% will continue to have symptoms two years after the initial diagnosis (8).

A recent study by Rathleff et al. 2015 investigated the efficacy of high-load strength training and gel heel inserts compared to plantar-specific stretching and gel heel inserts (9). Participants randomised to high-load strength training had a 29 points lower Foot Function Index after three months corresponding to a medium effect size. High-load

resistance exercise is frequently used during rehabilitation of tendinopathies, but optimal mode and dosages in reducing pain are unknown (9,11–14).

The exercise dose used in the study by Rathleff et al. was smaller than the exercise doses that have been used in the successful treatment of other tendinopathies (9,14–18). A larger dose could potentially lead to a faster recovery but this has yet to be investigated.

Poor adherence to exercises is often a large barrier to overcome in rehabilitation and may affect the outcome and the dose received negatively (19,20). Low self-efficacy is seen as one of the reasons for poor adherence and may be increased by a self-managed loading programme and patient education (20).

7 Specific objectives or hypotheses

Objectives

The purpose of this trial is to investigate whether a self-managed resistance training programme is more effective than a predetermined resistance training programme in improving the Foot Health Status Questionnaire pain domain score in individuals with plantar fasciopathy after a 12-week intervention.

Hypotheses

Hypothesis: the self-managed resistance training programme will lead to a larger improvement in the Foot Health Status Questionnaire pain domain score compared with the predetermined programme in individuals with plantar fasciopathy after a 12-week intervention.

8 Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)

Study design

This study, which is called "*The efficacy of a self-managed resistance training protocol versus a predetermined resistance training protocol in reducing pain individuals with plantar fasciopathy during a 12-week intervention: a randomised controlled superiority trial*", will be designed as a randomised, participant-blinded, superiority trial, with a 2-group parallel design to be conducted in Denmark. Reporting of this study will follow CONSORT guidelines for reporting non-pharmacologic treatments and TIDieR for intervention

description (21–23). Reporting of the protocol will follow the SPIRIT statement (24). The planning of the study was done in accordance with the PREPARE Trial guide (25). Before the inclusion of the first participant, the study was registered on clinicaltrials.gov.

Methods: Participants, interventions, and outcomes

9 Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained

The study will be conducted at the Research Unit for General Practice in Aalborg, Denmark.

10 Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)

Inclusion criteria: History of inferior heel pain for at least three months before enrolment; pain on palpation of the medial calcaneal tubercle or the proximal plantar fascia; thickness of the plantar fascia of 4.0 mm or greater and; mean heel pain of ≥ 20 mm on a 100 mm VAS during the previous week (26)

Exclusion criteria: Below 18 years of age; diabetes; history of inflammatory systemic diseases (26); prior heel surgery; pregnancy or; corticosteroid injection for plantar fasciopathy within the previous six months

The primary investigator who will be responsible for inclusion, exercise instructions and data collection will be a registered physiotherapist with 6 years of experience in treating patients with musculoskeletal disorders.

11a Interventions for each group with sufficient detail to allow replication, including how and when they will be administered

Intervention

The exercise used in both groups will be heel raises. Participants will be asked to complete the exercise standing with the forefoot on a step. The toes are maximally dorsi flexed by placing a towel underneath them. The participant is instructed to perform a heel raise to maximal plantar flexion in the ankle joint and afterwards to lower the heel to

maximal dorsi flexion. Supporting oneself for balance by placing the hands on a wall or a rail is allowed. The participants in the self-managed group are instructed in performing the exercise with a load as heavy as possible but no higher than 8RM and for as many sets as possible. The difference in how the exercise is prescribed between groups is displayed in Table 1. If the participants feel they can perform more repetitions than their load corresponds to (e.g. 10 repetitions when the load is supposed to be 8RM) an external load consisting of a backpack with books to add weight will be used.

Both groups receive patient education on their condition. They will be informed about what is known about the condition in terms of risk factors and aetiology, the pathology, activity modification, and the rationale for why their specific exercise programme (self-managed or predetermined) could lead to recovery. The participants of the predetermined group will be informed that this specific exercise and exercise programme has been found to be superior to stretching but it is important to follow the protocol as closely as possible. The participants of the self-managed group will be informed that this specific exercise has been found to be superior to stretching but based on previous research of other tendinopathies we believe that doing the exercise as heavy as possible but not heavier than 8RM and with as many sets as possible will increase the odds of recovery. Both groups are told that compliance to their protocol is very important and that compliance to the exercises are associated with their recovery. They are also informed about other types of evidence-based treatments however, they are asked to refrain from seeking other treatments during the course of the study. A silicone heel cup will be given to all participants. If the participant already uses an insole or any other type of foot orthosis they will be allowed to continue wearing this if they do not want to use the heel cup.

Table 1 Mechano-biological descriptors (27)

	Self-managed resistance training programme	**Predetermined resistance training programme**
1. Load magnitude	As heavy as possible but no higher than 8RM	Week 1+2: 12RM Week 3+4: 10RM From Week 5: 8RM
2. Number of repetitions	≥8 depending on the load	Week 1+2: 12 Week 3+4: 10 From Week 5: 8
3. Number of sets	As many as possible	Week 1+2: 3 Week 3+4: 4 From Week 5: 5

4. Rest in between sets	2 min	2 min
5. Number of exercise interventions (per (day) or week)	3.5/week	3.5/week
6. Duration of the experimental period ((day) or weeks)	12 weeks	12 weeks
7. Fractional and temporal distribution of the contraction modes per repetition and duration (s) of one repetition	3s concentric 2s isometric 3s eccentric	3s concentric 2s isometric 3s eccentric
8. Rest in-between repetitions ((s) or (min))	No	No
9. TUT ((s) or (min))	8s/repetition ≥64s/set ≥64s/training session	Week 1+2: 8s/repetition 96s/set 288s/training session Week 3+4: 8s/repetition 80s/set 320s/training session From Week 5: 8s/repetition 64s/set 320s/training session
10. Volitional muscular failure	Yes	Yes
11. Range of motion	Full range of motion	Full range of motion
12. Recovery time in-between exercise sessions ((h) or (d))	48 h	48 h

13. Anatomical definition of the exercise (exercise form)	The participant is standing with the forefoot on a step. The toes are maximally dorsi flexed by placing a towel underneath them. The participant is instructed to perform a heel raise to maximal plantar flexion in the ankle joint and afterwards to lower the heel to maximal dorsi flexion. Supporting oneself for balance by placing the hands on a wall or a rail is allowed.	The participant is standing with the forefoot on a step. The toes are maximally dorsi flexed by placing a towel underneath them. The participant is instructed to perform a heel raise to maximal plantar flexion in the ankle joint and afterwards to lower the heel to maximal dorsi flexion. Supporting oneself for balance by placing the hands on a wall or a rail is allowed.

11b Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)

The study may also be discontinued by participant request or withdrawal of informed consent. If any participant experiences an adverse event (e.g. an injury to the musculoskeletal system such as a muscle tear, a muscle strain, a sprained joint, injury from falling, delayed onset of muscle soreness equal to or greater than 20 mm on a 0 to 100 mm VAS that lasts for more than 48 h after performing the exercises or exacerbation of PF) and is not able to perform the exercise, the participant is asked to record the event and contact the primary investigator as soon as it occurs by phone, SMS or e-mail but the participant will not be withdrawn from the study.

11c Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)

All participants are told that compliance to the exercise is important and this will improve the odds of recovery. Complying with the exercise programme includes performing the exercise with the prescribed form, contraction time, number of repetitions and sets and the frequency the exercise is performed. Compliance is monitored by a self-reported training diary in which the participants are asked to fill out the number of repetitions, sets and the date the exercise was performed. The participants are also asked to record their use of

foot orthoses in the training diary as an estimated percentage of the time they have worn shoes. All participants will be contacted either by telephone or by e-mail two weeks after inclusion to ask them if they have experienced any difficulties with performing the exercises and to encourage them to continue performing the exercises.

11d Relevant concomitant care and interventions that are permitted or prohibited during the trial

All participants who do not wear an insole prior to the trial will receive a silicone heel cup but are asked to refrain from seeking other types of treatment during the course of the trial. Participants are told to register any use of analgesic or anti-inflammatory substances. They will be told that participating in physical activity is acceptable as long as they do not feel exacerbation of their symptoms that outlasts the physical activity.

12 Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended

Primary outcome:

- The primary outcome will be the change in the pain domain of the Foot Health Status Questionnaire (FHSQ) from baseline to the 12-week follow-up. The FHSQ is a self-report questionnaire ranging from 0 (poor foot health) to 100 (optimum foot health) that assesses multiple dimensions of foot health and function and has a high reliability (ICC=0.74-0.92) (28). The minimal important change of the pain domain is 14.1 points (29). A Danish translation of the original questionnaire will be used. The translation was made using a dual panel approach (30). The questionnaire will be filled out by the participant at baseline and at the 4- and 12-week follow-up.

Secondary outcomes:

- Change in the function, footwear and general foot health domains of the FHSQ.
- Global Rating of Change (GROC) at the 12-week follow-up. This will be used to measure the participants' self-reported recovery on a 7-point Likert scale ranging from "much improved" to "much worse". Participants are categorised as improved if they rate themselves as "much improved" or "improved" (category 6-7) and

categorised as not improved if they rate themselves from “slightly improved” to “much worse” (category 1-5).

- Difference in thickness of the plantar fascia measured in millimetres. Measurements will be performed using ultrasonography during baseline and at the 4- and 12-week follow-up. The participant is lying prone with the toes placed maximally dorsi flexed on the examination table a longitudinal scan is performed. An average of three measurements will be used. This method has been found reliable in a previous study (ICC=0.67-0.77) (31).
- The number of training sessions performed throughout the intervention measured by a training diary that each participant is handed out at baseline. The participants will be instructed in filling out the number of repetitions and sets performed and the day on which they performed the exercise.
- The time measured in days to the Patient Acceptable Symptom State (PASS). This will be used as a measure of when the participant achieves a self-reported satisfactory result and is therefore not necessarily a measure of complete recovery. PASS has been used to evaluate clinically relevant states in other musculoskeletal disorders and post-operative pain. (32–34) After the participant has reported PASS he or she is still instructed to continue performing the exercise as prescribed.
- Change in self-efficacy as measured by the Pain Self-Efficacy Questionnaire (PSEQ) from baseline to the 12-week follow-up. The PSEQ ranges from 0 (not at all confident) to 60 (completely confident) with lower scores indicating lower self-efficacy (35). The questionnaire will be filled out by the participant at baseline and at the 4- and 12-week follow-up. A Danish translation of the original questionnaire will be used. This translation has been validated in a Danish chronic pain population and has a high reliability (ICC=0.89) (36).
- Change in physical activity level as measured by the International Physical Activity Questionnaire short version (IPAQ). The questionnaire will be filled out by the participant at baseline and at the 4- and 12-week follow-up. A Danish translation of the original questionnaire will be used. The IPAQ is the most commonly used questionnaire for measuring physical activity among adults and consists of 9 items that provide information on the time spent performing vigorous and moderate activities, the time spent walking, and time spent sedentary during the past week. The IPAQ gives an estimate of the total weekly physical activity measured in MET-minutes per week and total minutes spent sitting.(37,38)

13 Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)

Table 2: SPIRIT figure for the schedule of enrolment, interventions and assessments.

		Study period			
	Enrolment	**Allocation**	**Post-allocation**		**Close-out**
TIMEPOINT**	**October 1st 2017 – February 1st 2018**	**October 1st 2017 – February 1st 2018**	***4-week follow-up***		**January 1st 2017 – May 1st 2018** ***(12-week follow-up)***
			12-week Intervention		
ENROLMENT:					
Eligibility screen	X	X			
Informed consent		X			
Allocation		X			
INTERVENTIONS:					
Self-managed group			←	→	
Predetermined group			←	→	
ASSESSMENTS:					
Diagnosis		X			
Foot Health Status Questionnaire		X	X		X
Plantar fascia thickness		X	X		X
Pain Self-Efficacy Questionnaire		X	X		X

International Physical Activity Questionnaire		X	X		X
Compliance			←	→	
Patient Acceptable Symptom State			←	→	
Anthropometric data	X				
Age	X				
Pain localization	X				
Global Rating of Change					X

14 Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations

It is expected that the self-managed group will experience a larger reduction of the FHSQ pain domain of 14.1 points compared with the predetermined group. This is equal to the minimal clinical important difference of the domain (29). Based on a standard deviation of 20 points, which is comparable to the overall standard deviations found in previous studies of this patient population (26,39–41), a two-sided 5 % significance level and a power of 80 %, a sample size of 33 participants in each group will be necessary. Taking into consideration possible drop-outs, we will include a total of 70 participants.

15 Strategies for achieving adequate participant enrolment to reach target sample size

Seventy participants with PF will be included in this study after being referred by their general practitioner in the North Denmark Region. In addition to the referrals, a Facebook post will be made to recruit participants. Participants will have the same eligibility criteria and undergo the same screening regardless of the origin of recruitment. Upon contacting the primary investigator, a telephone screening will be performed with questions regarding the eligibility criteria. If the potential participants appear to be eligible for inclusion they will be invited to a clinical examination at the Research Unit for General Practice where final eligibility will be confirmed.

Methods: Assignment of interventions (for controlled trials)

16a Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions

The participants will be will be block randomised in block sizes of 2 to 6 (1:1) into 2 parallel groups of 35 participants using a random number generator on www.sealedenvelope.com. The block sizes will be concealed to the primary investigator and will be stratified by sex.

16b Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned

After the participant has been enrolled the primary investigator will take a sequentially numbered opaque sealed envelope in which group allocation has been previously determined.

16c Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions

A researcher not involved in the study will generate the allocation sequence and is the only person who knows the block sizes. The primary investigator will enrol participants and assign them to the exercise protocols based on their randomisation.

17a Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how

The participants will be told that the study is about performing an exercise for treating PF and that there will be two groups that perform the exercise in different ways. They are not

informed about the primary outcome of the study or the differences between the training programmes.

17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial

N/A

Methods: Data collection, management, and analysis

18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol

The telephone screening contains questions about age, the duration of pain, history of systemic diseases, prior heel surgery, pregnancy, and previous corticosteroid injection for PF within the previous 6 months. During the physical examination self-reported data on height, weight, leisure time physical activity, previous care-seeking behaviour, mean heel pain during the week prior to the examination measured on a 0 to 100 mm VAS (0=no pain, 100=worst pain imaginable), pain locations using a pain manikin (42), and sick leave will be collected.

18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols

The 4-week follow-up will be planned during baseline and the 12-week follow-up will be planned during the 4-week follow-up together with the participants. The participants will be contacted by phone, SMS or e-mail one week prior to the follow-ups by the primary investigator to remind them of the appointments.

19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol

The participants will fill out the questionnaires themselves and the primary investigator will impute the answers into the FHSQ software which calculates the score of each domain. Data from the ultrasonography will initially be written in paper forms and afterwards entered electronically into an Excel spreadsheet. This will be done at the study site where data originated. All original paper forms will be kept in a locked cabinet at the study site. All data will be kept for 10 years after completion of the study which in accordance with The European Code of Conduct for Research Integrity.

20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol

All statistical analyses will be performed according to a pre-established analysis plan in consultation with a statistician. STATA ver. 14 will be used as statistical software. The primary intention-to-treat analysis will test the between-group difference in the FHSQ pain domain at the 12-week follow-up. In addition to this, between-group comparisons of the other FHSQ domains, PSEQ, IPAQ, and plantar fascia thickness will be performed using a repeated measures ANCOVA with the outcome as the dependent variable, time (baseline, 4 weeks and 12 weeks) as the within-subjects factor, group allocation as the between-subjects factor and the baseline value as the covariate. If any interactions are found, post hoc Bonferroni adjustments for multiple comparisons will be made. The between-group difference in time to PASS among participants who report PASS, and the number of training sessions performed during the trial using independent t-tests. The relative risk (RR) will be calculated for the dichotomized GROC to determine the probability of being improved and for the dichotomized PASS (Yes/No) to determine the probability of achieving a satisfactory result within the 12 weeks of intervention. The difference in mean training sessions performed per week from before to after PASS among participants who report PASS no later than during week 11 of the intervention will be investigated using a paired t-test. The number needed to treat will be calculated as 1/risk difference for the primary outcome. The association between the PSEQ score and compliance will be investigated using Pearson’s correlation coefficient.

20b Methods for any additional analyses (eg, subgroup and adjusted analyses)

N/A

20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)

The analyses will be by the intention-to-treat principle and participants are included in the analyses regardless of the exercise compliance they report.

Methods: Monitoring

21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

A data monitoring committee will not be established as the exercises are commonly used in the population of interest and do not pose a threat to the participants.

21b Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial

The exercises have previously been used for patients with this type of diagnosis. They tolerate it well and there will be no stopping rules planned.

22 Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct

The participants will be able to report any adverse events to the primary investigator when they occur by phone, SMS or e-mail. Expected adverse events are injuries to the musculoskeletal system such as a muscle teat, a muscle strain, a sprained joint, injury from falling or exacerbation of symptoms related to PF. Adverse events will be graded 1 to 5 according to the Common Terminology Criteria for Adverse Events v4.03 (43). A medical

doctor specialised in rheumatology or general practice will assess and grade the adverse event and ultimately have the decision whether the participant should be withdrawn from the study due to the adverse event. If the adverse event is a grade 1 (mild) the participant may be allowed to skip one or two training sessions without any assessment. If the adverse event recurs after having skipped the exercise, the participant will have to be assessed by the medical doctor before participation in the study is continued. If a participant experiences an adverse event and requests withdrawal from the study, data until the last exercise activity before the adverse event occurred will be included in the analyses. The primary investigator will report any incidents to the sponsor as quickly as possible and no later than 15 days after the participant reported the event. Sponsor will report any severe adverse events (grade 3-5) to the Ethics Committee of North Denmark Region no later than 7 days after being informed.

23 Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor

N/A

Ethics and dissemination

24 Plans for seeking research ethics committee/institutional review board (REC/IRB) approval

The study will be conducted according to the Declaration of Helsinki III and this protocol, template informed consent forms and participant information will be approved by the Ethics committee of North Denmark Region prior to the inclusion of participants.

25 Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)

Any modifications to the protocol that will impact the conduct of the study such as study objectives, study design, patient population, sample sizes, study procedures or significant administrative aspects will be communicated to the Ethics Committee of North Denmark Region for approval. The registration on clinicaltrials.gov will be updated if any of the abovementioned modifications are made.

26a Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)

The primary investigator will obtain informed consent by the participants.

26b Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable

N/A

27 How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial

Personal information about potential and enrolled participants will be collected during the telephone screening and during allocation. All data will be kept for 10 years after completion of the study which in accordance with The European Code of Conduct for Research Integrity.

28 Financial and other competing interests for principal investigators for the overall trial and each study site

The authors declare that they have no competing interests.

29 Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators

The primary investigator and all co-authors will have unlimited access to the final data set before publication. The data will afterwards be stored in a publicly accessible repository.

30 Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation

Any participants who suffer harm from trial participation will receive compensation by The Patient Compensation Association.

31a Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

We aim to publish positive, negative or inconclusive results of the study in a peer-reviewed journal. The project group will also present results at conferences. The working title of the future paper is “The efficacy of a self-managed resistance training protocol versus a predetermined resistance training protocol in individuals with plantar fasciopathy during a 12-week intervention: a randomised controlled superiority trial”.

31b Authorship eligibility guidelines and any intended use of professional writers

The definition of author is defined on ICMJE´s four criteria (1):

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

31c Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code

No later than 3 years after the final follow-up, we will deliver a completely anonymised data set to an appropriate data archive for sharing purposes.

32 Model consent form and other related documentation given to participants and authorised surrogates

33 Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

References

1. International Committee of Medical Journal Editors. Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals [Internet]. [cited 2017 Jan 2]. Available from: http://www.icmje.org

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