

Effectiveness of reducing tendon compression in the treatment of insertional Achilles tendinopathy: a randomised clinical trial

Aelvoet Florian, De Schamphelaere Lena, De Wilde Hanne

Student number: 01909422, 01908412, 01903601

Supervisor(s): Prof. Dr. Luc Vanden Bossche

Co-supervisor: Dr. Lauren Pringels

A dissertation submitted to Ghent University in partial fulfilment of the requirements for the degree of
Master of Science in Rehabilitation Sciences and Physiotherapy

Academic year: 2023 – 2024

Effectiveness of reducing tendon compression in the treatment of insertional Achilles tendinopathy: a randomised clinical trial

Aelvoet Florian, De Schamphelaere Lena, De Wilde Hanne

Student number: 01909422, 01908412, 01903601

Supervisor(s): Prof. Dr. Luc Vanden Bossche

Co-supervisor: Dr. Lauren Pringels

A dissertation submitted to Ghent University in partial fulfilment of the requirements for the degree of
Master of Science in Rehabilitation Sciences and Physiotherapy

Academic year: 2023 – 2024

ACKNOWLEDGEMENT

We would like to express our sincere gratitude to our supervisors, Luc Vanden Bossche and Lauren Pringels for their guidance, encouragement and support throughout the entire process of completing this master's thesis. Their expertise and constructive feedback have been instrumental in shaping this research and our academic growth. We are deeply grateful for the moral support, understanding and encouragement of our families, along with our friends and colleague students for their companionship.

We would like to acknowledge the commitment and dedication of the physiotherapists of Sports Medicine UZ Gent in providing the interventions. Additionally, we extend our appreciation to all the participants who invested their time and physical work contributing to the success of this study. Lastly, we would like to acknowledge the financial support by FIKO UZ Gent Impulse Funding. Without them it wouldn't have been possible to accomplish the study.

CONTENT

Acknowledgement	4
Lists	6
List of figures	6
List of tables	6
List of abbreviations	7
Abstract	8
Abstract (Dutch)	10
Introduction	12
Methodology	14
Trial design	14
Study setting	14
Eligibility criteria and recruitment	14
Allocation	15
Randomisation and blinding	16
Intervention	16
Outcome measures	18
Measurements	19
Statistical methods	20
Results	22
Participant enrolment and demographic variables at baseline	22
Linear mixed model	24
Primary outcome measure	24
Secondary outcome measures	27
Other outcome measures	33
Discussion	35
Conclusion	37
References	38
Popularising summary (Dutch)	41
Societal value and impact (Dutch)	42
Proof of submission to the ethics committee	44
Appendix	45

LISTS

List of figures

Figure 1	Flowchart of patient enrolment
Figure 2	Graph of estimated means VISA-A scores with 95% CI
Figure 3	Graph of estimated means VAS-ADL scores with 95% CI
Figure 4	Graph of estimated means VAS-HOP scores with 95% CI
Figure 5	Graph of estimated means tendon thickness with 95% CI

List of tables

Table 1	Inclusion and exclusion criteria
Table 2	ROM allowed in each subphase
Table 3	Continuum of exercise programme
Table 4	Study timeline of data collection
Table 5	Patient characteristics
Table 6	Estimated means and between-group differences of VISA-A
Table 7	Within-group differences of VISA-A
Table 8	Estimated means and between-group differences of VAS-ADL
Table 9	Within-group differences of VAS-ADL
Table 10	Estimated means and between-group differences of VAS-HOP
Table 11	Within-group differences of VAS-HOP
Table 12	Estimated means and between-group differences of tendon thickness
Table 13	Within-group differences of tendon thickness
Table 14	Estimated means of secondary outcome measures
Table 15	Other outcome measures
Appendix 1	Exercise programme

LIST OF ABBREVIATIONS

AT	Achilles tendinopathy
BMI	Body mass index
CI	Confidence interval
CONSORT	Consolidation Standards of Reporting Trials
CSAC	Cincinnati Sports Activity Scale
DF	Dorsiflexion
EQ-5D-5L	EuroQol 5 Dimension 5 Level Questionnaire
ESR	Energy storage and release
HTCR	High Tendon Compression Rehabilitation
IAT	Insertional Achilles tendinopathy
ID	Identity
ITT	Intention-to-treat
LEFS	Lower Extremity Functional Scale
LTCR	Low Tendon Compression Rehabilitation
MCID	Minimal Clinically Important Difference
mG	Gastrocnemius muscle
mm	Millimetre
Mod	Moderate
mS	Soleus muscle
n	Number
P	P-value
PF	Plantarflexion
PhD	Doctor of philosophy
PTLET	Progressive Tendon Loading Exercise Therapy
RCT	Randomised controlled trial
ROM	Range of Motion
RTS	Return To Sports
SD	Standard deviation
SPSS	Statistical Package for the Social Sciences
TSFK	Tampa Scale For Kinesiophobia
UZ	University hospital
VAS	Visual Analogue Scale
VAS-ADL	Average Visual Analogue Scale during daily activities over the last 7 days
VAS-HOP	Visual Analogue Scale during single leg hop test
VISA-A	Victorian Institute of Sport Assessment-Achilles questionnaire
W	Weeks
%	Percentage

ABSTRACT

Background

Achilles tendinopathy (AT) is a common and painful condition seen in both physically active and non-active individuals which can have major impact on daily life activities. AT is particularly common in running athletes and consequently negatively affects their performance. 20% to 25% of all AT patients have an 'insertional Achilles tendinopathy' (IAT), which is localised at the level of the insertion of the calcaneal tuberosity. IAT is thought to require a different approach than mid-portion AT, given that the Achilles tendon insertion is not only subjected to tensile load but also to compressive load. Therefore, literature recommends to minimise tendon compression during IAT rehabilitation. However, this recommendation lacks scientific validation.

Objectives

The aim of this study was to investigate whether conservative treatment with compressive load modification during rehabilitation (low tendon compression rehabilitation (LTCR)) leads to superior treatment effects on pain, functionality, and tendon structure compared to a traditional rehabilitation programme without compressive load modification (high tendon compression rehabilitation (HTCR)) in patients with IAT after 12 and 24 weeks.

Study design

Stratified, prospective, investigator-blinded, randomised controlled clinical trial.

Methods

Forty-two patients with clinically diagnosed IAT were included and randomised into either the HTCR group (control group, n = 22) or the LTCR group (experimental group, n = 20). Both groups followed a 12-week progressive tendon loading exercise therapy (PTLET) programme consisting of supervised sessions combined with daily home-based exercises. The primary outcome was the Victorian Institute of Sport Assessment-Achilles questionnaire (VISA-A) at baseline, 12 and 24 weeks, with a predetermined minimal clinically important difference (MCID) of 10. Secondary outcomes included patient reported outcomes, functional outcomes and ultrasonographic outcomes. Other outcomes were compliance to the exercise programme, return to sports (RTS) rate and subjective patient satisfaction. Linear mixed model analysis was performed using SPSS to compare the within- and between groups effects for measured variables.

Results

The VISA-A score improved significantly more in the LTCR group than the HTCR group both after 12 weeks (24.28 vs 11.02, mean between-group difference: 13.12, $p = <0.001$) and 24 weeks (28.21 vs 15.54, mean between-group difference: 12.52, $p = 0.005$). The predefined MCID was surpassed and thus considered clinically relevant. After 12 weeks, there was a significantly higher return to sports rate in the LTCR group compared to the HTCR group (100% vs 71.4%, $p = 0.021$) accompanied by a significantly higher subjective patient satisfaction (78.9% vs 38.1% 'good to excellent', $p = 0.012$).

Conclusion

Reducing compression in the treatment of IAT leads to superior clinical outcomes at both 12 and 24 weeks. Therefore, the implementation of LTCR is justified and should be the new standard in the conservative treatment of IAT.

Keywords

Insertional Achilles tendinopathy, exercise rehabilitation, modification, compression, randomised controlled trial.

ABSTRACT (DUTCH)

Achtergrond

Achillespees tendinopathie (AT) is een veelvoorkomende en pijnlijke aandoening die wordt gezien bij zowel fysiek actieve als niet-actieve personen en een grote impact kan hebben op het dagelijks leven. AT komt met name veel voor bij lopers en heeft bijgevolg een negatieve invloed op hun prestaties. 20% tot 25% van alle patiënten met AT heeft een 'insertionele achillespees tendinopathie' (IAT), die gelokaliseerd is ter hoogte van de insertie op de tuberositeit van het calcaneum. Er wordt verondersteld dat IAT een andere benadering dan de mid-portionele AT vereist, gezien de Achillespeesinsertie niet alleen wordt onderworpen aan trekbelasting maar ook aan compressie belasting. Een eerdere studie heeft aangetoond dat het verminderen van peescompressie tijdens de revalidatie succesvol kan zijn. Daarom wordt in de literatuur aanbevolen om de peescompressie tijdens de revalidatie van IAT te minimaliseren. Deze aanbeveling mist echter wetenschappelijke ondersteuning.

Doelstellingen

Het doel van deze studie was te onderzoeken of een conservatieve behandeling met aanpassing van de compressie belasting (low tendon compression rehabilitation (LTCR)) leidt tot superieure behandelresultaten op het gebied van pijn, functionaliteit en peesstructuur in vergelijking met een traditioneel revalidatieprogramma zonder aanpassing van de compressie belasting (high tendon compression rehabilitation (HTCR)) bij patiënten met een IAT na 12 en 24 weken.

Onderzoeksdesign

Het onderzoek was een gestratificeerde, prospectieve, onderzoeker-geblindeerde, gerandomiseerde, gecontroleerde klinische studie.

Methode

Tweeënveertig patiënten met klinisch gediagnosticeerde IAT werden geïncludeerd en gerandomiseerd in de HTCR groep (controlegroep, n = 22) of de LTCR groep (experimentele groep, n = 20). Beide groepen volgden een 12 weken durend 'progressive tendon loading exercise therapy' (PTLET) programma bestaande uit gesuperviseerde sessies gecombineerd met dagelijkse oefeningen thuis. De primaire uitkomstmaat was de 'Victorian Institute of Sport Assessment-Achilles' vragenlijst (VISA-A) gemeten bij aanvang, 12 en 24 weken, met een vooraf bepaald minimaal klinisch relevant verschil (MCID) van 10. Secundaire uitkomstmaten omvatten

door de patiënt gerapporteerde, functionele en ultrasonografische uitkomstmaten. Andere uitkomstmaten waren therapietrouw, sporthervatting (RTS) en subjectieve patiëntentevredenheid. Er werd een 'linear mixed model' via SPSS uitgevoerd om de effecten binnen en tussen beide groepen te vergelijken voor de gemeten variabelen.

Resultaten

De VISA-A score verbeterde significant meer in de LTCR-groep dan in de HTCR-groep zowel na 12 weken (24.28 vs 11.02, gemiddeld tussen-groepsverschil: 13.12, $p = <0.001$) als na 24 weken (28.21 vs 15.54, gemiddeld tussen-groepsverschil: 12.52, $p = 0,005$). De vooraf bepaalde MCID werd overschreden en dus als klinisch relevant beschouwd. Na 12 weken was er een significant hoger RTS-percentage in de LTCR-groep vergeleken met de HTCR-groep (100% vs 71.4%, $p = 0.021$), samen met een significant hogere subjectieve patiënten tevredenheid (78.9% vs 38.1% 'goed tot uitstekend', $p = 0.012$).

Conclusie

Het verminderen van compressie in de behandeling van IAT leidt tot superieure klinische resultaten zowel na 12 als na 24 weken. Bijgevolg is de implementatie van LTCR gerechtvaardigd en zou het de nieuwe standaard moeten zijn in de conservatieve behandeling van een IAT.

Trefwoorden

Insertionele achillespees tendinopathie, oefentherapie, modificatie, compressie, gerandomiseerde gecontroleerde studie.

INTRODUCTION

Achilles tendinopathy (AT) is a common and painful tendon injury that can easily become chronic.(1) Kujala et al. reported a cumulative incidence of almost 6% in the general population under 45 years that will suffer from AT. (2) The incidence in athletes is even higher: Ackermann and Renström notified that around 30% of the running athletes develop AT. (3) The impact of AT is major, considering that two-thirds of the athletes mention that tendon pain negatively affects their performance. (4)

Although many risk factors and possible mechanisms were described, the exact pathophysiology of AT has not been completely understood yet. (5–7) However, AT is mostly seen as an overuse injury, given that among athletes, 60% to 80% with AT reported a recent change or increase in training load (intensity and/or duration). Increase in work or daily activities can as well cause AT in non-athletes. (5–7)

When this pathology is localised at the level of the calcaneus tuberosity up to 2 cm proximally, it is called insertional Achilles tendinopathy (IAT). (8,9) Approximately 20% to 25% of all AT patients, and up to 28% of runners, are affected by IAT. (9,10) Clinically, IAT is characterised by heel pain that worsens with physical activity, stiffness that worsens with prolonged rest and swelling and tenderness at the tendon-bone junction. (11) Symptoms typically develop gradually, and early morning stiffness is a common feature. (12) These symptoms may advance to the point where activity is hindered and pain even occurs at rest. (11)

While tensile load is traditionally considered the primary cause of overload, recent research suggests that compressive load also plays a prominent role in the pathogenesis of IAT. (13,14) This concept can be explained by the “enthesis organ”, where the tendon insertion is exposed to compressive forces that occur during ankle dorsiflexion due to mechanical impingement between tendon, bursa and calcaneus bone. (15) Furthermore, the chondrogenic metaplasia, characterised by increased glycosaminoglycans, fluid, collagen type III, and enlarged, rounded tenocytes - typical structural manifestations of IAT - is also regarded as a response to compressive overload. Load management, aimed at controlling tendon irritation while simultaneously strengthening it, stands as a cornerstone in the treatment of tendinopathies. (13,16)

A study applying the "Alfredson protocol", consisting of conservative exercise therapies for IAT with no restrictions on ankle dorsiflexion (DF), has shown limited success, with only 32% of patients responding well to eccentric training. (17) Considering the potential of compressive overload in the etiopathogenesis of IAT, modifying or reducing compressive load during rehabilitation may offer a more effective approach to treating IAT. A recent pilot study introduced the "modified Alfredson protocol", which aimed to evaluate the efficacy of eccentric calf muscle training without dorsiflexion in patients with chronic IAT, with the intention of reducing tendon compression. This study concluded promising clinical outcomes in 67% of the patients. However, it has a weak evidential value as it is a short-term pilot study, with a small sample size and without a control group. (18)

Following these findings, the aim of our stratified, prospective, investigator-blinded, randomised controlled clinical trial is to determine whether conservative treatment with compressive load modification during rehabilitation leads to superior treatment effects on pain, functionality, and tendon structure compared to a traditional rehabilitation programme without compressive load modification in patients with IAT after 12 and 24 weeks.

METHODOLOGY

Trial design

The study was a stratified, prospective, investigator-blinded, randomised controlled clinical trial (RCT) that included both recreational and competitive athletes with IAT. All participants were randomised into two groups: the control group (high tendon compression rehabilitation (HTCR)) and the experimental group (low tendon compression rehabilitation (LTCR)).

Study setting

The trial was conducted at Ghent University Hospital, Belgium, from November 2022 to May 2024. The research protocol was approved by the University Ethical Committee (reference number: BC-11818 / study ID: 3978). The trial was registered on ClinicalTrials.gov (ID: NCT 05456620) prior to recruitment and processed according to Consolidation Standards of Reporting Trials (CONSORT) (19)

Eligibility criteria and recruitment

A wide range of potentially interested and suitable patients were approached by doctors working in and around Ghent. Additionally, posters and leaflets were distributed via social media and paid advertisements. Participants were recruited based on the inclusion and exclusion criteria (**Table 1**). In addition to these criteria, patients had to be willing to receive no additional physical therapy or other (para)medical treatment except those related to the study. Initial check of eligibility was verified by e-mail or telephone. All eligible participants received informed consent and were given time to consider participation. Patients willing to participate were invited to the hospital for baseline measures. All participants signed an informed consent before the commencement of the study.

The researcher will keep the data collected for up to 10 years after publication of the results in PhD thesis and scientific papers. The collected data is maintained in a pseudonymised database.

Table 1: Inclusion and exclusion criteria

Inclusion criteria

- (1) Age 18-60 years old
- (2) Diagnosed with insertional Achilles tendinopathy by a sports medicine physician (both clinical and ultrasound confirmation)
- (3) Have experienced symptoms for more than 3 months and less than 3 years
- (4) Playing running-based sports at least twice a week

Exclusion criteria

- (1) Have a history of Achilles tendon rupture or surgery
 - (2) Have other disorders of the Achilles tendon or ankle (mid-portion Achilles tendinopathy, paratenonitis, osteoarthritis, ...)
 - (3) Have rheumatological disorder (e.g. Spondylitis Ankylosis)
 - (4) Have metabolic or endocrine disorders, such as type I or type II diabetes
 - (5) Have had an Achilles injection in the past 3 months
 - (6) Have other conditions that prevent following an active exercise programme
 - (7) Have already been treated with physiotherapy, shockwave therapy or orthotics in the past 3 months
 - (8) Medication use with (fluoro)quinolones antibiotic in the past 2 years
 - (9) Currently pregnant
-

Allocation

After the initial check of eligibility by e-mail or telephone, suitable and interested patients were invited to the hospital for enrolment. Patients were asked to bring a completed questionnaire with the following patient characteristics: gender, date of birth, height, bodyweight, BMI, medical history, current medication, oestrogen therapy, smoking, number of training hours per week, type of sport, most painful side and duration of complaints. After reviewing inclusion and exclusion criteria, ultrasonographic and radiographic measures were taken to confirm IAT and to assess potential Haglund exostoses and/or intratendinous calcifications. Furthermore, a physical examination was performed to determine baseline scores for each outcome measure. Next, patient allocation was implemented through randomisation. Finally, a credibility/expectations questionnaire was conducted after being educated about the intervention group. This variable is also considered as a patient characteristic. (20)

Randomisation and blinding

After the baseline assessment, participants were randomly assigned in a 1:1 ratio to either the LTCR or HTCR group, with pain intensity (as measured by the Victorian Institute of Sports Assessment – Achilles questionnaire (VISA-A), < 50 or ≥ 50) and level of physical activity (according to the Cincinnati Sports Activity Scale (CSAC), level 1 or 2) as stratification variables.

The investigator was blinded for the allocated treatment during the entire period of data collection. After the baseline assessment, master's students in physical therapy coordinated the randomisation process and educated the subjects about which group they had been assigned to. During the study, patients were asked not to discuss their treatment practices with the primary investigator. Specific questions regarding the therapy had to be discussed with the treating physiotherapists or other researchers involved.

Intervention

Both the LTCR- and HTCR group followed a rehabilitation programme consisting of supervised therapies in the Centre for Sports Medicine at UZ Ghent combined with home-based exercises during 12 weeks. During the odd weeks patients received two sessions of supervised therapy, while during the even weeks only one session took place under supervision. Each day the patients did not have supervised therapy, they were expected to complete the home-based exercises.

The LTCR was composed of three different interventions. Initially, all patients were educated about the aetiology of their symptoms, the practical implementation of load management and the structure of the rehabilitation programme. Throughout this education, the role of tendon compression was explained using a short educational video and additional explanation by the assisting master's students. The importance of limiting this compression during rehabilitation was extensively highlighted. Secondly, each patient received orthotic treatment consisting of two pairs of heel-inserts. These elevate the heel to avoid excessive compression on the Achilles tendon due to ankle DF. The patients were instructed to wear their heel-inserts during daily activities and in the ESR and RTS phase. The third intervention consisted of progressive tendon-loading exercise therapy (PTLET). The PTLET contained four consecutive phases: (1) isometrics, (2) strength, (3) energy storage and release (ESR) and (4) return to sports (RTS). Each phase was further structured into a low, moderate and high load subphase. During these phases, the amount of tendon compression was limited by reducing DF of the ankle and prohibiting stretching. Towards the end of the

rehabilitation, DF was gradually reinstated as load capacity of the tendon allowed. **Table 2** shows the allowable amount of ROM in each subphase.

Table 2: ROM allowed in each subphase

Stage	1: Isometrics			2: Strength: 50°PF-...			3: ESR: 50°PF-...			4: RTS: 50°PF-...		
Subphase	Low	Mod	High	Low	Mod	High	Low	Mod	High	Low	Mod	High
ROM	15°PF	15°PF	15°PF	0° DF	0° DF	5°DF	0°DF	5° DF	10°DF	5°DF	10°DF	15°DF

In the HTCR group, all measures to reduce compressive load on the Achilles tendon were omitted. Therefore, these patients did not receive orthotic treatment, meaning both education and PTLET were the only therapeutic interventions used. In terms of education, patients received general information about the aetiopathogenesis of AT, the practical implementation of load management and the structure of the rehabilitation programme. In contrast to the LTCR group, education considering the role of compression in the onset and treatment was completely left out. The PTLET on the other hand had a similar structure to the LTCR group: all modalities regarding the number of sets, repetitions and training intensity were identical with one key difference: patients were required to perform all exercises with at least 15° ankle DF.

In all phases, tendon-loading exercises were preceded by a standard 5-minute warm-up and a 5-minute myofascial treatment (manually when in UZ Ghent, with a massage ball at home). The myofascial treatment differed in both groups: calf muscle release in the LTCR group versus Achilles tendon release (deep friction massage) in the HTCR group. Afterwards, patients performed a standard 5-minute cooling-down. Throughout these supplementary exercises, compressive load was reduced to an absolute minimum and no stretching was allowed in the LTCR group, whereas in the HTCR group these restrictions did not apply. In addition to this, stretching of the Soleus and Gastrocnemius muscle was included in the HTCR group.

Supplemental material was supplied, such as a USB stick containing videos of all exercises, as well as a written version of all exercises with their respective goal. In both study groups, patients filled in a questionnaire once a week to monitor pain scores. Progression to a subsequent subphase or new stage occurred when patients met predefined criteria. Progression onto the next subphase was possible if: (1) the visual analogue scale (VAS-score) during the phase specific exercises was lower than 5/10 and (2) the pain score the morning after was lower than 5/10. Progression towards a new stage was allowed if: (1) the stage-specific exercises were performed for at least one week,

(2) the high-load exercises were performed within the limits of acceptable pain (VAS <5/10), (3) pain the following morning was lower than 5/10 and (4) the level of pain did not increase throughout the week. The supervising physiotherapist was responsible for coordinating and adjusting this process. Premature cessation of the intervention was possible if a patient achieved and completed phase 4 earlier than the 12 week mark. **Appendix 1** demonstrates the exercise programme with stage-specific and supplementary exercises for both intervention groups.

Given the preference for relative rest instead of absolute rest, high load isometric exercises were implemented in each stage to alternate with the stage-specific exercises. The continuum is illustrated in **Table 3**.

Table 3: Continuum of exercise programme

DAY	Day 1	Day 2	Day 3	Day 4
PHASE	START			
1: Isometrics	Isometrics on a daily basis			
2: Strength	Strength	Isometrics	Strength	Isometrics
3: ESR	ESR	Isometrics	Strength	Isometrics
4: RTS	RTS	Isometrics	RTS	Isometrics

Outcome measures

Primary outcome measure

The primary outcome measure is the VISA-A Questionnaire; a validated questionnaire to assess pain and lower limb functionality in patients with Achilles tendinopathy. (21) The VISA-A score covers three domains associated with AT: pain, function and sport activities, resulting in a score from 0 to 100. Lower scores indicate more severe symptoms and limitations in functionality.

Secondary outcome measures

Patient reported outcomes

In addition to the VISA-A as primary outcome measure, the following patient reported secondary outcome measures consist of questionnaires: (1) Lower Extremity Functional Scale (LEFS), (2) Tampa scale for kinesiophobia (TSFK), (3) EuroQol 5 Dimension 5 Level Questionnaire (EQ-5D-5L), (4) a 100 point visual analogue scale for average pain (VAS; 100 represented maximal pain) during daily activities over the last seven days (VAS-ADL). (22–25)

Functional outcomes

To assess the functional performance of the muscle-tendon unit, two different tests were utilised: (1) Single leg heel-raise endurance test: evaluates the physical load capacity of the calf muscle. Participants were asked to stand with their pathological leg on a step with the knee extended, supporting themselves with their fingertips against the wall for balance, while avoiding a forward swing of the body. They were instructed to raise the heel as high as possible at a rate of one heel-raise every 2 seconds in rhythm to a metronome set at 60 beats per minute (26,27). When the participant stopped, could not maintain the frequency, or the technique was incorrect for two consecutive repetitions, the test was terminated. The number of repetitions was counted. (2) Single leg hop-test: the patients were instructed to jump on the pathological leg 10 times with the knee slightly flexed upon landing. VAS score was asked after completing the last jump, in which higher scores indicated more pain (VAS-HOP). (28)

Ultrasonographic outcomes

Secondary outcome measures related to tendon structure were evaluated using a classical ultrasound (GE Logiq S8). Two different tendon characteristics were examined in the longitudinal plane, 5 mm distally from the posterosuperior calcaneal border: (1) Antero-posterior tendon thickness (mm), and (2) neovascularisation (modified-Öhberg scale: grade 0 to 4, higher score indicates more Doppler flow in the peritendinous and intratendinous tissues). (26)

Other outcome measures

A few measurements were assessed at specific timepoints during or after completing the intervention: (1) Compliance to the exercise programme (percentage of days practised: assessed weekly until the end of the intervention), (2) Return to sports (RTS) rate (return to desired sport on pre-injury level - on a lower level or return to sports but not the desired sport - no return to sports), (3) Subjective patient satisfaction (overall rating of the intervention: excellent - good - moderate - bad). (29,30)

Measurements

All primary and secondary measurements were conducted at baseline, 12 weeks (i.e. termination of intervention) and 24 weeks follow-up. The physical examination and ultrasonographic measures were performed by the same investigator, who was blinded to group allocation. After completing the intervention programme, all patients were asked to fill in a short RTS and subjective patient

satisfaction questionnaire. A comprehensive timeline of all data collection over the course of the trial is visualised in **Table 4**.

Table 4: Study timeline of data collection

Timepoint	Study period			
	Baseline W0	Intervention W1 to 12	Follow-up W12 W24	
<u>Enrolment:</u>				
Eligibility screen	X			
Informed consent	X			
Allocation	X			
Education	X			
<u>Intervention:</u>				
HTCR		X		
LTCR		X		
<u>Assessments:</u>				
Patient characteristics	X			
Ultrasonography	X			
Radiography	X			
VISA-A	X		X	X
LEFS, TSFK, EQ-5D-5L, VAS-ADL	X		X	X
Single leg heel-raise test	X		X	X
VAS-HOP	X		X	X
Tendon thickness	X		X	X
Degree of neovascularity	X		X	X
Compliance to exercise programme		X		
RTS rate			X	X
Subjective patient satisfaction			X	X

Statistical methods

Statistical analysis was performed using IBM SPSS software 28. Differences between the HTCR and LTCR group were analysed according to the intention-to-treat (ITT) principle.

A sample size calculation was performed a priori on the basis of the primary outcome of VISA-A. A total of at least 13 patients for each rehabilitation group was needed to establish a minimal clinically important difference (MCID) of 10 points on the VISA-A score. (31) These calculations are assuming a standard deviation of 8.4 points, a power of 80% and a two-sided significance level of

5%. Accounting for a predicted 20% lost to follow-up, we sought to include a total of 32 patients. (30,32)

Drop-outs were only taken into account for descriptive analysis and were left out for further analysis. Normality of patient characteristics, ultrasonographic and radiographic data were verified both visually with quantile-quantile plots and bar charts as well as tested using Shapiro-Wilk. Data of both groups was summarised using descriptive statistics, and a descriptive analysis was carried out. For continuous variables, the mean and standard deviation or median and interquartile range were calculated depending on the distribution of the data. Afterwards, the two groups were compared with independent sample t-tests or Mann-Whitney U tests. For categorical variables, frequencies and percentages were calculated and the groups were compared using Fisher's exact tests. Values of all parameters were tested for uniformity.

The 'return to sports' variable was dichotomised into 'return to sports' (return to desired sport on pre-injury level / on a lower level) and 'no return to sports' (return to sports but not the desired sport / no return to sports). The variable 'patient satisfaction' was dichotomised as well, into 'satisfied' (good/excellent) and 'not satisfied' (moderate/bad). Compliance to exercise therapy was registered as a percentage and between-group difference was analysed with independent sample t-test or Mann-Whitney U test depending on the data distribution.

To analyse the longitudinal data for between-group and within-group differences in primary and secondary outcomes, a linear mixed model was used, including possible factors and covariates. To examine whether the VISA-A was influenced by the type of therapy during the time course, we added the interaction term "Type of therapy X Timepoint". The timepoint variable represents the moment where measurements were taken: baseline – 12 weeks follow-up – 24 weeks follow-up. Post-hoc Bonferroni tests were performed to analyse multiple comparisons. The model was adjusted for all predefined secondary outcome measures. The categorical variables 'return to sports' and 'patient satisfaction' were analysed using Fisher's exact test. Statistical significance in all analyses was defined at $p < 0.05$.

RESULTS

Participant enrolment and demographic variables at baseline

Between November 2022 and March 2024, a total number of 46 patients with IAT were eligible to start the clinical trial (**Figure 1**). All data was collected and analysed by May 2024.

After eligibility screening four patients were excluded due to not meeting the inclusion criteria (n=1) or refusing to participate (n=3). Forty-two patients were included and randomised to their allocated group: 22 in the HTCR group and 20 in the LTCR group. During the clinical trial two drop-outs were recorded: one in each group. One patient deliberately terminated the intervention early, but following the ITT principle, their data was included in the analysis. All remaining patients completed the 12 weeks follow-up, but due to ongoing data collection only 26 patients (11 HTCR and 15 LTCR) were analysed for the 24 weeks follow-up.

Characteristics as well as radiographic and ultrasonographic data of the 42 randomised patients, obtained at baseline, were summarised in **Table 5**. Most patients included had been struggling with persistent IAT, as the mean duration of complaints was 52.59 weeks in the HTCR and 49.70 weeks in the LTCR. The two groups were comparable with no significant between-group differences at allocation.

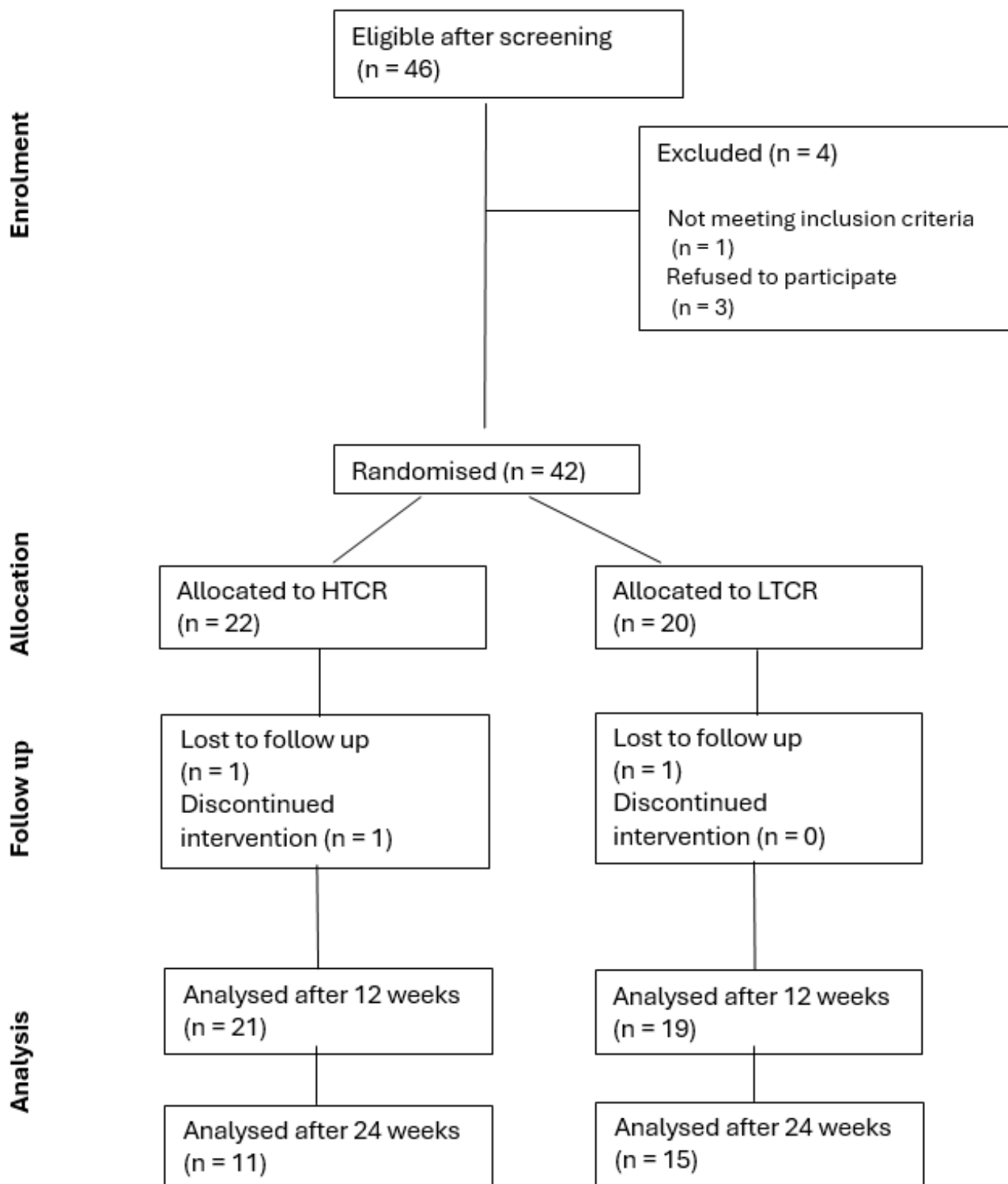


Figure 1: Flowchart of patient enrolment

Table 5: Patient characteristics

	HTCR	LTCR	P-value
Number (n)	22	20	
Sex			1
Male	16 (72.7%)	14 (70%)	
Female	6 (27.3%)	6 (30%)	
Age (years)	42.59 ± 11.30	42.10 ± 11.14	0.888
BMI (kg/m ²)	24.09 ± 2.36	25.07 ± 2.65	0.212
Training hours per week	5.41 ± 3.50	5.60 ± 2.74	0.846
Duration of complaints (weeks)	52.59 ± 43.20	49.70 ± 35.27	0.692
Smoking			1
No	21 (95.5%)	20 (100%)	
Yes	1 (4.5%)		
Pathological side			0.374
Left	12 (54.5%)	8 (40%)	
Right	10 (45.5%)	12 (60%)	
Haglund deformity			1
No	20 (90.9%)	19 (95%)	
Yes	2 (9.1%)	1 (5%)	
Calcifications			0.071
No	14 (63.6%)	18 (90%)	
Yes	8 (36.4%)	2 (10%)	
Credibility (%)	79.72 ± 10.91	74.92 ± 14.60	0.231

Continuous variables: mean ± SD

Categorical variables: n (%)

Linear mixed model

Sex, age, BMI, training hours per week, duration of complaints, smoking, pathological side and credibility were added to the linear mixed model as covariates and factors to define confounding effects on the dependent variable. However, for the primary and secondary outcomes, no variables had a significant effect on the dependent variable and were thus left out of the model for simplicity reasons.

Primary outcome measure

Changes in Achilles tendon pain and function during treatment were evaluated using the VISA-A questionnaire. The interaction effect “Type of therapy X Timepoint” was significant ($p < 0.001$), indicating a different course over time of the VISA-A score between both groups. The mean

between-group difference at baseline was not significant, implying that the VISA-A score in both groups could be considered even. However, at 12 and 24 weeks the estimated VISA-A scores were 13.12 ($p<0.001$) and 12.52 ($p=0.005$) higher in the LTCR group than in the HTCR group, respectively. These differences at 12 and 24 weeks exceed the predetermined MCID of 10 and therefore indicate clinically relevant differences. (**Table 6**)

Regarding the progression over time in both groups, estimated VISA-A scores improved significantly from 60.40 at baseline to 84.68 at 12 weeks ($p<0.001$) and 88.609 at 24 weeks ($p<0.001$) in the LTCR group. In the HTCR group, the estimated VISA-A scores also improved significantly from 60.55 at baseline to 71.56 at 12 weeks ($p<0.001$) and 76.09 at 24 weeks ($p<0.001$). These within-group differences exceed the predetermined MCID of 10 and are therefore also considered clinically relevant. In both groups the mean difference in VISA-A between 12 and 24 weeks follow-up was not significant (**Table 7**). The estimated mean VISA-A scores are listed in **Table 6**.

Figure 2 highlights the increase in estimated mean VISA-A scores for both the LTCR and the HTCR group but shows a significantly greater increase in the LTCR group.

Table 6: Estimated means and between-group differences of VISA-A

Timepoint	Estimated mean VISA-A HTCR	Estimated mean VISA-A LTCR	Mean difference LTCR – HTCR	95% CI	P value
Baseline	60.55 (55.47 - 65.62, 2.55)	60.40 (55.08 – 65.70, 2.67)	0.15 (3.69)	-7.50 – 7.21	0.969
Control 12W	71.56 (66.40 - 76.70, 2.59)	84.68 (79.26 – 90.11, 2.72)	13.12 (3.76)	5.63 – 20.61	<0.001
Follow-up 24W	76.09 (69.60 – 82.57, 3.27)	88.61 (82.75 – 94.47, 2.95)	12.52 (4.40)	3.79 – 21.26	0.005

Estimated mean VISA-A (95% CI, standard error)

Mean difference (standard error)

Table 7: Within-group differences of VISA-A

Type of therapy	Mean difference	95% CI	P value
HTCR			
0 vs 12W	11.02 (2.54)	4.78 – 17.25	<0.001
0 vs 24W	15.54 (3.23)	7.63 – 23.46	<0.001
12 vs 24W	4.52 (3.24)	-3.42 – 12.47	0.5
LTCR			
0 vs 12W	24.28 (2.67)	17.73 – 30.84	<0.001
0 vs 24W	28.21 (2.90)	21.09 – 35.33	<0.001
12 vs 24W	3.93 (2.91)	-3.23 – 11.08	0.546

Mean difference (standard error)

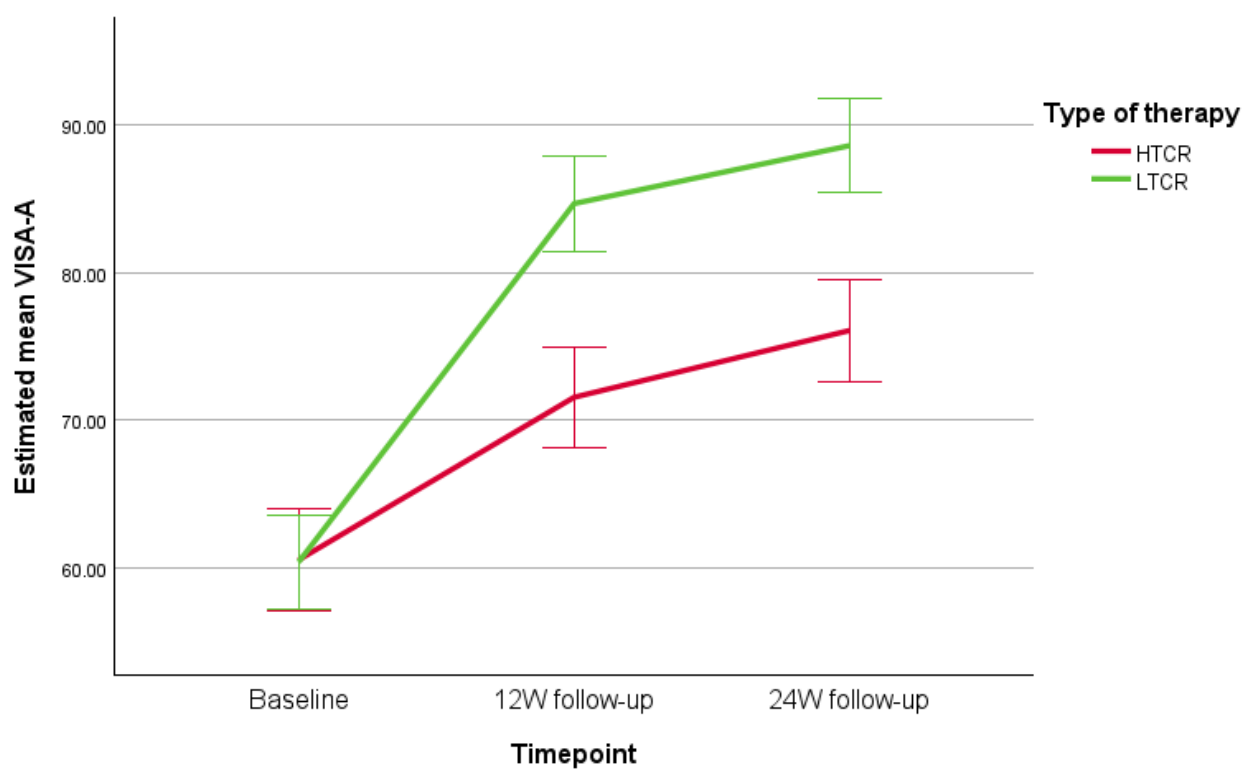


Figure 2: Graph of estimated mean VISA-A scores with 95% CI

Secondary outcome measures

A significant “Type of therapy X Timepoint” interaction effect was found for the variables VAS-ADL ($p=0.005$), VAS-HOP ($p=0.003$) and tendon thickness ($p=0.034$), but not for LEFS ($p=0.273$), TSFK ($p=0.531$), EQ-5D-5L ($p=0.992$), heel-raise endurance test ($p=0.078$) and neovascularisations ($p=0.183$). The estimated means and pairwise comparisons of each of these variables with accompanying P values are listed in **Table 14**.

(1) VAS-ADL

Within-group estimated VAS scores over the past 7 days improved significantly from 43.8 at baseline to 8.17 at 12 weeks ($p<0.001$) and 5.93 at 24 weeks ($p<0.001$) in the LTCR group. In the HTCR group, estimated VAS-ADL scores also improved significantly from 38.91 at baseline to 18.22 at 12 weeks ($p<0.001$) and 19.87 at 24 weeks ($p<0.001$). There was no significant improvement from 12 to 24 weeks in either group. (**Table 8 and 9**)

Between-group analysis showed a significant difference for VAS-ADL score at 12 and 24 weeks. At 12 weeks the mean difference was 10.05 ($p=0.043$) and at 24 weeks the mean difference was 13.94 ($p=0.020$) in favour of the LTCR group. (**Table 8**)

Figure 3 highlights the improvement in estimated mean VAS-ADL scores for both the LTCR and the HTCR group but shows a significantly greater decrease in the LTCR group.

Table 8: Estimated means and between-group differences of VAS-ADL

Timepoint	Estimated mean VAS-ADL HTCR	Estimated mean VAS-ADL LTCR	Mean difference LTCR – HTCR	95% CI	P value
Baseline	38.91 (32.33 - 45.49, 3.31)	43.80 (36.90 - 50.70, 3.47)	4.89 (4.79)	-4.64 - 14.42	0.310
Control 12W	18.22 (11.51 – 24.92, 3.37)	8.17 (1.12 – 15.22, 3.55)	-10.05 (4.89)	-19.78 – (-0.32)	0.043
Follow-up 24W	19.87 (11.07 – 28.67, 4.44)	5.93 (-1.83 – 13.68, 3.91)	-13.94 (5.91)	-25.68 – (-2.21)	0.020

Estimated mean VAS-ADL (95% CI, standard error)

Mean difference (standard error)

Table 9: Within-group differences VAS-ADL

Type of therapy	Mean difference	95% CI	P value
HTCR			
0 vs 12W	-20.69 (3.77)	-29.95 – (-11.43)	<0.001
0 vs 24W	-19.04 (4.74)	-30.67 – (-7.41)	<0.001
12 vs 24W	1.65 (4.76)	-10.03 – 13.34	1
LTCR			
0 vs 12W	-35.63 (3.96)	-45.36 – (-25.90)	<0.001
0 vs 24W	-37.88 (4.28)	-48.39 – (-27.36)	<0.001
12 vs 24W	-2.25 (4.31)	-12.84 – 8.35	1

Mean difference (standard error)

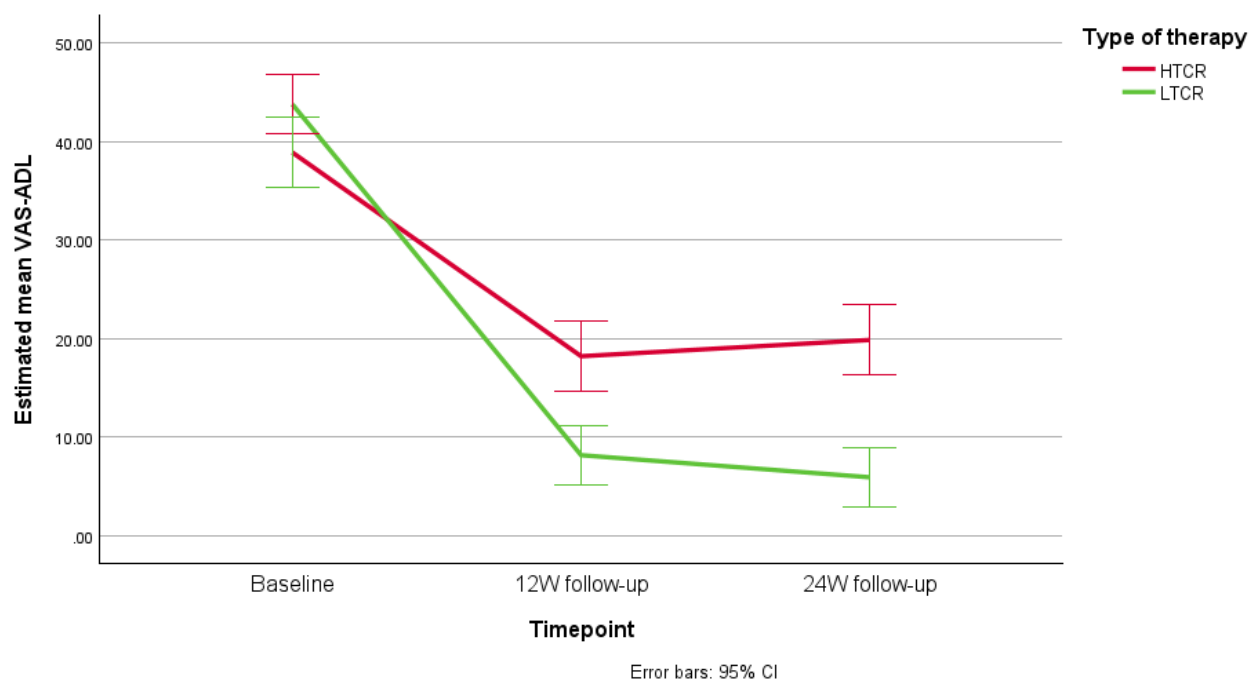


Figure 3: Graph of estimated means VAS-ADL scores with 95% CI

(2) VAS-HOP

Within-group estimated VAS-HOP improved significantly from 32.20 at baseline to 5.70 at 12 weeks ($p < 0.001$) and 5.50 at 24 weeks ($p < 0.001$) in the LTCR group. However, in the HTCR group no significant effect was found at any timepoint for the estimated VAS-HOP. There was no significant improvement from 12 to 24 weeks in either group. (**Table 10 and 11**) Considering the between-group analysis, a significant difference of 16.09 ($p = 0.004$) at 12 weeks and 14.23 ($p = 0.032$) in favour of the LTCR group was found. (**Table 10**)

Figure 4 highlights the improvement in estimated mean VAS-HOP scores for both the LTCR and the HTCR group but shows the significantly greater decrease in the LTCR group.

Table 10: Estimated means and between-group differences of VAS-HOP

Timepoint	Estimated mean VAS-HOP HTCR	Estimated mean VAS-HOP LTCR	Mean difference LTCR – HTCR	95% CI	P value
Baseline	27.77 (20.54 – 35.00, 3.64)	32.20 (24.62 – 39.78, 3.81)	4.43 (5.27)	-6.05 – 14.9	0.403
Control 12W	21.79 (14.42 – 29.17, 3.71)	5.70 (-2.05 – 13.45, 3.9)	-16.09 (5.38)	-26.80 – (-5.39)	0.004
Follow-up 24W	19.73 (9.99 – 29.47, 4.91)	5.50 (-3.06 – 14.06, 4.31)	-14.23 (6.53)	-27.19 – (-1.26)	0.032

Estimated mean VAS-HOP (95% CI, standard error)

Mean difference (standard error)

Table 11: Within-group differences of VAS-HOP

Type of therapy	Mean difference	95% CI	P value
HTCR			
0 vs 12W	-5.98 (4.23)	-16.37 – 4.41	0.486
0 vs 24W	-8.05 (5.31)	-21.07 – 4.98	0.403
12 vs 24W	-2.07 (5.34)	-15.16 – 11.02	1
LTCR			
0 vs 12W	-26.5 (4.44)	-37.42 – (-15.58)	<0.001
0 vs 24W	-26.7 (4.80)	-38.5 – (-14.91)	<0.001
12 vs 24W	-0.20 (4.84)	-12.09 – 11.68	1

Mean difference (standard error)

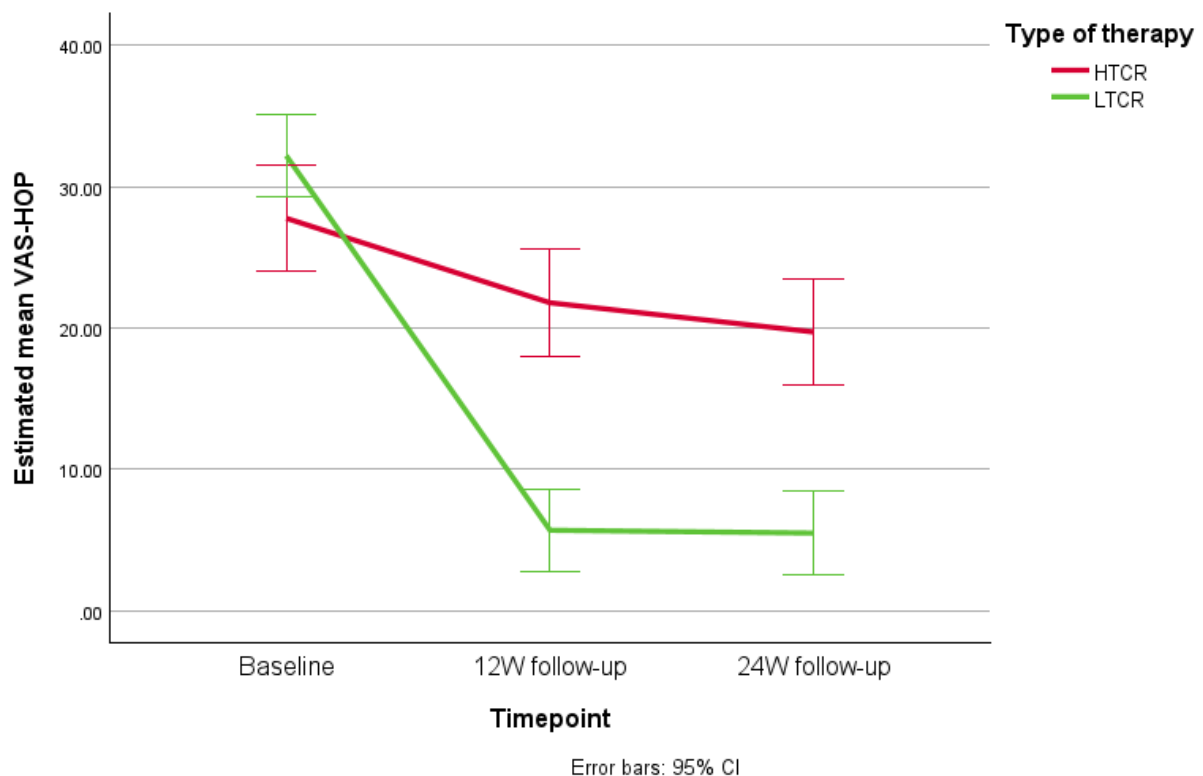


Figure 4: Graph of estimated means VAS-HOP scores with 95% CI

(3) Tendon thickness

Within-group analysis showed a significant improvement for the LTCR group. Mean tendon thickness improved from 5.52mm at baseline to 5.07mm at 12 weeks ($p < 0.001$) and to 4.88mm at 24 weeks ($p < 0.001$). In the HTCR group on the other hand, no significant differences could be found. (**Table 12 and 13**)

Between-group analysis showed no significant difference of mean tendon thickness at any of the measurements, although a trend can be seen in favour of the LTCR at 24 weeks. (**Table 12**)

Figure 5 highlights the significant improvement of tendon thickness in the LTCR group, although no significant effect could be found for the HTCR.

Table 12: Estimated means and between-group differences of tendon thickness

Timepoint	Estimated mean tendon thickness	Estimated mean tendon thickness	Mean difference LTCR – HTCR	95% CI	P value
Baseline	5.66 (5.23 – 6.08, 0.21)	5.52 (5.07 – 5.96, 0.22)	-0.14 (0.31)	-0.75 – 0.47	0.648
Control 12W	5.47 (5.04 – 5.90, 0.21)	5.07 (4.63 – 5.52, 0.22)	-0.39 (0.31)	-1.01- 0.23	0.208
Follow-up 24W	5.51 (5.06 – 5.97, 0.23)	4.88 (4.43 – 5.34, 0.23)	-0.63 (0.32)	-1.28 – 0.02	0.057

Estimated mean tendon thickness (95% CI, standard error)

Mean difference (standard error)

Table 13: Within-group differences of tendon thickness

Type of therapy	Mean difference	95% CI	P value
HTCR			
0 vs 12W	-0.19 (0.11)	-0.46 – 0.09	0.301
0 vs 24W	-0.14 (0.14)	-0.49 – 0.20	0.932
12 vs 24W	0.05 (0.14)	-0.3 – 0.39	1
LTCR			
0 vs 12W	-0.44 (0.11)	-0.72 – (-0.16)	<0.001
0 vs 24W	-0.63 (0.12)	-0.94 – (-0.33)	<0.001
12 vs 24W	-0.19 (0.12)	-0.49 – 0.11	0.387

Mean difference (standard error)

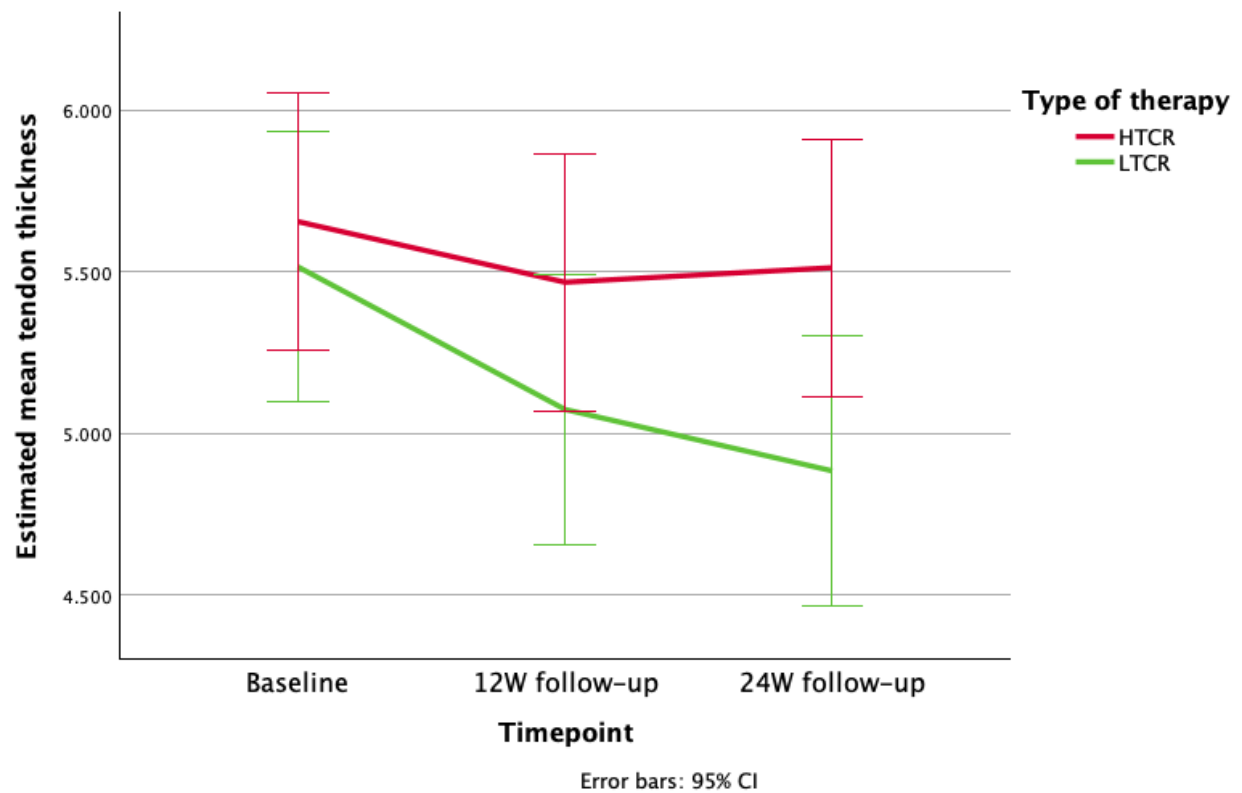


Figure 5: Graph of estimated means tendon thickness with 95% CI

Table 14: Estimated means of secondary outcome measures

	HTCR	LTCR	P-value
LEFS			
Baseline	60.5 (56.21-64.79, 2.15)	60.9 (56.40-65.40, 2.25)	0.898
Follow-up 12W	68.71(64.35-73.07, 2.18)	73.35 (68.77-77.93, 2.30)	0.148
Follow-up 24W	69.75 (64.36-75.14, 2.76)	74.72 (69.80-79.64, 2.47)	0.179
TSFK			
Baseline	35.14 (32.78-37.49, 1.18)	34.40 (31.93-36.87, 1.24)	0.669
Follow-up 12W	32.31 (29.91-34.71, 1.21)	32.50 (29.97-35.02, 1.27)	0.917
Follow-up 24W	33.44 (30.31-36.57, 1.58)	31.07 (28.31-33.84, 1.39)	0.264
EQ-5D-5L			
Baseline	0.70 (0.64-0.76, 0.03)	0.75 (0.68-0.81, 0.03)	0.267
Follow-up 12W	0.83 (0.77-0.90, 0.03)	0.89 (0.82-0.95, 0.03)	0.264
Follow-up 24W	0.86 (0.78-0.94, 0.04)	0.92 (0.85-0.99, 0.04)	0.298
Heel raise			
Baseline	19.82 (16.93-22.70, 1.44)	17.50 (14.47-20.53, 1.51)	0.272
Follow-up 12W	27.22 (24.21-30.23, 1.51)	28.54 (25.47-31.61, 1.54)	0.542
Follow-up 24W	28.14 (24.60-31.67, 1.78)	30.00 (26.73-33.26, 1.64)	0.444
Neovascularisations			
Baseline	1.41 (0.92-1.90, 0.25)	1.70 (1.18-2.22, 0.26)	0.419
Follow-up 12W	1.05 (0.53-1.56, 0.26)	0.87 (0.35-1.40, 0.26)	0.641
Follow-up 24W	0.90 (0.29-1.51, 0.31)	0.53 (-0.03-1.09, 0.28)	0.382

Estimated means (95% CI, standard error)

Other outcome measures

Table 15 shows an overview of the other outcome measures.

After 12 weeks, 71.4% in the HTCR group returned to their desired sport with a subjective patient satisfaction rate (good to excellent) of only 38.1%, whereas in the LTCR group 100% returned to their desired sport with a satisfaction rate of 78.9%. Both return to sports and satisfaction outcomes were found to be significantly different ($p=0.021$ and $p=0.012$ respectively). The compliance to the exercise programme was high in each group (HTCR = 84.13%, LTCR = 81.30%) and thus showed no significant difference.

After 24 weeks, 81.8% of patients in the HTCR group returned to their desired sport with a satisfaction rate of 36.4% compared to the LTCR group in which 93.3% returned to their desired sport with 93.3% satisfaction. 'Satisfaction' was the only significantly different outcome measure ($p=0.006$). Considering that only 26 patients completed the 24 weeks follow-up, data and P values may differ.

Table 15: Other outcome measures

Other outcome measures	HTCR	LTCR	P value
12 weeks follow-up	N = 21	N = 19	
Return to sports			0.021
No	6 (28.6%)	0	
Yes	15 (71.4%)	19 (100%)	
Satisfaction			0.012
Moderate/bad	13 (61.9%)	4 (21.1%)	
Good/excellent	8 (38.1%)	15 (78.9%)	
Compliance (mean $\pm$ SD)	84.13% $\pm$ 12.64	81.30% $\pm$ 14.33	0.511
24 weeks follow-up	N = 11	N = 15	
Return to sports			0.556
No	2 (18.2%)	1 (6.7%)	
Yes	9 (81.8%)	14 (93.3%)	
Satisfaction			0.003
Moderate/bad	7 (63.6%)	1 (6.7%)	
Good/excellent	4 (36.4%)	14 (93.3%)	

Continuous variables: mean $\pm$ SD

Categorical variables: n (%)

DISCUSSION

As the “modified Alfredson protocol” showed promising results in 67% of patients, the purpose of this study was to provide greater evidence, in the form of an RCT, in the treatment of patients with IAT. (18)

This RCT showed superior clinical outcomes for the experimental (=LTCR) group compared to the control (=HTCR) group in the treatment of active individuals with IAT. The VISA-A scores improved significantly in both groups and were also both clinically relevant as the predefined MCID of 10 was surpassed. However, the increase in VISA-A score in the LTCR group was far greater at both 12 weeks (24.28 vs 11.02) and 24 weeks (28.21 vs 15.54). The aforementioned results also exceed the predefined MCID, indicating that the LTCR approach is superior in reducing pain and improving function and functionality in patients with IAT.

Additional benefits of the LTCR over the HTCR included a greater reduction in VAS-ADL scores, with significant differences between both therapies of 10.05 at 12 weeks and 13.94 at 24 weeks. Furthermore, VAS-HOP scores only decreased significantly in the LTCR group, supplying additional evidence that reducing compression in the rehabilitation of IAT is clinically relevant.

The study also identified a significant decrease in tendon thickness, yet only in the LTCR group. This highlights that the LTCR approach improves not only patient-reported outcomes but also structural outcomes of the Achilles tendon.

This outcome is in line with the findings described in a study by Beyer et al. in which mid-portion Achilles tendon thickness decreased with both eccentric and heavy slow resistance exercise therapy. (33) It should however be noted that the predictive validity of ultrasonographic evaluations on patient reported outcome measures, such as pain and functionality, is limited and inconsistent. (34) Ultimately, this shows that reducing compression in the treatment of IAT can be more effective in reducing swelling and thus tendon thickness.

There was no significant interaction term “Timepoint X Type of therapy” for the amount of heel raises. This indicates that there is no different time course for both therapies concerning this variable. However, the number of heel raises increased from 19.82 at baseline to 28.14 at 24 weeks in the HTCR group and from 17.5 at baseline to 30.0 at 24 weeks in the LTCR group. This shows

that both therapies, regardless of the amount of compression on the tendon, can guarantee a functional improvement of the endurance capacity of the Gastrocnemius and Soleus muscles. Another highly relevant outcome was patient satisfaction with 78.9% of LTCR patients reporting a good to excellent satisfaction rate at 12 weeks, compared to only 38.1% for the HTCR patients. At 24 weeks this rose to 93.3% compared to 36.4%. At last, a significant difference in patients returning to their desired sport was seen at 12 weeks with 100% of LTCR patients returning compared to 71.4% of HTCR patients. At 24 weeks, there was no significant effect, but a positive trend in favour of the LTCR with 93.3% returning to sports in contrast to 81.8% in the HTCR group. It is however remarkable that an increase in RTS of 10.4% can be noticed in the HTCR group at 24 weeks. Suggested reasons are that patients in the HTCR group eventually returned to their desired sport despite bad outcomes or due to the natural healing process.

Strengths of this study include the high mean compliance in both groups (LTCR: 81.30% and HTCR: 84.13%), which could be explained by the thorough education prior to the start of the study, as well as the supplemental material provided and weekly supervision by a physiotherapist. A study shows that weekly feedback regarding compliance significantly improves the adherence to the therapy. (35) Patients were instructed to adhere to the exercise programme at least 5 days a week. This was monitored by the weekly questionnaires and patients were contacted if their compliance dropped lower. We are aware that this study heavily relied on unsupervised exercise therapy and therefore results might be better in a supervised programme. Another strength is the thoroughness of the initial screening and ultrasonographic evaluation, where exclusion criteria were followed very strictly to ensure the selection of active patients solitary IAT.

From a critical point of view, the most important limitation of this study is the fact that the LTCR consists of multiple interventions, such as heel-inserts, PTLET and myofascial therapy. Therefore, we can't analyse the individual impact of these individual interventions on the VISA-A score and other secondary outcomes. A recent study has however already shown that wearing heel-inserts immediately reduces pain during gait and also reduces symptom severity after 2 weeks of wear in patients with IAT. (36) Additional research regarding individual interventions is needed. Secondly, blinding of the patients regarding the intervention was not possible in this study, however, blinding of the main investigator for the assigned treatment was implemented. At last, it should be mentioned that data collection after 24 weeks was not fully completed due to the deadline of this master's thesis, therefore not all data were analysed with the possibility of varying results.

CONCLUSION

In this study both groups of patients showed significant improvement in pain and function, indicating that exercise therapy should be the gold standard in the treatment of IAT. However, LTCR demonstrated superior clinical outcomes. Reducing DF in the early phases of rehabilitation in the form of PTLET, cessation of stretching and wearing heel-inserts can thus be responsible for more efficient rehabilitation. Therefore, implementation of this approach is justified and should be the new standard in the conservative treatment of IAT.

REFERENCES

1. Sobhani S, Dekker R, Postema K, Dijkstra PU. Epidemiology of ankle and foot overuse injuries in sports: A systematic review. *Scand J Med Sci Sports* [Internet]. 2013 Dec [cited 2024 Apr 24];23(6):669–86. Available from: <https://pubmed.ncbi.nlm.nih.gov/22846101/>
2. Kujala UM, Sarna S, Kaprio J. Cumulative incidence of achilles tendon rupture and tendinopathy in male former elite athletes. *Clin J Sport Med* [Internet]. 2005 May [cited 2024 Apr 24];15(3):133–5. Available from: <https://pubmed.ncbi.nlm.nih.gov/15867554/>
3. Ackermann PW, Renström P. Tendinopathy in Sport. *Sports Health* [Internet]. 2012 May [cited 2024 Apr 24];4(3):193. Available from: <https://pubmed.ncbi.nlm.nih.gov/22846101/>
4. Janssen I, van der Worp H, Hensing S, Zwerver J. Investigating Achilles and patellar tendinopathy prevalence in elite athletics. *Res Sports Med* [Internet]. 2018 Oct 25 [cited 2024 Apr 24];26(1):1–12. Available from: <https://pubmed.ncbi.nlm.nih.gov/29064298/>
5. Sederberg M, Cushman DM. Current Treatments of Insertional Achilles Tendinopathy. *Curr Phys Med Rehabil Rep* [Internet]. 2020 Dec 1 [cited 2024 Apr 24];8(4):354–63. Available from: https://www.researchgate.net/publication/344372684_Current_Treatments_of_Insertional_Achilles_Tendinopathy
6. Silbernagel KG, Hanlon S, Sprague A. Current Clinical Concepts: Conservative Management of Achilles Tendinopathy. *J Athl Train* [Internet]. 2020 May 1 [cited 2024 Apr 24];55(5):438. Available from: <https://pubmed.ncbi.nlm.nih.gov/34387348/>
7. Chronic Achilles tendinopathy. A survey of surgical and histopathologic findings - PubMed [Internet]. [cited 2024 Apr 24]. Available from: <https://pubmed.ncbi.nlm.nih.gov/7634699/>
8. Barbachan Mansur NS, Pereira VF, Monteiro Cunha HC, Nunes CG, Ferreira DS, Sato VN, et al. Diagnosis of Achilles Insertional Tendinopathies by Algometry. *Pain Med* [Internet]. 2021 Nov 1 [cited 2024 Apr 24];22(11):2670–5. Available from: <https://pubmed.ncbi.nlm.nih.gov/34387348/>
9. Kvist M. Achilles tendon injuries in athletes. *Sports Med* [Internet]. 1994 [cited 2024 Apr 24];18(3):173–201. Available from: <https://pubmed.ncbi.nlm.nih.gov/7809555/>
10. Chen W, Cloosterman KLA, Bierma-Zeinstra SMA, van Middelkoop M, de Vos RJ. Epidemiology of insertional and midportion Achilles tendinopathy in runners: A prospective cohort study. *J Sport Health Sci*. 2024 Mar 1;13(2):256–63.
11. Maffulli N, Saxena A, Wagner E, Torre G. Achilles insertional tendinopathy: state of the art. *Journal of ISAKOS*. 2019 Jan 1;4(1):48–57.
12. Albers IS, Zwerver J, Diercks RL, Dekker JH, Van Den Akker-Scheek I. Incidence and prevalence of lower extremity tendinopathy in a Dutch general practice population: a cross sectional study. *BMC Musculoskelet Disord* [Internet]. 2016 Jan 13 [cited 2024 Apr 24];17(1). Available from: <https://pubmed.ncbi.nlm.nih.gov/26759254/>
13. Cook JL, Purdam C. Is compressive load a factor in the development of tendinopathy? *Br J Sports Med* [Internet]. 2012 Mar 1 [cited 2024 Apr 24];46(3):163–8. Available from: <https://bjsm.bmj.com/content/46/3/163>
14. Almekinders LC, Weinhold PS, Maffulli N. Compression etiology in tendinopathy. *Clin Sports Med* [Internet]. 2003 Oct 1 [cited 2024 Apr 24];22(4):703–10. Available from: <http://www.sportsmed.theclinics.com/article/S027859190300067X/fulltext>
15. Benjamin M, Moriggi B, Brenner E, Emery P, McGonagle D, Redman S. The “enthesis organ” concept: why enthesopathies may not present as focal insertional disorders. *Arthritis Rheum* [Internet]. 2004 Oct [cited 2024 Apr 24];50(10):3306–13. Available from: <https://pubmed.ncbi.nlm.nih.gov/15476254/>
16. Mechanobiology of tendon adaptation to compressive loading through fibrocartilaginous metaplasia - PubMed [Internet]. [cited 2024 Apr 24]. Available from: <https://pubmed.ncbi.nlm.nih.gov/10850819/>

17. Fahlström M, Jonsson P, Lorentzon R, Alfredson H. Chronic Achilles tendon pain treated with eccentric calf-muscle training. *Knee Surgery, Sports Traumatology, Arthroscopy* [Internet]. 2003 Aug 26 [cited 2024 Apr 24];11(5):327–33. Available from: <https://link.springer.com/article/10.1007/s00167-003-0418-z>
18. Jonsson P, Alfredson H, Sunding K, Fahlström M, Cook J. New regimen for eccentric calf-muscle training in patients with chronic insertional Achilles tendinopathy: results of a pilot study. *Br J Sports Med* [Internet]. 2008 Sep [cited 2024 Apr 24];42(9):746–9. Available from: <https://pubmed.ncbi.nlm.nih.gov/18184750/>
19. Cuschieri S. The CONSORT statement. *Saudi J Anaesth* [Internet]. 2019 Apr 1 [cited 2024 Apr 24];13(Suppl 1):S27. Available from: [/pmc/articles/PMC6398298/](https://pubmed.ncbi.nlm.nih.gov/32988930/)
20. Rabusin CL, Menz HB, McClelland JA, Evans AM, Malliaras P, Docking SI, et al. Efficacy of heel lifts versus calf muscle eccentric exercise for mid-portion Achilles tendinopathy (HEALTHY): a randomised trial. *Br J Sports Med* [Internet]. 2021 May 1 [cited 2024 Apr 24];55(9):486–92. Available from: <https://pubmed.ncbi.nlm.nih.gov/32988930/>
21. Robinson JM, Cook JL, Purdam C, Visentini PJ, Ross J, Maffulli N, et al. The VISA-A questionnaire: a valid and reliable index of the clinical severity of Achilles tendinopathy. *Br J Sports Med* [Internet]. 2001 [cited 2024 Apr 24];35(5):335. Available from: [/pmc/articles/PMC1724384/](https://pubmed.ncbi.nlm.nih.gov/11724384/)
22. McCormack J, Underwood F, Slaven E, Cappaert T. THE MINIMUM CLINICALLY IMPORTANT DIFFERENCE ON THE VISA-A AND LEFS FOR PATIENTS WITH INSERTIONAL ACHILLES TENDINOPATHY. *Int J Sports Phys Ther* [Internet]. 2015 Oct [cited 2024 Apr 24];10(5):639. Available from: [/pmc/articles/PMC4595917/](https://pubmed.ncbi.nlm.nih.gov/26595917/)
23. Vallance P, Hasani F, Crowley L, Malliaras P. Self-reported pain with single leg heel raise or single leg hop offer distinct information as measures of severity in men with midportion and insertional Achilles tendinopathy: An observational cross-sectional study. *Physical Therapy in Sport* [Internet]. 2021 Jan 1 [cited 2024 Apr 24];47:23–31. Available from: https://www.researchgate.net/publication/345203854_Self-reported_pain_with_single_leg_heel_raise_or_single_leg_hop_offer_distinct_information_as_measures_of_severity_in_men_with_midportion_and_insertional_Achilles_tendinopathy_An_observation_al_cross-
24. Lewis TL, Yip GCK, Robertson K, Groom WD, Francis R, Singh S, et al. Health-related quality of life in patients with Achilles tendinopathy: Comparison to the general population of the United Kingdom. *Foot Ankle Surg* [Internet]. 2022 Oct 1 [cited 2024 Apr 24];28(7):1064–8. Available from: <https://pubmed.ncbi.nlm.nih.gov/35279393/>
25. Mansur NSB, Matsunaga FT, Carrazzone OL, Schiefer Dos Santos B, Nunes CG, Aoyama BT, et al. Shockwave Therapy Plus Eccentric Exercises Versus Isolated Eccentric Exercises for Achilles Insertional Tendinopathy: A Double-Blinded Randomized Clinical Trial. *Journal of Bone and Joint Surgery*. 2021 Jul 21;103(14):1295–302.
26. Ko VMC, He X, Fu SC, Yung PSH, Ling SKK. Clinical effectiveness of pulsed electromagnetic field therapy as an adjunct treatment to eccentric exercise for Achilles tendinopathy: a randomised controlled trial. *Trials* [Internet]. 2023 Dec 1 [cited 2024 Apr 24];24(1). Available from: <https://pubmed.ncbi.nlm.nih.gov/37308969/>
27. Hébert-Losier K, Wessman C, Alricsson M, Svantesson U. Updated reliability and normative values for the standing heel-rise test in healthy adults. *Physiotherapy* [Internet]. 2017 Dec 1 [cited 2024 Apr 24];103(4):446–52. Available from: <https://pubmed.ncbi.nlm.nih.gov/28886865/>
28. Van Oosten CCM, Van Der Vlist AC, Van Veldhoven PLJ, Van Oosterom RF, Verhaar JAN, De Vos RJ. Do High-Volume Injections Affect the Ultrasonographic Neovascularization in Chronic Achilles Tendinopathy? A Randomized Placebo-Controlled Clinical Trial. *Clin J Sport Med* [Internet]. 2022 Sep 1 [cited 2024 Apr 24];32(5):451–7. Available from: <https://pubmed.ncbi.nlm.nih.gov/36083324/>

29. De Vos RJ, Weir A, Van Schie HTM, Bierma-Zeinstra SMA, Verhaar JAN, Weinans H, et al. Platelet-rich plasma injection for chronic Achilles tendinopathy: a randomized controlled trial. JAMA [Internet]. 2010 Jan 13 [cited 2024 Apr 24];303(2):144–9. Available from: <https://pubmed.ncbi.nlm.nih.gov/20068208/>
30. Breda SJ, Oei EHG, Zwerver J, Visser E, Waarsing E, Krestin GP, et al. Effectiveness of progressive tendon-loading exercise therapy in patients with patellar tendinopathy: a randomised clinical trial. Br J Sports Med [Internet]. 2021 May 1 [cited 2024 Apr 24];55(9):501–9. Available from: <https://pubmed.ncbi.nlm.nih.gov/33219115/>
31. Murphy M, Rio E, Debenham J, Docking S, Travers M, Gibson W. EVALUATING THE PROGRESS OF MID-PORTION ACHILLES TENDINOPATHY DURING REHABILITATION: A REVIEW OF OUTCOME MEASURES FOR MUSCLE STRUCTURE AND FUNCTION, TENDON STRUCTURE, AND NEURAL AND PAIN ASSOCIATED MECHANISMS. Int J Sports Phys Ther [Internet]. 2018 Jun [cited 2024 Apr 24];13(3):537. Available from: <https://pubmed.ncbi.nlm.nih.gov/30444591/>
32. Rompe JD, Furia J, Maffulli N. Eccentric loading compared with shock wave treatment for chronic insertional achilles tendinopathy. A randomized, controlled trial. J Bone Joint Surg Am [Internet]. 2008 [cited 2024 Apr 24];90(1):52–61. Available from: <https://pubmed.ncbi.nlm.nih.gov/18171957/>
33. Beyer R, Kongsgaard M, Hougs Kjær B, Øhlenschläger T, Kjær M, Magnusson SP. Heavy Slow Resistance Versus Eccentric Training as Treatment for Achilles Tendinopathy: A Randomized Controlled Trial. Am J Sports Med [Internet]. 2015 Jul 3 [cited 2024 May 15];43(7):1704–11. Available from: <https://pubmed.ncbi.nlm.nih.gov/26018970/>
34. Lalumiere M, Perrino S, Nadeau MJ, Larivière C, Lamontagne M, Desmeules F, et al. To What Extent Do Musculoskeletal Ultrasound Biomarkers Relate to Pain, Flexibility, Strength, and Function in Individuals With Chronic Symptomatic Achilles Tendinopathy? Frontiers in rehabilitation sciences [Internet]. 2021 [cited 2024 May 15];2. Available from: <https://pubmed.ncbi.nlm.nih.gov/36188777/>
35. Chen J, Xu J, Zhao L, Zhang J, Yin Y, Zhang F. The effect of electronic monitoring combined with weekly feedback and reminders on adherence to inhaled corticosteroids in infants and younger children with asthma: a randomized controlled trial. Allergy Asthma Clin Immunol [Internet]. 2020 Jul 29 [cited 2024 May 15];16(1). Available from: <https://pubmed.ncbi.nlm.nih.gov/32922454/>
36. Alghamdi NH, Pohlig RT, Seymore KD, Sions JM, Crenshaw JR, Grävare Silbernagel K. Immediate and Short-Term Effects of In-Shoe Heel-Lift Orthoses on Clinical and Biomechanical Outcomes in Patients With Insertional Achilles Tendinopathy. Orthop J Sports Med [Internet]. 2024 Feb 1 [cited 2024 May 15];12(2). Available from: <https://pubmed.ncbi.nlm.nih.gov/38332846/>

POPULARISING SUMMARY (DUTCH)

Achillespeesstendinopathie of -ontsteking is een veelvoorkomend probleem dat voornamelijk de actieve hardlooppopulatie treft. Deze blessure kan onderverdeeld worden in twee types: de 'midportionele' en 'insertionele' achillespees tendinopathie (IAT). Bijna 30% van de patiënten heeft de insertionele vorm, waarbij de ontsteking optreedt ter hoogte van de aanhechting aan het hielbeen. Deze blessure kenmerkt zich door hielpijn, zwelling, ochtendstijfheid en verminderde functie. De symptomen kunnen uiteindelijk activiteit belemmeren tot de pijn zelfs in rust optreedt.

Uit eerder onderzoek is gebleken dat insertionele achillespeesklachten slechts weinig verbetering kennen via een traditionele peesbehandeling. In studies werd later aangetoond dat compressie van de pees tegen het hielbeen een belangrijke component is in de ontwikkeling en instandhouding van een IAT. Het reduceren van deze compressie kan bijgevolg een effectieve aanpak zijn. Compressie ter hoogte van de pees ontstaat wanneer men met de voorvoet op een traprede staat en de hiel laat zakken tot onder de horizontale.

Deze klinische studie omvatte uitsluitend patiënten met een IAT. Zij werden verdeeld in twee groepen: de controlegroep (HTCR; high tendon compression rehabilitation) en de experimentele groep (LTCR; low tendon compression rehabilitation). Beide groepen ontvingen een 12 weken durend progressief oefenprogramma. De controlegroep ontving de conventionele behandeling met oefentherapie, stretching en diepe dwarse fricties op de pees. De experimentele groep kreeg daarentegen enkele aanpassingen; oefeningen met steeds een minimale compressie op de achillespees, massage van de kuit en zooltjes om de hielen op te hogen in het dagelijks leven.

De resultaten laten zien dat de patiënten die de compressie-reducerende behandeling ontvingen significant minder pijn rapporteren en een beter herstel ervaren in vergelijking met de conventionele benadering. Significant meer individuen waren in staat om hun gewenste sport al dan niet weer op het oude niveau te beoefenen samengaand met een grotere tevredenheid over de gehele therapie. Bovendien toonde beeldvorming aan dat structurele veranderingen in de pees gunstiger waren in de experimentele groep. Dit betekent dat niet alleen de symptomen werden verlicht, maar dat ook de pees zelf gezonder werd.

Uit ons onderzoek kunnen we dus vaststellen dat deze vernieuwde therapie efficiënter is in de behandeling van een IAT en dus als nieuwe standaardtherapie kan gebruikt worden.

SOCIETAL VALUE AND IMPACT (DUTCH)

Deze bevindingen zijn van grote waarde voor zowel de medische wereld als de patiëntenpopulatie:

(1) Betere levenskwaliteit: Dit onderzoek biedt een effectievere behandelmogelijkheid voor een blessure die vaak moeilijker te behandelen is. Mensen kunnen vaker hun activiteiten hervatten, ongeacht of het gaat om sport, werk of dagelijkse activiteiten, wat zorgt voor een betere kwaliteit van leven en welzijn. Uit het onderzoek bleek dat patiënten die de experimentele behandeling ondergingen, vaker hun gewenste sport terug konden beoefenen, al dan niet op het oorspronkelijke niveau. Bovendien toonde de experimentele groep in het onderzoek een grotere tevredenheid over de therapie en het behaalde resultaat.

(2) Vermindering van zorgkosten: Naarmate patiënten een effectievere behandeling krijgen, zal het aantal behandelingen afnemen aangezien patiënten beter herstellen. Patiënten hoeven minder lang te revalideren, waardoor de druk op de gezondheidszorg afneemt. Tegelijkertijd zullen de medische kosten die gepaard gaan met het aantal behandelingen dalen. De vernieuwde behandeling heeft dus economische voordelen voor zowel individuen als gezondheidszorgsystemen.

(3) Preventieve voordelen: Deze bevindingen dragen bij aan de preventie van insertionele achillespeesklachten. Door meer aandacht te besteden aan biomechanica en de rol van compressie kunnen sporters preventieve maatregelen nemen om overbelastingsblessures te voorkomen. Verdere educatie over dit gegeven zal resulteren in een afname van het aantal insertionele achillespees ontstekingen.

Kortom, het reduceren van compressie tijdens de behandeling van insertionele achillespees tendinopathie komt niet alleen ten goede aan individuen met deze blessure, maar heeft ook een aanzienlijke maatschappelijke meerwaarde door het verbeteren van herstel, het verminderen van zorgkosten en het bevorderen van preventie.

Effectiviteit van het reduceren van peescompressie bij de behandeling van insertionele achillespees tendinopathie

INSERTIONELE ACHILLESPEES TENDINOPATHIE

= ontsteking van de achillespees ter hoogte van de
aanhechting op het hielbeen

SYMPTOMEN:

zwelling
pijn
ochtendstijfheid
verminderde functie



ONDERZOEK

- Patiënten met insertionele achillespees tendinopathie
- Experimentele (LTCR) en controle (HTCR) groep
- Oefenprogramma gedurende 12 weken volgens PTLET (progressive tendon loading exercise therapy)
- Randomized controlled clinical trial

LTCR (low tendon compression rehabilitation)

- Educatie
- Heel-inserts
- Myofasciale therapie m. triceps surae
- PTLET met gelimiteerde dorsiflexie

HTCR (high tendon compression rehabilitation)

- Educatie
- Diepe dwarse fricties achillespees
- Stretching m. Triceps surae
- PTLET met minstens 15° dorsiflexie

RESULTATEN

Significante verbetering LTCR

- minder pijn en verbeterde functionaliteit (VISA-A)
- hogere tevredenheid
- hogere return to sport



MAATSCHAPPELIJKE MEERWAARDE/ IMPACT:

- Betere levenskwaliteit
- Vermindering van zorgkosten
- Preventieve voordelen



PROOF OF SUBMISSION TO THE ETHICS COMMITTEE

Referentienummer. BC-11818

Studie overzicht. Titel onderzoek: De rol van peescompressie bij de behandeling van een insertionele achilles tendinopathie: een gerandomiseerde klinische studie
Protocolcode:
Hoofdonderzoeker: Luc Vanden Bossche
Opdrachtgever: UZ Gent

Fase Study ongoing, enrollment

Status HIRUZ/EC Advies CME gegeven

Status FAGG/CT college Niet van toepassing

Status FANC Niet van toepassing

OPGELET! Via onderstaande link zal u **na de goedkeuring** de status van het verloop van de studie kunnen bijhouden.
Volgende meldingen dienen verplicht via deze link te gebeuren:
- de start van de rekrutering
- de eerste inclusie
- het einde van de studie
- het indienen van de studieresultaten

Link naar opvolgen studie nadat alle goedkeuringen gegeven zijn: Opvolging studie na goedkeuring

Advies CME goedgekeurd

Datum advies CME 2022-06-16

EC nummer (indien van toepassing):

EU referentienummer (indien van toepassing):

BC nummer (indien van toepassing): BC-11818

EUDAMED nummer (indien van toepassing):

Studenten

 Naam

Emile Callebaut (emile.callebaut@ugent.be)

Florian Aelvoet (florian.aelvoet@ugent.be)

Hanne Roos De Wilde (hanne.dewilde@ugent.be)

Lena De Schampheleere (lena.deschampheleere@ugent.be)

Milan Anckaert (milan.ankaert@ugent.be)

Robbe Capelleman (robbe.capelleman@ugent.be)

APPENDIX

Stage	Subphase	Exercises LTCR	Exercises HTCR
Warming-up		Circulatory ankle DF & PF	Circulatory ankle DF & PF
Myofascial therapy		Calf muscle release – massage ball	Achilles tendon release – massage ball
1: isometrics	Low	Isometric wall press – mG Isometric PF – mG Isometric wall press – mS Isometric PF – mS	Isometric wall press – mG Isometric PF – mG Isometric wall press – mS Isometric PF – mS
	Moderate	Isometric heel raise – mG Isometric seated heel raise Isometric heel raise wall seated	Isometric heel raise – mG Isometric seated heel raise Isometric heel raise – mS
	High	Isometric unipodal heel raise – mG Isometric unipodal heel raise – mS Isometric unipodal seated heel raise	Isometric unipodal heel raise – mG Isometric unipodal heel raise – mS Isometric unipodal seated heel raise
2: strength	Low	Dynamic PF – mG Dynamic PF – mS Seated heel raise	Dynamic plantar flexion – mG Dynamic plantar flexion – mS Seated heel raise
	Moderate	Heel raise – mG Heel raise – mS Unipodal seated heel raise	Heel raise – mG heel raise – mS Unipodal seated heel raise – mS
	High	Unipodal heel raise – mG Unipodal heel raise – mS Lunge hold soleus raise	Unipodal heel raise – mG Unipodal heel raise – mS Lunge hold soleus raise – mS
3: ESR	Low	Plyometric heel raise – mG Plyometric heel raise – mS Continuous vertical jumps	Plyometric heel raise – mG Plyometric heel raise – mS Continuous vertical jumps
	Moderate	Double exchange Linear load & lift Continuous lateral jumps	Double exchange Linear load & lift Continuous lateral jumps
	High	Split jump lunge Single leg rope-skipping Lateral hops outside	Split jump lunge Single leg rope-skipping Lateral hops outside
4: RTS	Low	Running 10' – moderate speed Bilateral cutting manoeuvre V-run + jumping	Running 10' – moderate speed Bilateral cutting manoeuvre V-run + jumping
	Moderate	Running 15' – moderate speed Unilateral cutting manoeuvre V-run + jumping	Running 15' – moderate speed Unilateral cutting manoeuvre V-run + jumping
	High	Running 15' – intense speed Unilateral cutting manoeuvre V-run + jumping	Running 15' – intense speed Unilateral cutting manoeuvre V-run + jumping
Cooling-down		Circulatory ankle DF & PF	Circulatory ankle DF & PF Seated Gastrocnemius stretch Standing Gastrocnemius stretch

			Seated Soleus stretch Standing Soleus stretch
--	--	--	--

Appendix 1: Exercise programme

Gastrocnemius muscle (mG), Soleus muscle (mS), plantarflexion (PF)