Assessing neuromuscular control of the ankle in individuals with recent acute lateral ankle ligament rupture, individuals with chronic ankle instability, and healthy individuals: 'single-leg stance on a wobble board' test

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1) to assess possible confounding factors in measuring neuromuscular control of the ankle with a *single-leg stance wobble board* test2) to compare neuromuscular ankle control with the *single-leg stance wobble board* test between individuals with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bone and joint injuries
Study type	Observational non invasive

Summary

ID

NL-OMON37650

Source
ToetsingOnline

Brief title
2Wobble

Condition

- Bone and joint injuries

Synonym
acute lateral ankle sprain; chronic ankle instability

Research involving

Human

Sponsors and support

Primary sponsor: Spaarne Ziekenhuis
Source(s) of monetary or material Support: Stichting Linneusinstituut

Intervention

Keyword: ankle sprain, balance board, center of pressure, force plate

Outcome measures

Primary outcome

Single-leg-stance Wobble Board test, assessed by ground reaction forces

parameters *mean centre of pressure velocity* and *mean horizontal ground

reaction forces*.

Secondary outcome

Postural control: mean centre of pressure velocity and mean horizontal ground

reaction forces during single-leg-stance with eyes open and closed on a Kistler

force plate

Ground reaction forces during one-leg-hop test

Orthopaedic clinical ankle examination

Foot pressure management using the Footscan® during two-leg-stance and gait

Subjective severity of the functional ankle instability (questionnaire):

- Cumberland Ankle Instability Tool (CAIT)

- Chronic Ankle Instability Scale (CAIS)

Clinical ankle score (form will be filled in by investigator):

- Karlsson score

Pre-injury and actual activity level:

- Tegner score

- One of four classes according to the International Knee Documentation Committee standards: (1) strenuous, which includes jumping, pivoting, hard cutting (football, soccer, volleyball, tennis, hockey); (2) moderate, which involving agility of the lower limbs but not jumping, hard cutting, or pivoting (heavy manual work, skiing); (3) light, which includes sports that do not involve agility of the lower limbs (light manual work, jogging, running); or (4) sedentary. Activity level was defined on the basis of the most strenuous work or leisure activities that the patient performed on a regular basis.

Study description

Background summary

Injuries to the lateral ankle ligaments are the most common injuries across a wide variety of sports, accounting for approximately 25% of all sports-related injuries. People who suffer from lateral ankle sprains are likely to re-injure the same ankle within a year. Moreover, 10-20% develop chronic ankle instability with daily impairment and this group has an increased risk to develop ankle osteoarthritis. Considering the effectiveness of dynamic balance board training in reducing ankle sprain recurrence risk, a single-leg stance on a Wobble Board test might be expected to increase sensitivity in measuring neuromuscular control of the ankle. If so, this new single-leg-stance wobble board test could be of clinical importance in developing a classification scheme for lateral ankle sprains, thereby contributing to a proper treatment selection.

Study objective

1) to assess possible confounding factors in measuring neuromuscular control of the ankle with a *single-leg stance wobble board* test
2) to compare neuromuscular ankle control with the *single-leg stance wobble board* test between individuals with recent acute lateral ankle ligament rupture and healthy controls
3) to assess the diagnostic value of a *single-leg-stance wobble board* test in discriminating between individuals with chronic ankle instability and healthy

controls

Study design

1) cross-sectional observation of 100 healthy individuals with no ankle problems
2) case-control comparison between 40 individuals with acute lateral ankle ligament rupture (grade II/III) and 40 healthy controls selected out of the 100 healthy individuals. Matched on group level for age, gender and other important variables assessed during analysis of design 1.
3) case-control comparison between 20 individuels with chronic ankle instability and 20 healthy controls selected out of the 100 healthy individuals. Matched on group level for age, gender and ohter important variables assessed during analysis of design 1.

Study burden and risks

Participants with ankle problems are required to visit the human movement laboratory of the Spaarne Hospital once, for a period of 45-60 minutes. Participants without ankle problems will be measured at the company of their daily work. In total, 24 one-leg-stance tests of 10 seconds have to be performed. Additionally, subjects have to perform 6 trials of a small single-leg hop test. Furthermore, a two-leg-stance and a gait cycle on a digital footscan have to be carried out. Besides the functional tests, an orthopaedic physical examination of both ankles will be done. Thereafter, 2 short questionnaires (Cumberland Ankle Instability Tool, Chronic Ankle Instability Scale) have to be filled out to assess subjective functional ankle instability and 1 questionnaire about detailed history of injuries and training. The use of the one-leg stance with and without a Wobble Board are widely accepted and performed without supervision in rehabilitation programs of acute and chronic ankle instability.
According to the researcher there are no extra risks involved with participating in the present study.

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

18-40 years old, BMI < 30
1) 100 healthy individuals with no ankle problems, and no acute lateral ankle sprain in the last year, and no current diminished activity due to lower extremity/back problems in the past.
2) 40 individuals with recent (<7 days) acute lateral ligament rupture grade II/III (partial- or complet rupture): signs of lateral haematoma, swelling and pain with palpation of the lateral ligament complex after 5-7 days post-injury. Furthermore, no pre-existent chronic ankle instability, and no acute lateral ligament rupture in the last 1 year, and no pre-existent diminished activity due to lower extremity/back problems in the past.
3) 16-20 individuals with chronic ankle instability: residual symptoms of *giving way* and feelings of ankle joint instability for a minimum period of 6 months.

Exclusion criteria

Signs of neurological disease
Signs of vestibular disease
Signs of orthopaedic disease (other than the inclusion criteria)
History of fractures or current associated fractures of the lower extremities
No other current injuries of the lower extremity or back
Insufficient knowledge of the Dutch language

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-06-2013
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	10-07-2012
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	NL39212.094.11