

¹ Postgraduate Program in Rehabilitation and Functional Performance, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Minas Gerais, Brazil

² Medicine College, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Minas Gerais, Brazil

³ Postgraduate Program in Health Sciences, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Minas Gerais, Brazil

Background: Ankle sprain is a common condition in the general population, with a prevalence of 11.88%, and an incidence of seven sprains per 1000 exposures in athletes, resulting in a high frequency of chronic ankle instability. Therefore, effective therapies are increasingly sought after by clinicians. Cryotherapy is a low-cost and easy-to-use treatment option, being considered a potentially effective therapy in the acute inflammatory phase due to preclinical research findings, which suggest that cryotherapy can control inflammatory processes and promote local analgesia by decreasing nerve conduction velocity, which could lead to improved clinical outcomes. However, the current literature lacks evidence on clinical outcomes to support its use, raising the importance of new randomized controlled trials with low risk of bias and appropriate comparison groups.

Objectives: The aim of this not applied study protocol is to investigate the effectiveness of cryotherapy on function, pain intensity, swelling, and dorsiflexion range of motion in people with an acute episode of ankle sprain.

Methods: This is a two-arm prospective randomized controlled trial protocol, designed according to the SPIRIT guideline. People over 18 years old with a clinical diagnosis of grade I or II ankle sprain, and time of up to 72 hours from the injury episode, will be randomly allocated in the Ice Group, which consists of home medical prescription of immersion of the ankle in an ice bucket or, secondarily, ice packs, combined with elevation and non-steroidal anti-inflammatory drugs or to the No-Ice Group, which consists of the same medical prescription as the experimental group, but with no ice included. Our primary outcome is function, as measured by the Lower Extremity Functional Scale (LEFS). Our secondary endpoints are pain intensity (Numeric Pain Scale, 0-10), swelling (figure-eight method), and dorsiflexion range of motion (goniometry). Follow-ups will be performed at post-treatment (7 to 14 days) and 12 weeks after allocation. A sample size of 82 participants will be required for a minimum detection of the estimated 9-point effect size of the primary endpoint, with a power of 80%, a power of 5%, and an expected dropout rate of 20%. Statistical analysis will be performed following the intention-to-treat principle. Data normality will be tested by the Kolmogorov-Smirnov test. Parametric data will be analysed with mixed effects models for repeated measures with post-hoc Bonferroni analysis, and in case of non-parametric data, with generalized linear models of mixed effects. Effect sizes will be interpreted based on their minimal clinically important differences.

Results and implications: The results of this study may help to clarify the effects of cryotherapy in the treatment of acute ankle sprains and may guide clinicians in making better decisions.

Keywords: Cryotherapy, Ankle injuries, Randomized Controlled Trial

Conflict of interest: The authors declare no conflict of interest.

Acknowledgment: We thank the Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM) and the CNPq, CAPES (Finance Code 001), and FAPEMIG for support and scholarships.

Ethics committee approval: Research Ethics Committee of the Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM) (58542222.2.0000.5108).

<https://doi.org/10.1016/j.bjpt.2024.100819>

223

EFFECTIVENESS OF CRYOTHERAPY ON FUNCTION, PAIN, EDEMA AND RANGE OF MOTION IN ACUTE ANKLE STRAIN: FROST RANDOMIZED CONTROLLED TRIAL PROTOCOL

Júlio Pascoal de Miranda¹, Whesley Tanor Silva¹, Rodrigo Oliveira Mascarenhas², Hytalo de Jesus Silva³, Vinicius Cunha de Oliveira^{1,3}

¹ Postgraduate Program in Rehabilitation and Functional Performance, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Minas Gerais, Brazil

² Department of Physiotherapy, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Minas Gerais, Brazil

³ Postgraduate Program in Health Sciences, Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM), Diamantina, Minas Gerais, Brazil

Background: Ankle sprain is a condition with a high incidence in the general population and athletes and can cause direct costs (expenses with medical appointments and medication) and indirect costs (absence from work and loss of productivity). Cryotherapy is often recommended for the management of this condition, however current evidence supporting cryotherapy is still uncertain. A systematic review is needed to inform clinicians and patients about the current quality of evidence for the effectiveness of cryotherapy after an episode of an acute ankle sprain.

Objectives: The aim of this systematic review was to investigate the effectiveness of cryotherapy on pain, edema, range of motion, function, and recurrence after acute ankle sprains.

Methods: This systematic review of randomized controlled trials was reported following the PRISMA checklist and some stages were conducted according to the Cochrane recommendations. Protocol was prospectively registered in PROSPERO (CRD42020166411) and Open Science Framework (<https://osf.io/x6p23>). Searches for randomized controlled trials evaluating the effectiveness of cryotherapy on pain, swelling, range of motion, function, and recurrence outcomes in people with acute ankle sprains were performed in six databases (MEDLINE, COCHRANE, EMBASE, AMED, PSYCINFO and PEDRO, without language or date restriction, until January 2021). Study selection, data extraction, and assessment of the methodological quality of included studies were conducted independently by two reviewers, with discrepancies resolved by a third reviewer. Estimates were presented as Difference of Means (MDs) with 95% confidence intervals (CIs). The quality of evidence was assessed using the GRADE approach.

Results: Two randomized controlled trials with a high risk of bias (methodological quality < 6 on the 0-10 PEDro scale) were included. There were no studies investigating the effectiveness of cryotherapy alone on our outcomes of interest. Both studies evaluated the additional effects of cryotherapy, comparing cryotherapy as an adjunct to another active intervention with the active intervention alone. Evidence with a high level of uncertainty shows that cryotherapy does not increase the effects of the other intervention for the outcomes edema (MD = 6.0; 95% CI: -0.5 to 12.5), pain (MD = -0.03; 95% CI: -0.34 to 0.28) and range of motion (p > 0.05).

Conclusion: The results of this study conclude that the current literature lacks evidence supporting the use of cryotherapy in the management of acute ankle sprains. There is an urgent call for higher quality RCTs to clarify the evidence on the effectiveness of cryotherapy in this condition.

Implications: Clinical guidelines should reassess recommendations regarding the use of cryotherapy in the management of acute ankle sprains. Clinicians should look for therapies with more robust scientific evidence as a first-line treatment for this condition.

Keywords: Cryotherapy, Ankle injuries, Randomized Controlled Trial