Protocol

Administrative information

1.Title

A randomized controlled trial on the effect of Early progressive strength exercise for treatment of acute Achilles tendon rupture. The Achilles tendon Back-On-Track study.

2.Trial registration

2a Trial registration

The study will be registered at ClinicalTrials.gov: nr and date

2b WHO Trial Registration Data Set

Data category	Information
Primary registry and trial identifying number	Clinical Trials
Date of registration in primary registry	23 January 2021
Secondary identifying numbers	Ethics Committee N-20200041
Source(s) of monetary or material support	Physiotherapy and Occupational therapy, Aalborg University Hospital
Primary sponsor	Physiotherapy and Occupational therapy, Aalborg University Hospital
Secondary sponsor(s)	Orthopaedic department, Aalborg University Hospital
Contact for public queries	mc@rn.dk
Contact for scientific queries	mc@rn.dk
Public title	The Achilles tendon Back-On-Track study. A randomised controlled trial on the effect of Early progressive strength exercise for treatment of acute Achilles tendon rupture.
Scientific title	A randomised controlled trial on the effect of Early progressive strength exercise for treatment of acute Achilles tendon rupture.
Countries of recruitment	Denmark
Health condition(s) or problem(s) studied	Achilles tendon rupture
Intervention(s)	Early progressive strength exercise programme
Key inclusion and exclusion criteria	Inclusion criteria: Patients with acute Achilles tendon rupture treated non-surgically. Diagnosed and treatment initiated within 3 days (of their injury). Age 18 – 65, able and willing to participate in the intervention. Able to speak and understand Danish

	Exclusion criteria: Achilles tendon rupture close to insertion on calcaneus or in the musculotendinous junction of the triceps surae. Previous Achilles tendon rupture or other conditions in either leg causing lower leg disability (pain, deficits in strength or range of movement). Treated with Fluoroquinolons or Corticosteroids within the last 6 months. Diabetes or rheumatic diseases. Severe medical illness: ASA score higher than or equal to 3 (ASA: American Society of Anesthesiologists physical status classification system)
Study type	Randomized controlled trial
Date of first enrollment	January 2021
Target sample size	82
Recruitment status	Not yet recruiting
Primary outcome(s)	Achilles Tendon total Rupture Score ATRS
Key secondary outcomes	ATRS, IPAQ short form, ATRA, Achilles tendon length, fear of re-rupture, adverse events, isometric strength and endurance, compliance, cost-effectiveness outcomes

3. Protocol version

Version 1.0 23Jan2021

4. Funding

The Physiotherapy and Occupational therapy department and Orthopaedic Surgery department at Aalborg University Hospital has guaranteed for the funding of the PhD study. This work was also supported by the Danish Physiotherapist Research Foundation, North Denmark Region Research foundation, AP Møller Lægefonden, Toyotafonden, Praksisfonden for fysioterapi, Danish Society of Sports Physical Therapy

5. Roles and responsibilities

5a Names, affiliations, and roles of protocol contributors

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This study is initiated by Marianne Christensen physiotherapist MHSc PhD student and she is the project manager. The project will be conducted with MC as primary investigator as part of her Ph.D.-studies. MC and MSR wrote the first draft of the protocol. ILK, JAZ and KGS all made valuable scientific additions to the draft. ILK is chief orthopaedic foot surgeon and has the clinical responsibility for the study. MSR, ILK, JAZ and KGS provided contribution to the study design, contents of the intervention and the evaluation methods.

5b Name and contact information for the trial sponsor

Physiotherapy and Occupational Therapy department, Orthopaedic department,
Clinic Head- and Orto,
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5c Role of study sponsor and funders

Sponsor is a part of the study, but is not involved in design, planning and analysis of the study. Sponsor will collaborate to ensure the right conditions for planning and conduct of the study and the publication of the results. Sponsor is non-commercial and declares no conflict of interest.

The funding sources will have no influence in the design of this study and will not have any role during the study execution, interpretation of the data or dissemination of results.

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

Introduction

6. Background and rationale

6a Description of research question

Acute Achilles tendon rupture is a common injury and in Denmark the incidence has increased in recent years from 18.2/100.000 in 1984 and up to 31.17/100.000 in 2013.(1,2) Rupture usually occurs at age 30-50 with a male to female ratio 3-5:1.(1–3) The Achilles tendon is the largest and strongest tendon in the human body and is crucial for normal gait and running.(4) Historically surgical treatment has been favoured mainly because the re-rupture rates are lower compared to non-surgical treatment (3 vs 13%, respectively).(5,6) However, there is a risk of wound infection in surgical treatment compared to non-surgical and the results after a deep infection are often devastating.(7,8)

Regardless of choice of either surgical or non-surgical treatment, long-term muscular deficits and a decreased function after Achilles tendon rupture is found up to 7 and 10 years later.(9–11) The majority of the patients are of working age and a deficit in physical performance will have impact on returning to work and sports.(12–14) The risk of not being able to return to work or sport has potential influence on patients quality of life, risk of lifestyle diseases and healthcare economics.

There have been promising results in treatments using early functional rehabilitation (EFR) during the first eight weeks of treatment after both surgical and non-surgical treatment. The re-rupture rate with non-surgical treatment combined with EFR is reported similar to the rates with surgical treatment, which is an improvement compared to the former non-surgical treatment with immobilization.(7,15–18) The intention with early functional rehabilitation is to minimize the loss of muscle strength that is inevitable in the immobilizing period. Laboratory studies have also indicated that early loading of the ruptured tendon will improve the tendon healing in animals(19,20) and clinical studies have confirmed this.(21)

Several studies have reported use of controlled ankle/foot exercises, but few studies examined the effect of the exercises on its own and even fewer combined with non-surgical treatment.(22–25) We conducted a systematic review investigating the EFR used in the first 8 weeks of treatment and it showed very heterogeneus intervention protocols.(26) The components used in the EFR ranged from early weight-bearing and controlled range of motion ankle/foot exercises to strength exercises. The resistance exercises used in the early phase were most often isometrics, seated heel-rises or resistance exercises with an elastic band, but many studies did not describe the exercises and lacked information of exercise descriptors (eg. load, repetitions, sets) needed for a replication.(27)

Based on the results from this systematic review and our clinical expertise we designed a new, well-defined treatment protocol with exercises that were initiated earlier and with more progression than standard care today. We recently tested the feasibility of this new treatment protocol (N-20180072) which showed that the early initiation of exercises was highly feasible and patient acceptability was high. Based on our findings from 1) the systematic review and 2) our recently completed feasibility study, we now wish to test and compare this intervention to the current standard care that is delivered today. Such an intervention has the potential to negate the negative long-term functional consequences of Achilles tendon ruptures. By enhancing the physical function in the early stage, patients will have less sick leave and be able to return to work earlier. We expect that restoring early function could also positively benefit long-term outcome.

6b Explanation for choice of comparators

The standard care exercise program is the standard treatment in the hospitals in the North Denmark Region. It is considered a safe treatment and well accepted in Denmark and in international literature. This program will be included in both study arms and the early progressive exercises will be an add-on to the standard treatment.

7. Objectives

The purpose of this trial is to investigate the efficacy of standard care versus standard care combined with an early exercise program in improving the Achilles tendon Total Rupture Score ATRS(28) score 13 weeks after non-surgical treated Achilles tendon rupture.

We hypothesize that individuals with Achilles Tendon rupture randomized to standard care and early exercises will have a significantly higher ATRS score (primary outcome) after 13 weeks (primary endpoint) compared to individuals receiving standard care only.

8. Description of trial design including type of trial

The trial is designed as a randomized, superiority trial with a 2-group parallel design with two centers. Reporting of the protocol follows the SPIRIT(29) statement and TIDieR(30) and CERT(31) for intervention description. The preparation of the trial, including publishing this trial protocol, was done in accordance with the PREPARE Trial guide. Before the inclusion of the first participant, the trial will be registered on clinicaltrials.gov.

Potential participants who are excluded during the physical examination and eligible participants who decide to withdraw before randomization will be asked to be part of a concurrent observational cohort.

Methods: Participants, Interventions, and Outcomes

9. Study setting

Participants will be recruited from the outpatient clinics at Orthopaedic department in Aalborg and Hjørring. Participants will attend baseline and complete the intervention at these two locations. The intervention will take place at the hospital and as home exercise. The physical follow-up will be done at Aalborg University Hospital after 9, 13 and 52 weeks. Links to the questionnaires used will be sent by REDCap (Vanderbilt University, Nashville, TN, USA)(32) to participants' e-mail address for 9, 13, 26 and 52 week follow-ups.

10. Eligibility criteria

Inclusion criteria:

- Patients with acute total Achilles tendon rupture treated non-surgically (Standard care of treatment in North Denmark Region)
- Diagnosed within 3 days (of their injury)
- Age 18 - 65, able and willing to participate in the intervention
- Able to speak and understand Danish

Exclusion criteria:

- Achilles tendon rupture close to insertion on calcaneus or in the musculo-tendinous junction of the triceps surae
- Previous Achilles tendon rupture or other conditions in either leg causing lower leg disability (pain, deficits in strength or range of movement)
- Treated with Fluorquinolons or Corticosteroids within the last 6 months
- Diabetes or rheumatic diseases
- Severe medical illness: ASA score higher than or equal to 3.(33)

Excluded patients and patients not willing to participate will follow the usual program of rehabilitation for non-surgical treatment at the hospitals.

11. Interventions

11a Interventions for each group with sufficient detail to allow replication

The exercise intervention take place while the participant is still in the immobilizing period with an orthosis. The exercises are designed as a daily home training program.

General information for both groups:
All participants receive general information about Achilles tendon rupture, tendon healing, choice of treatment and risks. The long-term prognosis of the Achilles tendon rupture is associated with lack of muscle strength and physical function and therefore forms the rationale for performing the exercise therapy. This information will be delivered both verbally and in a written leaflet.

A: Standard exercise program. Initiated at the 2-week (14 days) appointment in the outpatient clinic and a booster visit in the sixth week in the physiotherapy. The exercises are performed 5 times daily and with 25 repetitions:

- **Range of motion.** In the third week the participant is instructed to take the orthosis off and begin range of motion. The exercises are dorsal/plantar flexion and pronation/supination. For both exercises it is emphasized that dorsiflexion is restricted beyond neutral position of the foot. Position: seated with the foot hanging free from the chair and not resting on the floor. They carefully perform active dorsiflexion towards neutral and a passive plantarflexion. After one week gradually active plantarflexion is allowed.

- **Resistance strength exercise with elastic band**. In the sixth week the participant is instructed to do plantarflexion from neutral position with the resistance from an elastic band (low resistance). They are not allowed to pull the foot in dorsiflexion beyond neutral foot position. Position: seated with straight knee.

B: Standard exercise program plus add-on exercises. There will be an introduction to the exercises in week 2 (from day 7) and booster visits after 1 and 3 weeks. The sessions will be approx. 45 min.:

- **Range of motion (identical to standard care).** In the third week the participant is instructed to take the orthosis off and begin range of motion. The exercises are dorsal/plantar flexion and pronation/supination. For both exercises it is emphasized that dorsiflexion is restricted beyond neutral position of the foot. Position: seated with the foot hanging free from the chair and not resting on the floor. They carefully perform active dorsiflexion towards neutral and a passive plantarflexion. After one week gradually active plantarflexion is allowed.
- **Resistance strength exercise with elastic band (identical to standard care)**. As in the standard treatment, **plus Add-on** that starts one week earlier and contains progression. In the fifth week the participant is instructed to do plantarflexion from neutral position with the resistance from an elastic band. They are not allowed to pull the foot in dorsiflexion beyond neutral foot position. They are instructed to progress by pulling the elastic band tighter or to change to a stronger elastic band. Position: seated with straight knee.
- **Isometric contraction.** In the second week while still immobilized in the orthosis the participant is instructed to do isometric contractions of the leg muscles/triceps surae. In the beginning it will be short time under tension (TUT) and low load and then progression as the participant feels comfortable. Progression of load will be a) allowing to push the forefoot against the bottom of the walker with more pressure, b) performing isometric contractions while standing. Position: can be seated, standing or lying down with bent or straight knee.
- **Seated heel-rise.** In the third week the participant is instructed to do a seated heel-rise while in the orthosis with the heel on the wedges and with open straps to allow movement. The wedges under the heel of the foot prevents excessive dorsiflexion of the foot. Progression is done with external weight on the knee. As the wedges are removed during the treatment the range of motion is increased. A book or a rolled towel is placed under the front of the orthosis to stabilize. Position: seated with bent knee in 90 degrees and possibly a cushion on the chair to compensate for the height of the orthosis with wedges. Alternative in the last three weeks is a supine pelvic lift combined with heelrise.
- **Progression**: The participant is instructed to progress the resistance exercises when they can. It is emphasised that the exercises must not cause sudden or severe pain in the tendon, but muscle soreness is to be expected. The exercise exertion should be within 2-5 on the Borg Scale.

Schedule of the exercise program and Exercise descriptors is presented in appendix.

Rehabilitation after the intervention period:

All participants are referred to rehabilitation in group sessions led by a physiotherapist from week 9 to 17. The program follows a standard protocol with exercises for strength and function progressing over time and there is advice for home exercise.

11b Criteria for discontinuing or modifying allocated interventions

Exercise sessions begin with assessing the progression of the tendon healing. In the first weeks with immobilization and physical examination is not possible, the participant is asked if there has been any constant or sudden pain or swelling and if there has been any excessive load to the tendon. At the 2-week appointment in the outpatient clinic the standard procedure is to examine any reported symptoms and perform a physical examination of the tendon and muscle structure.
In case of deviation from the protocol or adverse events, the Data and Safety Monitoring Board (see 21.a) will decide to either continue with modifications or to withdraw the participant from the study.

11c Strategies to improve adherence

During the first visits, the participants are informed about the importance of adherence to the exercise intervention. At the sessions the physiotherapists will use verbal encouragement to motivate the patients to perform the exercises. To promote adherence to the home exercise program there will be a pamphlet with detailed description of the exercises and a training journal.
Each appointment will be registered in the hospital booking system and this features a possibility of having text messages prior to the appointments. If the participant fails to attend an appointment, the physiotherapist will arrange another appointment. If the participant decides to leave the study, the reason for leaving will be registered.

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

During the first nine weeks of treatment the patients are advised to avoid activities with high load on the foot, and to focus on oedema prophylaxis and training for a better overall result. Most activities of daily living will be possible, but it is advisable to take sick leave from work in the first two to nine weeks or longer depending on the workload.

12. Outcomes

During the initial clinical examination, we will collect the following descriptive data: age, height, body mass, educational level, work and sports activity status, trauma cause and smoking.

Primary outcome:

The primary outcome is Achilles tendon Total Rupture Score (ATRS), which is a validated self-reported questionnaire for acute Achilles tendon rupture.(28) It consists of 10 items concerning

limitations related to symptoms and physical function. Each item is rated from 0 (very limited function) to 10 (not at all limited). Items: strength, fatigue, stiffness, pain, activities of daily living, walking on uneven surfaces, walking quickly upstairs or uphill, running, jumping and hard physical labour. The ATRS is validated in a Danish population and is used in the Danish Achilles Database DADB.(12,34) The primary endpoint is 13 weeks. The questionnaire will also be filled out at baseline to re-call a pre-rupture level and at the 26- and 52-weeks follow-up.

Secondary outcomes:

International Physical Activity Questionnaire (IPAQ) short form Danish version. It consists of 7 items concerning physical activity as time spent performing vigorous and moderate activities, the time spent walking and sitting 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.(35) The questionnaire will be filled out at baseline (to re-call a pre-rupture level) and at the 13, 26 and 52 weeks follow-up.

Achilles tendon resting angle (ATRA) is validated as an indirect measure of the Achilles tendon length.(36–38) The ATRA will be measured at 13 and 52 weeks.

Ability to perform a standing Heel-rise. The participants will be classified as being able to perform a single-leg heel-rise if they are able to lift the heel at least 2 cm while keeping the knee straight. Position is standing with ankle in a neutral position and fingertips on the wall for balance support.(39,40) Measured at 13 and 52 weeks.

Achilles tendon properties - length measured by ultrasound using Copenhagen Achilles length measure (CALM) for tendon length(41) will be performed at 9, 13 weeks and 52weeks.

Isometric muscle strength – is measured as maximal isometric plantar flexor muscle strength using a Fysiometer.(42) The leg is placed on a Wii platform and secured with a belt around the knee and the Wii platform. When the isometric contraction is performed, the Wii is calculating the maximum peak force and the rate of force. Position: seated with 90 degrees flexion in hip and knee. Measured at 9, 13, 52 weeks.

Muscle endurance is measured with the MuscleLab measurement system (Ergotest Technology, Oslo, Norway).(39) External weight load on the knee is calculated to 50% of the bodyweight. A linear encoder is attached to the heel of the shoe. When heel-rise is performed, the string is pulled, and the sensor measures the muscle endurance. Measured seated at 13 weeks and standing at 52 weeks.

The fear of re-rupture. When asked, patients often mention the fear of re-rupture and feeling the "pop" of the tendon as the worst thing that could happen again. This could influence the willingness to participate in the early exercises and how much they will load during the exercises.

The Tampa scale of Kinesiophobia (TSK) is used and validated for backpain, but has previously been used for Achilles tendon rupture evaluation as the questions about kinesiophobia could have associations to how patients with Achilles tendon rupture manage rehabilitation and return to sports.(40) The questionnaire consists of 17 items concerning pain and kinesiophobia and has 4 answers from "Strongly disagree" to "Strongly agree". Measured at baseline, 9, 13 and 52 weeks.

Question: Were you afraid to do the prescribed load when performing the exercises? If yes why? Measured at 9 weeks

Compliance with the intervention: The participants will register the number of exercise sessions they perform each day in a training journal. The timeframe will be from the day they start the exercises to the end of week 9.

Safety and Adverse events. The number of serious and minor adverse events is registered in a pre-defined list based on Common Terminology Criteria for Adverse Events(43) and the participants will be asked open questions at each session. Serious adverse events are re-rupture, non-union of the tendon or symptomatic deep vein thrombosis (DVT). Muscle soreness or mild pain is considered inevitable and normal when initiating exercises after a period of immobilization.

Cost-effectiveness outcomes. To evaluate the cost-effectiveness of the intervention, we will use self-reported health state as measured by the EQ-5D-5L.(44) Work productivity outcomes are measured using the Work Productivity and Activity Impairment Questionnaire WPAI:GH and condition-related expenses as measured by a self-developed questionnaire. The EQ-5D provides a simple descriptive profile and a single index value for health status and has been used extensively in research to measure QALYs gained and thereby perform health economic evaluations. The questionnaires will be filled out during all follow-ups.

13. Participant timeline

Baseline data will be collected at the first appointment in the outpatient clinic. During the intervention the participants will be followed closely and monitored on progression of tendon healing and adverse events. Assessment of outcome takes place at 9, 13, 26 and 52 weeks and will include patient reported questionnaires and physical measurements.

RCT	**STUDY PERIOD**							
	Enrolment	**Post-allocation**				**Follow-up**		**Close-out**
TIMEPOINT	***Day 1-7***	***1 week***	***2 weeks***	***4-8 weeks***	***9 weeks***	***13 weeks***	***26 weeks***	***52 weeks***
ENROLMENT:								
Eligibility screen	X							
Informed consent	X							
Allocation	X							
INTERVENTIONS:								
Intervention A			◆—	—	—◆			
Intervention B		◆—	—	—	—◆			
Concurrent observational cohort			◆—	—	—◆			

BASELINE ASSESSMENTS:								
Pre-score ATRS, IPAQ	X							
Demographics	X							
ASSESSMENTS questionnaires:								
ATRS						X	X	X
IPAQ						X	X	X
EQ5D-5L	X				X	X	X	X
Tampa scale of Kinesiophobia TSK	X					X		X
General health V2.0 (WPAI:GH)					X	X	X	X
ASSESSMENTS physical:								
ATRA					X	X		X
Achilles tendon length (by ultrasound)					X	X		X
Achilles tendon cross-sectional area (by ultrasound)					X	X		X
Ability to perform single Heel-rise						X		X
Isometric muscle strength					X	X		X
Ability to do single leg heelrise						X		
Muscle endurance						X		X
Compliance with the intervention					X			
Complications		◆	◆	◆	◆	◆	◆	◆

14. Sample size

Sample size calculations are based on the primary endpoint ATRS with a clinically relevant difference at 10 point and estimated standard deviation 15 point. With a two-sided 5% significance level and a power of 80%, the sample size will be 37 in each group and a total of 82 participants when allowing for potential dropouts.

15. Recruitment

The participants are recruited in the Orthopaedic outpatient clinics at Aalborg and Hjørring. All relevant subjects will pass through these departments. All medical and administrative staff involved in treating the patients in the Emergency departments and the outpatient clinics will be informed of the study and notified of the inclusion/exclusion criteria. There will be written information for staff and information handouts for patients. Daily, the referral lists in the outpatient clinics will be searched to retrieve all incoming referrals of acute Achilles tendon ruptures. Patients potentially eligible for the study will be contacted by telephone and screened by the Primary Investigator (MC)

or a project physiotherapist. If the patient is interested in participating and is eligible, an early appointment in the outpatient clinic or a telephone meeting is arranged, where the patient receive the oral information about the project. Final inclusion will take place at this meeting if the eligibility is confirmed. After the telephone contact the written information is also send by email (in e-Boks). It will be ensured that the participants have at least 24 hours to read the document before the oral information. Patients will be given the possibility of contacting the project manager by phone or Email, if they have questions.

Methods: Assignment of Interventions (for controlled trials)

Allocation

16a Sequence generation

Randomization of participants is performed using a random number generator on www.sealedenvelope.com and it will be stratified by sex, as female sex is less present and is associated with lower outcome in the ATRS. Block randomized in random concealed block sizes of 2-4 (1:1) into two parallel groups is used to avoid imbalance in the randomization between the intervention groups.

16b Allocation concealment mechanism

A researcher not involved in the trial will generate the allocation sequence and is the only person who knows the block sizes. The randomization results are kept in opaque sealed envelopes and stored in a locked cabinet where only the project personnel performing the randomization has access.

16c. Implementation

In practice, after a participant has been enrolled, has filled out baseline questionnaires and received initial information regarding the practicalities of participation, the Primary investigator will inform the project secretary of the new participant. The project secretary will open the envelope and assign the participant to the allocated treatment based on randomization. The notes in the envelopes state group allocation number and the intervention. The secretary will inform the participant and the physiotherapy department regarding the randomization results. The randomization is coded so that the Primary investigator does not know which intervention is linked to which group number (Group 1 or 2).

17a Blinding(masking)

The Primary investigator (MC) will be responsible for performing the statistical analyses and will remain blinded to the coding until after the analyses have been performed. The analyses will be

performed after the examination that includes the primary endpoint (the 13-week follow-up) of the last participant. All follow-up examinations will be blinded for the group allocation.

It is not possible to blind the participants to the content of the allocated exercise program, but we will minimize the information regarding the differences of the two treatment arms. In the participant information sheet and the oral information, participants will be informed that the study compares two different courses of exercise treatment, which both include the treatment services that are normally offered. The specifics of the differences between the exercises will not be shared with the participants. The reasons for not informing participants about the specific content of the intervention are two-fold. First, given the simplicity of the intervention, knowledge about the actual content would increase the likelihood that participant would, to some degree, implement these strategies in their rehabilitation, for instance by increasing their exercise dose. This would lead to contamination of the control condition of this trial, leading to possible underestimation of the effectiveness of the intervention in question. Secondly, by keeping participants blind to treatment allocation, the negative effects (such as disappointment) of not receiving the intervention in question, could be avoided. This is important as these effects could negatively affect the outcomes, with a risk of an overestimation of the effect of the intervention in question.

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

In case of adverse events that are considered associated with the intervention, the treatment allocation will be revealed to the patient and the treating clinician in the outpatient clinic.

Methods: Data collection, management, and analysis

18 Data collection methods

18a Plans for assessment and collection of outcome, baseline, and other trial data

Baseline data will be collected at the first appointment in the outpatient clinic or online via link in an email after the oral information has taken place. The Informed consent is filled out in Redcap before baseline information. During the intervention the participants will be followed closely and monitored on progression of tendon healing and adverse events. Assessment of outcome takes place at 9, 13, 26 and 52 weeks and will include patient reported questionnaires and physical measurements. Participant data will be stored in REDCap hosted at Aalborg University Hospital.

The personnel providing the randomization, exercise interventions and follow-up will follow standardized protocols for the intervention and receive training before initiation of the study. During the study there will be quality control regarding adherence to the protocols.

18b Plans to promote participant retention and complete follow-up

During the first visits, the participants are informed about the importance of adherence to the exercise intervention. They will follow the usual plan for clinical follow-up in the outpatient clinic,

where the staff can assist in solving any problems with attaining the study follow-ups. In case of adverse events or deviation from the treatment plan, the follow-up sessions will be executed if possible. For example, if physical examinations are not possible due to re-rupture, then only the patient questionnaires will be completed.

19. Data management

All data will be stored electronically and are handled according to the General Data Protection Regulation. Participant data will be stored in REDCap hosted at Aalborg University Hospital. It is a secure web application for building and managing online surveys and databases and has secure logged entry. Data processor agreements and protocols will be stored on a secure server at Aalborg University Hospital. Any paper forms will be kept in a locked room in the outpatient clinics at the study sites. To prevent data entry errors, data collection instruments have been developed in REDCap so that required data must be included or an error will be displayed, and validation of each field has been chosen (e.g. if the format of the data does not appear to be a date in the field 'Date', an error is displayed). All data will be kept for 10 years after completion of the trial in accordance with The European Code of Conduct for Research Integrity.

20. Statistical methods

20a Statistical methods for analysing primary and secondary outcomes

The primary intention-to-treat analysis will investigate the between-group difference in ATRS. We will use a linear mixed effects regression model with the participant as random effect and time 13, 26 and 52 weeks, group allocation (standard care vs standard care plus add-on) and baseline value as fixed effects. Conclusions will only be drawn based on the primary endpoint (13 weeks).

All statistical analyses will be performed by a blinded data analyst according to a pre-established analysis plan. This plan is written in consultation with a statistician and will be published on the Aalborg University website before the inclusion of the last participant. STATA will be used as statistical software. We will use Q-Q plots and histograms to assess data normality.

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 intention-to-treat principle is used for analyses and all participants are included in the analyses regardless of the compliance to the intervention.

Methods: Monitoring

21. Data monitoring

21a Composition of data monitoring committee (DMC)

Safety of the tendon healing has great importance in this study. There will be a Data and Safety Monitoring Board with the principal purpose of monitoring data and safety. The study setup will aim at preventing adverse events by monitoring the tendon healing and setting threshold values for initiation and progressing the exercises in the intervention. The data monitoring committee will be composed of the primary investigator, the project physiotherapists, the chief orthopaedic foot surgeon (ILK) and an orthopaedic surgeon not otherwise involved in the study. They will assess all matters regarding data and safety and will grade all adverse events and decide whether to delay the proceeding of the intervention or the participant should be withdrawn from the study due to the adverse event. Presentation of each item on the agenda will be blinded for the primary investigator. The adverse events will be graded 1 to 5 according to the Common Terminology Criteria for Adverse Events v4.03.(43)

Action and treatment of adverse events will start immediately following the usual treatment protocols. The assessment of the adverse event in the DMC will be done within 7 days for serious adverse events. Serious Achilles tendon injury adverse events are re-rupture, non-union of the tendon or deep vein thrombosis (DVT). Muscle soreness or mild pain is considered inevitable and normal when initiating exercises after a period of immobilization and will not be considered an adverse event.

21b Description of any interim analyses and stopping guidelines

If the rate of re-rupture or other serious adverse events is noted to be exceptionally high or increases rapidly after the intervention has been implemented, the DMC can recommend terminating the trial.

22. Harms

All participants receive information about possible adverse events relative to the Achilles tendon rupture in general and to the specific intervention. In case of serious adverse events they are encouraged to seek immediate medical attention and for minor adverse events to contact the project physiotherapist by phone. At each session the participants will answer questions of possible adverse events during and between the sessions. During and after completion of the study the included participants will also be followed in the outpatient clinic and in The Danish Achilles tendon Database (DADB).

23. Auditing

N/A

Ethics and Dissemination

24. Research ethics approval

Before initiation of the study, approval of the study protocol, informed consent and participant information will be approved by:

- The Physiotherapy and Occupational therapy department and the Orthopaedic Department at Aalborg University Hospital
- The Ethics committee of North Denmark Region. Project identification number: N-20200041

As this is designed as an add-on intervention to standard of care, all participants will receive an evidence-based treatment that is at least equal to standard care today.

25. Protocol amendments.

Important protocol modifications are registered and approved by The Ethics committee of North Denmark Region.

26ab. Consent or assent

The primary investigator will obtain informed consent from the participants.

27. Confidentiality

All personal data collected on potential and enrolled participants is collected by telephone screening, at baseline appointment or at study sessions. Data will be kept secure and for 10 years. The GDPR – General Data Protection Regulation is followed. The study is registered at The Danish Data Protection Agency at Aalborg University Hospital.

28. Declaration of interests

All authors have no competing interests.

29. Access to data

All authors will have access to the full dataset before publication. The dataset will be stored at the sponsor site, Aalborg University hospital.

30. Ancillary and posttrial care

During and after completion of the study the included patients will be followed in the outpatient clinic and in The Danish Achilles tendon Database (DADB). Any serious adverse event occurrence

will be reported and consulted with the Chief foot surgeon (ILK) within three days for re-ruptures or DVT and within 7 days for minor adverse events. Participation in the study will be covered under the Patient Compensation Association (Patienterstatningen).

31a. Dissemination policy

The results of the study will be submitted for publication regardless of the result being positive, negative or inconclusive. Publication will be aimed at an international peer-reviewed journal. The preliminary title is: "A randomised controlled trial on the effect of Early progressive strength exercise for treatment of acute Achilles tendon rupture. The Achilles tendon Back-On-Track study". The results will also be presented at relevant physiotherapy and orthopaedic conferences. Guidelines and the exercise protocol will be made available for online download, to ensure translation of the research results into useful information for clinical practice.

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

All co-authors are expected to make substantial scientific contributions that will qualify them as co-authors according to the International Committee of Medical Journal Editors (ICMJE) recommendations for authorship(45):

- 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.

MC will draft the manuscript with input from all the authors. MSR, ILK, JAZ and KGS will all participate with valuable scientific contributions to the manuscript. All authors have no competing interests.

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

Data will be available upon reasonable request.

Appendixes

32. Informed consent materials

33. Biological speciments

None

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Informeret samtykke til deltagelse i et sundhedsvidenskabeligt forskningsprojekt.

Forskningsprojektets titel:

Akillessenen på banen igen. Et randomiseret kontrolleret studie af effekten af tidlig progressive styrketræning til akut Akillessene ruptur.

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden at miste mine nuværende eller fremtidige rettigheder til behandling.

Jeg giver samtykke til, at deltage i forskningsprojektet, og har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn: _____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser for dig?:

Ja _____ (sæt x) Nej _____ (sæt x)

Erklæring fra den, der afgiver information:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet information:

Dato: _____ Underskrift: _____

Projektidentifikation:
Videnskabsetisk Komité for Region Nordjylland projektnr N-20200041

RCT study. Schedule of exercise program.

Exercises		Iso	Heelrise Iso ROM	Heelrise Iso ROM	Elastic 1 Heelrise Iso ROM	Heelrise Iso stand Elastic 1 ROM	Elastic 2 Heelrise Iso stand Elastic 1 ROM	Elastic 2 Heelrise Iso stand Elastic 1 ROM	Elastic 2 Heelrise Iso stand Elastic 1 ROM
Weeks	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**
Immobilizing	Walker, 3 wedges			Walker, 2 wedges		Walker, 1 wedge		Walker, no wedge	
Weight bearing	Non WB		P- WB, 2 crutches		P-WB, 1-2 crutches		Full WB, crutches for long walk		
Rationale		A. Facilitation		B. Initiation of load			C. Progression to more load		
Total exercise dose (time under tension)		Facilitation of muscle activity by isometric contraction without ROM		Slow controlled movement to avoid peak forces on tendon while prioritizing long TUT to maintain/increase strength			Improve strength (go to failure IF THEY ARE comfortable with it)		
Progression		Progress from A to B: If patient feel comfortable doing facilitating exercises If clinical screening is OK at "2-week follow-up" (no tendon gap, equal ATRS, no pain during exercises).		Progress from B to C: If patient feel comfortable doing "initiation of load" exercises. If exercises are managed well - with regards to Toigo descriptors, - without persistent pain or discomfort during and after exercises, - no compensating movements while performing exercises.			Progress from C to exercise and mobilize without walker boot: The decision to discontinue the walkerboot is done at the Outpatient clinic. The exercises should provide the foundation for the patient to be confident in future decisions of choosing sufficient amount of load to improve the muscle performance while still avoiding too much strain on the healing tendon (i.e. avoid strenuous load, avoid stretching in dorsiflexion with load)		

Blue: Standard exercise program. Orange: Add-on exercises. Iso: Isometric contractions. Elastic 1: Light load (yellow-red). Elastic 2: Progression of load to stronger elastic band (red, blue, green). WB: Weight bearing. P-WB: Partial weight bearing. Heelrise is seated. ROM is unloaded range of movement.

Appendix

Toigo & Boutellier exercise descriptors	**Isometric contraction**	**Seated heel-rise**	**Elastic band**
X1 Load magnitude	15-20 RM	15-20 RM Progress to 15RM week 6/7	15-20 RM Progress to 15RM week 6/7
X2 number of repetitions	5	10-15	10-15
X3 number of sets	5	3	3
X4 rest btw sets	5 sec	10 sec	10 sec
X5 number of exercise interventions	Every hour (approx 12 hours per day) for week 2-3, then change to 5 times per day in week 4-9	5 per day	5 per day
X6 duration of the experimental period	Week 2 to 9	Week 3 to 9	From week 5 to 9
X7 Fractional and temporal distribution of the contraction modes per repetition and duration (s) of one repetition	5 sec	3s shortening 3s isometric 3s lengthening	3s-3s-3s (Focus is on the concentric phase. Important not to push beyond the neutral position in the eccentric phase)
X8 Rest in-between repetitions	2	2	2
X9 Time under tension	125s per session 1625s per day (hourly) 625s per day (5 times)	270-405s per session 1350-2025s per day	270-405s per session 1350-2025s per day
X10 Volitional muscular failure	No	No	No
X11 Range of motion	No range of motion. The foot is immobilized in equinus according to the number of wedges.	From plantarflexed foot position on the wedges to more plantarflexed, when performing the heel-rise	Dorsiflexion above neutral is not allowed. Full plantarflexion allowed.
X12 Recovery time in-between exercise sessions	1 hour	3 hours	3 hours

X13 Anatomical definition of the exercise (exercise form)	Isometric contraction is performed inside the walkerboot with the foot in equinus according to the week-plan. Push the forefoot against the bottom of the walker and feel the contraction of the leg muscles as if you are going to make a heel-rise, but the walker boot restricts your motions. Extend the big toe to minimize the activity of the muscles for the big toe and increase activity of the leg muscles. From week 6 the exercise can be performed in standing.	Seated heel-rise with leg in walker with "the wedges of the week". Open straps and liner of walker. Knee in 90 degrees position. Hold one hand at the back of the walker to stabilize. Lift the heel from the walker/wedges. Make sure that you are using the leg muscles and not pulling up the leg with your thigh muscles. Extend the big toe to minimize the activity of the muscles for the big toe and increase activity of the leg muscles. Rest the foot on the forefoot pad rather than on the toes alone. Progression: add weight on knee (either water bottle, upper body, weights - sandbag/kettlebell)	Performed seated with straight knee. Wrap the elastic band around the forefoot and hold both ends in the hand. Tighten the band, but make sure that the foot is not pulled beyond 90 degrees. Press the foot down against the tightened elastic band as far as you can move the foot. Hold the position and then slowly pull up the foot again, but still with a tightened band. Progression: Tighten the band or change the band to other color (more strength)
Level of load	Borgs scale – Perceived exertion during exercise (/10) is used to guide the patients to progress or regress the load in each exercise. The recommended level being "easy" to "hard" (2-5/10). It is emphasized that the exercises must not cause sudden or severe pain in the tendon, but muscle soreness is to be expected.		
Progression	Progression of the exercises will be a continuous process. There are three main phases: facilitating, initiation of load, progression to more load. When progressing to the next phase or new type of exercise the following criteria must be observed: The load magnitude of the present exercise should be accomplished with the patient feeling comfortable doing the exercises and without persistent pain or discomfort during and after exercises.		