Comparison of two different exercise programs in mid-portion Achilles tendinopathy: a randomized trial.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20566

Source
NTR

Brief title
ASET-study

Health condition

Achilles tendinopathy
Exercise therapy
Treatment

Achilles tendinopathie
Oefentherapie
Behandeling

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Sport Medisch Centrum Papendal
Source(s) of monetary or material Support: University Medical Center Utrecht
Sport Medisch Centrum Papendal

Intervention

Outcome measures

Primary outcome

- Victorian Institute of Sports Assessment - Achilles (VISA-A) questionnaire

- Visual Analog Scale (VAS) for pain during sports activities

Secondary outcome

- VAS for pain during activities of daily life

- Morning stiffness

- Quality of life (EQ5D, SF-12)

- Perceived recovery

- Jumping height

- Plantar flexor endurance

- Variables related to cost-effectiveness

Study description

Background summary

Background:
Mid-portion Achilles tendinopathy (AT) is a common overuse injury of the lower extremity, often challenging for patients and therapists. Exercise therapy (i.e. tendon loading) is considered crucial in conservative management, but the most effective exercise program is unknown. Alfredson's eccentric program and Silbernagel's concentric-eccentric program have both shown beneficial results in the treatment of AT, but it is unknown whether any program is superior for use in clinical practice.

Objective:
To investigate the difference in effectiveness between the Alfredson eccentric and the Silbernagel concentric-eccentric exercise program on patient-reported function and pain

during sports in patients with chronic mid-portion AT after 12 weeks.

Study design:
Prospective multicenter single blind randomized controlled trial.

Study population:
A total of 86 recreational male athletes (18-60 years of age) with a clinical diagnosis of unilateral Achilles tendinopathy will be included.

Intervention:
Two exercise programs will be compared. The first is the Alfredson eccentric exercise program, in which participants perform eccentric heel-drops on their injured leg, twice daily, for three sets of 15 repetitions, and both with a straight and bent knee (i.e. 180 repetitions per day). The other program is the Silbernagel concentric-eccentric program, in which participants perform various 2-legged and 1-legged heel-raising exercises, for three sets of 15 repetitions, but in this program exercises are only performed once daily.

Main study parameters/endpoints:
The primary outcome measures for this study will be patient-reported function in daily activities and sport (measured with the Dutch version of the Victorian Institute of Sport Assessment – Achilles questionnaire) and pain during sports activities (measured with a visual analog scale) after 12 weeks.

Study objective

It is hypothesized that the Silbernagel exercise program yields at least similar results in terms of symptom reduction (VISA-A score and VAS score)compared with the Alfredson eccentric exercise program.

Study design

Baseline, 12 weeks, 6 months, and 12 months.

Intervention

Two different loading programs for the plantar flexor muscle-tendon unit; i.e. isolated eccentric loading according to the Alfredson program, or a combination of concentric and eccemtric loading according to the Silbernagel program.

Contacts

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Eligibility criteria

Inclusion criteria

- Clinical diagnosis of unilateral mid-portion Achilles tendinopathy (Achilles tendon pain and swelling 2-7 cm from calcaneal insertion);

- Duration of symptoms at least three months;

- Age 18-60 years of age;

- Participating in sport involving Achilles tendon loading (i.e. running and/or jumping);

- Able to comply with both exercise programs.

Exclusion criteria

- Bilateral symptoms;

- Diagnosis of insertional Achilles tendinopathy (insertion of Achilles tendon onto posterior

aspect of the calcaneus);

- Washout period of < four weeks from other treatments;

- Corticosteroid injections in the region of the Achilles tendon in the previous 12 months;

- Other lower limb injuries in previous 12 months;

- Previous surgery in the affected limb;

- History of Achilles tendon rupture in affected limb;

- Systemic diseases, such as rheumatoid arthritis and diabetes mellitus.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	86
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47905
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5503
NTR-old	NTR5638
CCMO	NL56035.041.15
OMON	NL-OMON47905

Study results