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Randomised controlled trial of physical therapy in ankle sprains

Submission date	Recruitment status
02/09/2009	No longer recruiting
Registration date	**Overall study status**
04/09/2009	Completed
Last Edited	**Condition category**
23/01/2017	Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MCT-94833

Study information

Scientific Title

Efficacy of a physical therapy intervention for the early treatment of acute ankle sprains identified in the emergency department: a randomised controlled trial

Study objectives
What is the efficacy of a standardised physical therapy intervention plus usual emergency medical care, versus usual emergency medical care alone, in enhancing functional recovery at 3 months post-injury?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, 21 /07/2009

Primary study design
Interventional

Study design
Single-centre parallel-group randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Ankle sprain

Interventions
Control arm:
Eligible study subjects assigned to the control arm will receive usual care only. This consists of:
1. Ruling out of ankle fractures and grade 3 ligament ruptures
2. Assessment and advice provided by ED nursing and physician staff according to their practice, supported by
3. A printed set of standard discharge instructions

Experimental arm:
Eligible study subjects assigned to the experimental arm will receive usual care (as per control arm) plus a standardised physical therapy intervention aimed at returning the patient to his/her full pre-morbid activity level. Individuals will be seen by one of two therapists within 2 business days of receiving a referral, and will be seen by the same therapist throughout the treatment course. A treatment plan consisting of thirty minute sessions and home exercise will be developed for each patient based on a standard approach requiring assessment of recovery and progression through 4 stages. We expect most patients will require between 3 and 5 sessions. Those with risk factors for chronic ankle instability (e.g. anterior and inversion laxity, functional insufficiency) may require more.

Stage I is focused on managing the acute/subacute symptoms using modalities to decrease pain and swelling and protecting the joint from secondary inflammation and further injury due to instability while promoting pain-free weight bearing as tolerated. These treatment activities may continue into Stage II, although with reduction in pain, more emphasis on improving passive

and active range of motion (ROM) through stretching, mobilisation and progressive resistance exercises introduced. In Stage III a more aggressive approach to regaining full ROM in all movement directions, and building strength and endurance in all muscle groups is adopted to increase joint stability and strength. Individualised progressive resistance programs using isometric, isotonic and isokinetic exercises to strengthen muscle groups throughout the ROM and also combined movements (e.g. circumduction). As the patient achieves full weight-bearing and can tolerate resistance exercise at slow and fast velocities without pain, then proprioception training and activity-specific training can be initiated - the focus of Stage IV. This advanced stage prepares the individual to return to full activity by restoring full strength and joint mobility, reducing mechanical and functional insufficiencies that are risk factors for chronic ankle instability and recurrent injury. Depending on the activity level and risk factors for recurrence and chronic instability, protection may be prescribed during activity.

As part of their treatment, patients will receive a home exercise program which they are encouraged to complete 2 - 3 times/day. These programs will be progressed in difficulty as the individual's strength and tolerance improves.

Outcomes will be measured at 3 and 6 months with the 3-month data being used for the primary analyses.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Excellent recovery at 3 months from the effects of the ankle sprain as measured using the FAOS

Key secondary outcome(s)
1. Assessment of recovery for total FAOS and domain-specific scores measured as a continuous variable
2. Functional recovery, as assessed by FAOS, at 1 month and 6 months post-injury (in addition to the primary 3 month endpoint)
3. Clinical and laboratory-based outcome measures of ankle recovery
4. Recurrence of sprain injury in the same ankle

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Subject presents for medical treatment to one of two emergency departments (EDs) in Kingston, Ontario, within 48 hours of injury
2. Aged 16 years and older, both sexes
3. Mentally competent
4. Incident grade 1 or 2 ankle sprain, defined as an initial visit for an acute injury to the lateral and /or medial ligament ankle complex (includes avulsion fractures less than 5 mm at ligament insertion sites)
5. Agrees to attend for laboratory testing and follow-up telephone calls

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Key exclusion criteria
1. Baseline Foot and Ankle Outcome Score (FAOS) greater than 450
2. Initial diagnosis of ankle fracture or grade 3 ligament rupture
3. Need for fixed immobilisation or surgery declared by attending medical staff
4. Other soft tissue injuries including direct blows or abrasions
5. Multiple injuries that may impair functional recovery of the ankle (including injury to both ankles)
6. Prior diagnosis of (same) ankle sprain in 6 months preceding ED presentation
7. Other mobility limiting condition (e.g. arthritis or neurological disease/injury affecting lower limb)

Date of first enrolment
01/10/2009

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Canada

Study participating centre
Kingston General Hospital
Kingston
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Sponsor information

Organisation
Queen's University (Canada)

ROR
https://ror.org/02y72wh86

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (ref: MCT-94833)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/11/2016		Yes	No