Comparison of a patient-specific, gradually progressive exercise program guided by clinical parameters with an eccentric exercise program in people with chronic mid portion achillestendinopathy;

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Our aim is to investigate whether our TendoMáx program (gardually increasing loading program, guided by clinical parameters) is more effective in reducing pain and improving function than an eccentric exercise program in patients with a chronic mid-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON42918

Source
ToetsingOnline

Brief title
Comparison of 2 exercise programs in mid portion achillestendinopathy

Condition

- Tendon, ligament and cartilage disorders

Synonym
Achillestendinitis, overuse of the Achillestendon

Research involving

Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: n.v.t.

Intervention

Keyword: Achillestendinopathy, Exercise therapy, Functional outcome, Pain

Outcome measures

Primary outcome

Difference in function (VISA-A) between the 2 exercise programs at 16 weeks compared to baseline

Secondary outcome

1) Function (VISA-A) at week 4, 8 and 12 compared to baseline

2) Pain (NPRS average, best, worst, functional test) after 16 weeks compared to baseline

3) Pain (NPRS) during the isometric exercises vs eccentric exercises

3) Pain (NPRS) alteration just before and after the exercise therapy during the first 4 weeks

4) Patiënt satisfaction (GPE) at 16 weeks

5) Compliance (%) during the exercise program (16 weeks)

6) Function (VISA-A) at the long term; at week 24, 36 and 52 compared to baseline

7) Pain (NPRS) at the long term; at week 24, 36 and 52 compared to baseline

Study description

Background summary

The department of sports medicine at the Maxima Medical Centre has special consulting hours focussing on Achilles tendon complaints. We see around 100 patients a year with an overuse injury of the Achillest endon (Achillestendinopathy).
This is a common, often chronic injury in a heterogeneous patientgroup. Achillestendinopathy is a clinical diagnosis based on the presence of the triad of pain, swelling en decreased load capacity.

The injury is very common amongst runners and jumping athletes, but around 1/3 of the patients has a sedentary lifestyle (Longo 2009). Besides the heterogenity of the population, the injury is also very heterogeneous.
The insertion and the mid-portion tendinopathy are considered as separate entities, where the tendinopathy progresses in different stages (a continuum), from reactive to failed healing and eventually degeneration (Cook & Purdam 2009).
This heterogenity makes the applying of the correct treatment a big challenge.

Remedial therapy is seen as the cornerstone of the treatment, where the excentric programme of Alfredson (1998) is the best known. This form of remedial therapy proved effective during several scientific studies, with a decrease of pain (decrease of VAS score of 4- 94%) and an increase of function (increase of VISA-A-score of 37-111%) (Habets 2015). The long-term effects are also reasonably good. An increase of 52% VISA A after one year has been described (de Jonge 2008) as well as a decrease of pain with 42 % (Roos 2003). The national guideline of the Sports Medicine Association advises therefore to start with an excentric programme. However, the excentric remedial therapy does not work for 24-45% (Alfredson & Lorentzon 2000, Longo 2009). The number of non-responders is probably higher in non-athletes, than in athletes (Savana 2007).

During TendoMax consulting hours we often see patients with longterm complaints and with whom the excentric remedial therapy didn't work (long-term). We therefore (by necessity) developed our own multimodal programme, with the general principle of adjusting the load to the load capacity. For this, we use our own TendoMax exercise programme and load management. Additional, we add some co-interventions (if indicated) : improving the bio-mechanics (shoe advice and eventually fitting assesment for shoe soles), improving the functional stability, eliminating moving disorders through manual therapy/medicine, prolotherapy (injections with a glucose solution) or the prescription of NSAID's (Ibuprofen) and in exceptional cases Extracorporeal ShockWave Therapy.

Because a lot of people have already tried excentric exercise therapy when

consulting the TendoMax consulting hours, we found it necessary to optimize the exercise therapy. We saw possibilities because theoretically, some observations can be made on the exercise therapy according to Alfredson; It is not adjusted to the individual patient (concerning load capacity and sporting history/wish). There is virtually no trainingsregime in terms of frequency and intensity; with no adjusting by means of clinical parameters. This is not patient-friendly, the exercises are for most patients too painful and too heavy. Also, this way of exercise therapy is in practice difficult to combine with the "rules" of loadregulating (loadmanagement; load based on complaints, max. NPRS 4/10). Possibly because of this the therapy compliance might also not be optimal. In the reference literature the excentric remedial therapy compliance varies from 72% (>50% therapy compliance) (de Vos 2007) to only 27-50% with a therapy compliance of > 75% (Yelland 2011, Roos 2004). Especially these aspects have been integrated into the TendoMax remedial programme, based on basal trainingfysiological principles (supercompensation, dosed overload, individual variability, reversibility) best practices and recent literature. It has a progressive build-up, where the in- and outflowlevel are adapted to (load capacity of) the patient. Guiding here are the clinical parameters (pain and after response), that might possibly make the remedial therapy a less painful/heavy experience and can be better combined with load management, hopefully leading to a higher therapy compliance.
In addition we offer several excercises (adjusted to the patient and the phase of the complaints), in order to train multiple properties of the tendon. With this we hope to get better results in the long run.
A standard treatment duration with this programma can't be determined, because it depends on the actual and desired load capacity of the Achilles tendon of the patient. The scientific literature that supports our remedial practice programme, relates particularly to literature on patellar tendinopathy. So it seems that the isometric exercise appears to be antalgic (Rio 2014, v. Ark 2014, Naugle 2012) and the heavy slow resistance training (concentric/excentric) shows in the short as well as in the long term an improvement of the clinical parameters (pain and function) and leads to a good patient satisfaction (Kongsgaard 2010). Silbernagel(2001) showed that combined concentric/excentric excercises lead to clinical improvement with the Achillestendinopathy.
A systematic review (Habets & van Cingel 2014) clarified that excentric therapy, but also other forms of remedial therapy, are effective, but there have been few studies into the optimal meaning of remedial therapy within the treatment of Achillestendinopathy.
We now have approximately 2 years of experience with our own remedial therapy programme and earlier (unpublished) research (N=51) showed a statistical significant increase of the VISA-A of 65 % (46,0 (+/- 19,2) to 75,7 (+/- 18,8)) and a decrease of the NPRS of 52 % (4,8 (+/- 2.1) to 2,3 (+/- 1,5)) after 16 weeks. Therefore in this research we would like to compare it directly with the excentric therapy of Alfredson.

Study objective

Our aim is to investigate whether our TendoMáx program (gardually increasing loading program, guided by clinical parameters) is more effective in reducing pain and improving function than an eccentric exercise program in patients with a chronic mid-portion Achilles tendinopathy.

Study design

Design: Randomized controlled trial
Setting: TendoMáx, outpatient clinic for Achilles tendon injuries. Single centre study.
Open study, blinding for evaluation.
Inclusion: 21-11-2016 en 21-11-2018.
Sample size: 62 patients.
Outcome measurements: AAS* , NPRS**, VISA-A***, patient satisfaction, compliance (%)

* AAS score: Ankle Activity Score; A score based on level and type of sport.
** NPRS : Numeractic Pain Rating Scale. We use the NPRS for measuring the pain just before and just after performing the exercises (in the first 4 weeks); but we also use an average NPRS for the whole week, a score for the best en worst moment during the week and a NPRS during a functional test.
*** VISA A: Victorian Institution Sports Assessment Achilles Questionnaire: a valid measurement instrument for measuring Achilles tendon function

Intervention

Eccentric exercise program:
Load progression is based on time, pain is not a restriction for exercise therapy.

Phase 1: Strengthening. Heel drop with extended en bent knee. Starting with 2d 3x10 rep's (double leg) building up to 2d 3x13 rep's (single leg)
Phase 2: Strenghtening; Heel drop with extended en bent knee. Starting with 2d 3x15hh (single leg) and building up to extra weights (until 15kg)
Phase 3: Return to sport; If no complaints remained = return to sport. Decreased complaints: gradually returning to sport, starting with increasing exposure time and intensity during training and thereafter during a match.

TendoMáx exercise program:

load progression is guided by clinical parameters (pain and morning stiffness)

Phase 1: Decreasing reactivity; Isometric heel raise, building up from 3d 3x30s (doule leg) to 3d 3x45s (single leg)
Phase 2; Strength; Concentric heel raise/Excentrisch heel drop with extended and bent knee. Building up from 2d 4x6rep's (double leg) to 2d 4x6 rep's + extra weight up to 20% of body weight (sinlge leg). Moreover, a progressive walking schedule is started.
Phase 3: Sportspecific exercises and building up maximal strength. Heel drop starting with 1d3x15 rep's with 15RM- value to 1d3x 4rep's with 4RM- value. Moreover, a progressive running schedule is started.
Phase 4: Gradually returning to sport, starting with increasing frequence, exposure time and intensity during training and thereafter during a match.

Study burden and risks

Participants have to abide the exercise program.
Moreover participants should fill out online questionnaires;
- intake meeting: AAS, NPRS average, VISA-A
- week 1 t/m 4 (per e-mail, weekly): NPRS average, NPRS just before and after exercises, compliance
- week 4 (per e-mailby phone): VISA A
- week 8 (appointment tendomax/per e-mail): VISA- A, compliance (week 5 t/m 8)
- week 12 (per e-mailby phone): VISA- A , compliance (week 9 t/m 12)
- week 16 (appointment tendomax)per e-mail): VISA-A, compliance (week 813 t/m 16), NPRS average, patient satisfaction
- week 24, 36 en 52 (by phoneper e-mail): VISA-A, NPRS average

Extra time investment:
- 10 times an online questionnaire per e-mail phone call (15-510 minutes) for data collection
- 1 time an appointment with the investigator after the consultation at TendoMax, (15 minutes); informing about study, randomisation and filling out the questionnaires and procedure considering these questionnaires (15 minutes)

The only risk is a temporary increase in complaints. There is no risk of complications or significant side-effects.

Contacts

Public
Maxima Medisch Centrum

De Run 4600

Veldhoven 5500 MB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5500 MB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age* 18 jaar;
clinical diagnosis (pain, swelling, decreased function) of midportion achillestendinopathy (2-7 cm proximal to the insertion at the calcaneus);
complaints for 3 months or more.

Exclusion criteria

Insertional tendinopathy of the achillespees;
not able to perform *heavy-load* excentric exercises;
Clinical suspicion of an acute (partial) rupture of the achilles tendon;
Previous surgical treatment of the Achilles tendon;
(Systemic) disease, that influence the prognosis and recovery (Diabetes Mellitus, Reumatoïd Disease, Artritis, OsteoArtritis of the knee/ankle/foot, lower leg or ankle injury).
Wash out period 6 weken (temporary exclusion)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2016
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO Date:	05-08-2016
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	13-12-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL57711.015.16