FlyWheel Training (FWT) study: eccentric overload training on a flywheel ergometer versus standard excentric training for the treatment of patellar tendinopathy in athletes.

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The objective of this study is to evaluate if overload eccentric training on a flywheel ergometer, guided by a physiotherapist, is an appropriate training for athletes with patellar tendinopathy to reduce pain and a faster return to sport. The pain...

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

Summary

ID

NL-OMON39954

Source
ToetsingOnline

Brief title
Eccentric overload training for patellar tendinopathy.

Condition

- Tendon, ligament and cartilage disorders

Synonym
patellar tendinopathy; jumpers knee

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Fyzzio international bv,Sport Medisch Centrum JBZ;Nederlands Instituut voor de Opleiding tot Sportarts;CZ Fonds

Intervention

Keyword: Eccentric exercises, Flywheel Training, Patellar tendinopathy, RCT

Outcome measures

Primary outcome

The primary outcome measure is the validated dutch version of the Victorian Institute of Sports Assessment- Patellar (NL-VISA-P) questionnaire (Zwerver et al, 2009), which quantifies the pain and activity level. The NL-VISA-P score ranged from 0 to 100, where 0 denotes no activity and maximum pain and 100 denotes maximum activity and no pain. This is a validated questionnaire, specifically designed for evaluating outcome in Patellar tendinopathy. When there is pain in both knees the score for the most painful side is registered.

Secondary outcome

VAS (Visual Analogue scale for pain) at three functional tests: patient gives a number on a scale from 0-10 whereas 0= no pain and 10= terrible pain. We take this score after 10 times on a declineboard of 25 degrees, the triple hop test and the maximal jump test (Zwerver 2010)

Furthermore a log that keeps track of the degree of pain (VAS) after every training / match and the degree of pain the morning after exercise is filled out.

Study description

Background summary

Jumper's knee or patellar tendinopathy is an injury of the patellar tendon and is a common injury in sports, among elite and non-elite athletes. Despite of the high prevalence in athletes, there is still no effective treatment and return-to-sport is often many weeks or even months. Earlier research showed an overall prevalence among elite athlets of 14%, up to 45% and 32% in volleyball and basketball athletes (Liam et al, 2011). Among non-elite athletes there is an overall prevalence of 8,5%, up to 14% for volleyball playres (Zwerver, 2011). There is no effective treatment for patellar tendinopathy, no treatment brings the athlete back to previous sports level in an acceptable period of time (Zwerver 2011, Cook et al, 2001, Gaida et al, 2011).

At this moment, treatment consist of prolonged rehabilitation to restore the balance between capacity and load (Zwerver et al, 2008). Eccentric exercises are the main component of most treatment protocols.

Eccentric training could have a positive effect and improve clinical status and function in patients diagnosed with chronic tendinopathy. Eccentric muscle contraction is a contraction with lengthening of the muscle-tendon-complex. Squat exercises and exercises on a decline board, both forms of eccentric training, showed positive results in pain reduction and return to sport. Eccentric training by squat-exercises using a flywheel provides a reinforcement of the eccentric action, which is called an eccentric overload.

The flywheel is accelerated by the upward component of a squat (concentric action of the m. quadriceps). During the downward (eccentric) component of a squat the accelerated flywheel ensures a downward weight which is decelerated by the patient. This downward weight is proportional to the forces delivered by the patient during the upward component of a squat, even if this is greatly reduced due to tiredness, at the end of the exercise. In other words, the acceleration of the flywheel and subsequently the eccentric overload are determined by the concentric power delivered by the patient.

Eccentric training by using a flywheel showed in earlier research a higher EMG activity, with a muscle activation close to maximal in both the concentric and eccentric exercises. Beside this a hypertrophy of the quadriceps was measured after three weeks of overload eccentric training on a flywhel ergometer. Another study on the effect of eccentric training by using a leg-press flywheel ergometer on patients with patellar tendinopathy, showed a reduction of subjective pain after six weeks of training.

Our hypothesis is that overload eccentric training on a flyweel ergometer,

guided by a physiotherapist, is more effective in reducing pain and a faster return to sport versus standard eccentric training for athletes with patellar tendinopathy.

Study objective

The objective of this study is to evaluate if overload eccentric training on a flywheel ergometer, guided by a physiotherapist, is an appropriate training for athletes with patellar tendinopathy to reduce pain and a faster return to sport. The pain and exercise capacity will be measured by the NL-VISA-P.

Our recent (pilot)study showed improvement of pain and function in just 6 weeks (Timmermans et al, 2012, report internship VUmc)

Our research question:
Is overload eccentric training on a flywheel ergometer more effective in reducing pain and improving exercise capacity measured by the NL-VISA-P versus standard eccentric training in athletes with patellar tendinopathy?

Study design

The study is a multicenter randomised controlled trial looking at the effect of treatment of patellatendinopathy with overload excentric training using a flywheel compared to standard eccentric training.

The diagnosis is confirmed by a sports physician with experience in patella tendinopathy.

After inclusion there is determination of the VAS score at 3 functional tests and VISA-P.

The Flywheel group will be assigned to 6 weeks (2 sessions per week) of overload excentric training using a flywheel ergometer, supervised by a physical therapist.

The Standard group is assigned to 6 weeks (2 sessions per week) standard eccentric training, supervised by a physical therapist. .

Intervention

Supervised overload eccentric training of the patellar tendon using a flywheel ergometer.

Study burden and risks

Burden:

One extra physical examination is performed

Filling out questionnaires (general questionnaire and NL-VISA-P) at 6 measuring moments

Three functional tests are requested by an independent physical therapist

The actual training consists of 6 weeks of training, 2 times a week 30 minutes (for both groups)

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

> 6 weeks pain of the patellar tendon

> 1 hour sports participation/ week
Age > 18 years
Maximum of 80 points on the NL-VISA-P

Exclusion criteria

- Knee surgery in history
- History of meniscal or anterior cruciate ligament injury
- If there is a more likely cause for knee pain by physical examination or ultrasound
- Systemical diseases which are a contra-indication for pressure increasing moments (valsalva) - Injections in the patellar tendon
- Age >50 years
- Excentric physical therapy or shockwave therapy in the past 6 weeks
- Other (recent) knee pathology
- Inflammatory disease of the joints
- Local infections arround the patellar tendon

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):	01-03-2013
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2013
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	30-10-2013
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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: 24586
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42622.028.13
OMON	NL-OMON24586