

# Effect of early supervised physiotherapy on recovery from acute ankle sprain: randomised controlled trial

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## Abstract

**Objective** To assess the efficacy of a programme of supervised physiotherapy on the recovery of simple grade 1 and 2 ankle sprains.

**Design** A randomised controlled trial of 503 participants followed for six months.

**Setting** Participants were recruited from two tertiary acute care settings in Kingston, ON, Canada.

**Participants** The broad inclusion criteria were patients aged  $\geq 16$  presenting for acute medical assessment and treatment of a simple grade 1 or 2 ankle sprain. Exclusions were patients with multiple injuries, other conditions limiting mobility, and ankle injuries that required immobilisation and those unable to accommodate the time intensive study protocol.

**Intervention** Participants received either usual care, consisting of written instructions regarding protection, rest, cryotherapy, compression, elevation, and graduated weight bearing activities, or usual care enhanced with a supervised programme of physiotherapy.

**Main outcome measures** The primary outcome of efficacy was the proportion of participants reporting excellent recovery assessed with the foot and ankle outcome score (FAOS). Excellent recovery was defined as a score  $\geq 450/500$  at three months. A difference of at least 15% increase in the absolute proportion of participants with excellent recovery was deemed clinically important. Secondary analyses included the assessment of excellent recovery at one and six months; change from baseline using continuous scores at one, three, and six months; and clinical and biomechanical measures of ankle function, assessed at one, three, and six months.

**Results** The absolute proportion of patients achieving excellent recovery at three months was not significantly different between the physiotherapy (98/229, 43%) and usual care (79/214, 37%) arms (absolute difference 6%, 95% confidence interval -3% to 15%). The observed trend towards benefit with physiotherapy did not increase in the per protocol analysis and was in the opposite direction by six months. These trends remained similar and were never statistically or clinically important when the FAOS was analysed as a continuous change score.

**Conclusions** In a general population of patients seeking hospital based acute care for simple ankle sprains, there is no evidence to support a clinically important improvement in outcome with the addition of supervised physiotherapy to usual care, as provided in this protocol.

**Trial registration** [ISRCTN 74033088](https://www.isrctn.com/ISRCTN74033088) ([www.isrctn.com/ISRCTN74033088](http://www.isrctn.com/ISRCTN74033088))

## Reviewer: 2 - Patient and Public Reviewer

Comments:

Is the article important?

The research is important in terms of providing evidence for better use of healthcare resources, patient's time and costs and for providing a clear answer to a common question about how much care it takes to make a difference in simple ankle sprain.

Will it help our readers to make better decisions and, if so, how?

It can help hospital staff, clinicians and patients understand what best care consists of for simple ankle sprain.

Will the article add enough to existing knowledge? Yes, it is better to answer one research question well and in a way that the evidence can be put into practice than to complicate it with the inevitable "what is".

Does the article read well and make sense? Does it have a clear message?

The article is beautifully written, clear and concise with a message that can be summarized in one sentence. "Home care with instruction from ED is sufficient for simple grade 1/2 ankle sprain however I am not sure that PT is understated; see analysis and research question.

Originality and Relevance

long-term morbidity from simple ankle sprains has been documented in 30% to 70% of patients, at times ranging from 6 months to 7 years' post-injury so it is a question that benefits from tangible evidence and improved care path ways. A general medical journal is the right place as this is a common problem that needs solving. From the authors own including Cochrane reviews.

Kerkhoffs GMMJ, Struijs PAA, Marti RK, Assendelft WJJ, Blankevoort L, van Dijk CN. Different functional treatment strategies for acute lateral ankle ligament injuries in adults. *Cochrane Database Syst Rev.* 2002(3):CD002938. doi: 10.1002/14651858.CD002938.

Kerkhoffs GMMJ, Rowe BH, Assendelft WJJ, Kelly KD, Struijs PAA, van Dijk CN. Immobilisation and functional treatment for acute lateral ankle ligament injuries in adults. *Cochrane Database Syst Rev.* 2002(3):CD003762. doi: 10.1002/14651858.CD003762.

Kerkhoffs GMMJ, Handoll HHG, de Bie R, Rowe BH, Struijs PAA. Surgical versus conservative treatment for acute injuries of the lateral ligament complex of the ankle in adults. *Cochrane Database Syst Rev.* 2007(2):CD000380. doi: 10.1002/14651858.CD000380.pub2.

Birrer RB, Fani-Salek MH, Totten VY, Herman LM, Politi V. Managing ankle injuries in the emergency department. *J Emerg Med.* 1999;

Scientific reliability Research question: this was clearly defined and appropriately answered. Overall design of study was appropriate and adequate to answer the research question. However, I question the use of only excellent recovery as according to the literature cited in the study excellent recovery was not assured and it may be that good or adequate recovery would provide additional valuable information as those that are slower to recover may benefit from additional supportive care rather than a home prescription/advice package.

Participants & Descriptions: Participants were adequately described, the conditions and both interventions were well defined, inclusion and exclusion criteria was clear and a rationale was given for this. They were representative of patients who present with an ankle sprain and the uncertainties were clearly stated in the introduction and the discussion. Given the prevalence it is highly likely that most of the population or their loved ones will face this challenge at some time in their lives.

Methods: These were very well done, even the way prospective sample size was calculated was excellent although I found the 81% power somewhat odd and wondered if this was adjusted according to expected admissions? The study was fully reported with a completed CONSORT with page #s. The detail level provided was excellent. The ethical considerations and approvals were appropriate and the weaknesses of the question and the need for extended research to meet the needs of participants was clearly stated in the discussion with appropriate references. There was a sensitivity analysis.

Analysis: The forest plot shows a benefit for physical therapy in the first three months. This is the typical length of a sprain so to say that there was no benefit at six months highly disregards the aspect of physical therapy in terms of speed of recovery and quality of life for the patients. Following this rationale if I have no pain relief for an acute injury I may recover given time however I will suffer needlessly. The other aspect of PT is that it can be a check to see if a more serious injury or grade of sprain was missed. ERs are busy and GPs may not have the focus at hand for this specific injury whereas PTs see this everyday. I recommend that the advantages be clearly stated for the first three months with a rationale. This would have been an excellent place for involving patients and the therapists in the study as a short narrative report and acknowledgement would add to the study and could increase public involvement and good will. Authors report "We do note that 43% of patients in the physical therapy arm and 38% in the control arm did not reach 'excellent' recovery by 6 months". This is indicative that treatment is inadequate or expectations are high and that PT may have recorded poor recovery from a functional standpoint where self report may minimize the problems.

Interpretation and conclusions: These were well signposted, warranted by and sufficiently derived from/focused on the data. There were no distractions or irrelevant conclusions and

the findings were discussed in the light of previous evidence. The study was elegantly presented and the message was clear even at a lay level.

References: These were up to date, appropriate for the content and relevant with no glaring omissions.

Abstract/summary/key messages/what this paper adds — reflect accurately what the paper says?

CONSORT was included, there was no protocol although this could be found by linking all other files were informative

Participant involvement and Dissemination: I recommend the patients consulted in the pilot project be placed in acknowledgements at their input was integral for the success of the study. In addition, I recommend that participants/patients be offered a download to the full research study as well as a lay summary as offering only the summary is patronizing and does not contribute to the spirit of informed shared decision making we want to acknowledge in the culture of health. Patients can choose to read at the deeper level or be content with the summary as is the case for all readers but without access directions this choice is not afforded them.

Additional Questions:

Please enter your name: Amy Price

Job Title: Neurocognitive consultant and researcher

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Reimbursement for attending a symposium?: No

A fee for speaking?: No

A fee for organising education?: No

Funds for research?: No

Funds for a member of staff?: No

Fees for consulting?: No

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If you have any competing interests (please see BMJ policy) please declare them here: I have no competing interests to declare

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