Effectiveness of a 12-week self-myofascial release therapy on pain and tendon stiffness in active recreational runners with self-reported Achilles tendon complaints

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The purpose of this study will be to evaluate and compare the effectiveness of a multifocal SMR treatment on pain and stiffness compared to ECC in active recreational runners with self-reported Achilles tendon complaints.Research question: Is a 12-...

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

Summary

ID

NL-OMON44629

Source
ToetsingOnline

Brief title
SMR in active recreational runners with achilles tendon complaints

Condition

- Tendon, ligament and cartilage disorders

Synonym
Achilles tendon complaints (pain, stiffness)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: achilles tendon, ECC, foamrolling, self-myofascial release

Outcome measures

Primary outcome

The following primary outcomes will be assessed at baseline and post-treatment

(12 weeks after baseline).

- VISA-A score

- Mechanical pain threshold

- Self-perceived clinical progress (GROC)

VISA-A and GROC will also be assessed every week throughout the study.

Secondary outcome

A web-based log will be developed in order to collect data on:

- running exposure (hours/week, km/week, and times/week);

- level of pain during running assessed with an 11-point NRS (0 to 10);

- adherence to the assigned treatment (SMR or ECC); and

- competing interventions (performance of other interventions alongside with

the assigned treatment including medication).

Data on these secondary outcomes will be collected every week throughout the

study (12 weeks).

Study description

Background summary

Running is a popular sports activity that triggers a variety of health benefits (Hespanhol Junior et al. 2015; Lee et al. 2014; Chakravarty et al. 2008). Although outweighing the risks in most cases, its positive effects are compromised by the burden stemming from running-related injuries (RRI). The incidence of RRIs in recreational runners is about 7.7 RRIs per 1,000 hours of running (Videbaek et al. 2015). Achilles tendinopathy (AT), is one of the most common disorders among professional and recreational runners (Kujala et al. 2005; Lopes et al. 2012), accounting for about 9% to 15% of all RRIs in Dutch runners (Hespanhol Junior et al. 2016; Hespanhol Junior, van Mechelen and Verhagen 2016). It is thought to develop due to overuse with several other risk factors, and brings with it a risk of becoming chronic (Järvinen et al. 2005.). Symptoms consist of pain, morning stiffness and tenderness to palpation, while at least one of the symptoms has to have been apparent for at least 3 months (Kraemer et al. 2012.). There seems to be a pathological continuum from a healthy Achilles tendon to AT (Kraemer et al. 2012), which in turn represents a risk factor for tendon rupture (Järvinen et al. 2005). This suggests that by treating complaints such as pain or stiffness of the Achilles tendon as early as possible, the progression into chronic symptoms and further degeneration could possibly be prevented.

A plethora of non-pharmaceutical treatments mainly targeting the Achilles tendon and the calf muscles have been proposed to ease the symptoms. Anatomically, the Achilles tendon does not only fuse with the calf muscles but also displays a fibrous continuity to the plantar aponeurosis (Wilke et al. 2016a). Albeit not necessarily linked to the pathology, the finding of a thickened plantar aponeurosis in patients with Achilles tendinopathy underpins this paradigm (Stecco et al. 2013). A lot of times the same treatments that have shown to be effective for mid portion Achilles tendinopathy are prescribed for insertional Achilles tendinopathy. This is being done despite lack of prove that it is effective for this specific origin of the problem. It is known that aetiology, injury mechanism, treatment and rehabilitation differ between the two pathologies (Wiegerinck et al. 2013). This implies that multifocal approaches might open new frontiers. Tackling dysfunctions of aponeurosis, tendon, and calf muscles might hence be more effective than interventions limited to one structure only. Furthermore, if effective, they could prove more practical to prescribe in case of lack of clarity about the exact origin

of the complaints, or in case of more than one origins of symptoms in the same Achilles tendon.

Eccentric exercise (ECC) has proven to represent an effective and safe conservative treatment for Achilles tendinopathy (Malliaras et al. 2013; Alfredson and Lorentzon 2000). One of the main advantages of this method is that patients can be instructed by a physiotherapist or exercise therapist to perform the exercises without supervision (Rompe, Furia and Maffulli 2009; Alfredson et al. 1998). However, as the exercises require muscular contraction, it is unable to directly target the plantar aponeurosis. Like ECC, self-myofascial release (SMR) can also be performed in a home-based setting. SMR claims to mimic the effects of manual therapy and might thus operate through similar mechanisms as ECC, which has been suggested to stimulate collagen I production and reverse pathological neovascularization (Ohberg and Alfredson 2004, Langberg et al. 2006). Moreover, although evidence is scarce so far, SMR has been described to loosen fascial adhesions and cross-links, increase the gliding capacities of connective tissue layers, decrease muscle tension and to alter mechanical stiffness. SMR does not impede athletic performance (Beardsley und ¦karabot 2015). It has also been suggested that SMR might have, as all manual therapies, a potentially pain-relieving effect. These analgesic effects may be mediated by either peripheral, spinal or supra-spinal mechanisms (Bialosky et al. 2009.). All of the above mentioned processes might help to restore physiological tendon function. We found only 3 studies examining the effect of SMR on the calves, none of which specifically target to measure the effect on pain and tendon stiffness after a period with regular interventions (Halperin et al. 2014, Healey et al. 2014, Peacock et al. 2015).

Study objective

The purpose of this study will be to evaluate and compare the effectiveness of a multifocal SMR treatment on pain and stiffness compared to ECC in active recreational runners with self-reported Achilles tendon complaints.

Research question: Is a 12-week multifocal SMR treatment more effective in treating self-reported Achilles tendon complaints than ECC in active recreational runners?

Study design

This study is designed as a two-armed, single-blind, randomised controlled trial that will be conducted in accordance with the declaration of Helsinki and adhering to the CONSORT guidelines. Each subject will provide informed consent before inclusion. After a baseline measurement of subjective complaints and mechanical pain threshold the included participants will be randomly allocated (1:1) to an intervention group (i.e., SMR) and an active control group (i.e., ECC). Randomization will be stratified based on average running exposure

(whether or not subjects run more or less than 5 hours per week). The outcome measures will be assessed again 12 weeks after baseline measurements. Additionally, running exposure, pain, adherence to the treatment, and competing interventions will be assessed every week throughout the 12-week treatment period through an online-log.

Intervention

All subjects will be instructed on how to perform the exercises by instructional videos and written protocols. The exercises (SMR or ECC) are to be carried out 7 days a week for 12 weeks, twice a day.

In the SMR group, the participants will use a foam roller and a foam ball to self-massage the plantar aponeurosis and the calf muscles twice a day for 90 seconds, respectively. In order to standardise the exerted pressure, a value of 6-7 for the on a numerical rating scale (NRS) ranging from 0 (no discomfort) to 10 (maximal discomfort) will be advised.

In the ECC group, the participants will perform an eccentric loading program based on Alfredson et al. 1998. The participants will be instructed to allow pain at the same amount as the SMR group during the sets.

Study burden and risks

The research will cost the participants time. They will come to the research location two times, each appointment will last for approximately 15 minutes. Furthermore, participants will follow a 12-week plan of exercises which will take approximately 15 minutes per day. In addition to that the participants will fill in an online questionnaire every week, which will in turn cost maximum 15 minutes each time.
The only risk associated with participation will be that half of the participants will not get one of the standard treatments (ECC) before the end of the study. Furthermore, participants are expected to get muscle aches during the first days of the trial and the exercises themselves can be painful. The measurement of the mechanical pain threshold can also cause discomfort at that moment. All these mentioned aches will last a short time and are of temporary character, ultimately leading to a decrease of the pain and discomfort cause by the achilles tendon complaints.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

active recreational runners older than 18 years, self-reported achilles tendon complaints (pain, stiffness)

Exclusion criteria

(1) presence of severe cardiovascular, neurologic, endocrine, psychiatric, or orthopaedic diseases (except Achilles tendinopathy); (2) simultaneous participation in other studies; (3) pregnancy or nursing period; (4) regular intake of analgesic drugs (5) symptoms to severe that they cause complete *inability to run*, (6) younger than 18 years of age.

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):	25-01-2018
Enrollment:	74
Type:	Actual

Medical products/devices used

Generic name:	foamroller
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL62376.029.17