Alfredson versus Silbernagel exercise therapy in chronic mid-portion Achilles tendinopathy: a randomized controlled trial

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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.

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

Summary

ID

NL-OMON47905

Source
ToetsingOnline

Brief title
ASET study

Condition

- Tendon, ligament and cartilage disorders

Synonym
Achilles tendinopathy; achilles tendinitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Achilles tendinopathy, Exercise therapy, Rehabilitation, Training

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome measures will be pain during daily activities, morning stiffness, perceived recovery, quality of life, and functional outcome measures (jumping height and plantar flexor endurance). Furthermore, differences in primary and secondary outcome measures in the mid-term and long term will be investigated, and the association between baseline variables and level of improvement will be investagated. Finally, a cost-effectiveness analysis between both exercise programs will be conducted.

Study description

Background summary

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.

Study 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

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.

Study burden and risks

There are no known risk factors for participation in this study, and research has demonstrated no adverse effects for (eccentric) training in AT. Participants will be assessed at baseline, 12 weeks, and at 6 and 12 months. At baseline, several demographic and anthropometric data will be collected. Baseline and follow-up assessment comprises several questionnaires on patient-reported function, pain, morning stiffness, perceived recovery, and quality of life. Furthermore, several physical tests will be performed: a countermovement jump to investigate jumping height, a heel-raise test to evaluate plantar flexor endurance, and isometric strength measurements of the hip abductors, extensors, and external rotators. Participants are asked to keep their exercise compliance during the intervention period in a diary, and data on injury-related medical costs will be collected though a questionnaire at follow-up assessments (cost-effectiveness).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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 18-65 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 in the previous 12 months;
- 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
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2016
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO Date:	10-08-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-10-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	04-04-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20566
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL56035.041.15
OMON	NL-OMON20566