



Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Full body cryotherapy for symptom reduction in patients with fibromyalgia
Topic exploration report number:	TER258

Introduction and aims

Fibromyalgia is a condition characterised by chronic generalised musculoskeletal pain. In addition to chronic pain, the symptoms often include fatigue, joint stiffness, issues with sleep and headaches. The neurogenic origin of fibromyalgia is thought to result from an imbalance in the levels of neurotransmitters and consequently the body's inflammatory response. Whilst there are a wide range of pharmacological and non-pharmacological management approaches available, there is, as yet, no curative treatment.

Full body cryotherapy involves the exposure to extreme cold as a therapeutic agent for pain relief. Cryotherapy is typically delivered in short sessions (between two and five minutes) in an environmentally controlled chamber. Cryotherapy sessions are often part of a course of treatments where repeated sessions are followed by a period without cryotherapy.

Health Technology Wales researchers searched for evidence on the effectiveness of full body cryotherapy for symptom reduction in people with fibromyalgia.

Summary of evidence

Secondary evidence

Guidance/guidelines

HTW researchers did not identify any guidance or guidelines specific to the use of full body cryotherapy for fibromyalgia.

Systematic reviews

We did not find any systematic reviews looking specifically at cryotherapy for the reduction of fibromyalgia symptoms.

Economic evaluations

No Economic evaluations were identified for full body cryotherapy for fibromyalgia.

Primary studies

We identified three potentially relevant primary studies. The trial approach, intervention and duration varied across the available studies. The broad findings suggest that full body cryotherapy results in a reduction in fibromyalgia-related symptoms over the short term.

A randomised control trial of 24 fibromyalgia patients assessed whether whole body cryotherapy results in improved quality of life compared to standard care (Vitenet et al. 2018). Ten sessions of cryotherapy were performed over a period of eight days in the intervention arm (n=11) while the control group did not change anything in their everyday activities (n=13). Quality of life was measured at baseline and at one month after treatment using the 36-Item Short Form Health Survey (SF-36). The cryotherapy group experienced an increase in physical and mental health in comparison to the control group.

A randomised crossover trial of 60 fibromyalgia patients assessed the impact of whole body cryotherapy on pain and disease-specific fibromyalgia scores in comparison to rest (Rivera et al. 2018). The Intervention group (n=34) was treated on alternate days for a duration of three weeks while the control group (n=26) received three weeks of rest. This was followed by a one-week washout period, after which the treatment groups were inverted such that those people initially in the control group receive three weeks of cryotherapy while those initially treated with cryotherapy became controls. The results were limited to assessing the initial phase of the trial due to residual effects of cryotherapy. A reduction in fibromyalgia impact questionnaire score, visual analogue pain scale and the combined index of severity of fibromyalgia score were all observed in the intervention group. Five patients reported adverse events, ranging from muscle stiffness and headaches to difficulty with sleeping.

A non-randomised controlled trial with 100 participants compared outcomes from a group treated with 15 cryotherapy sessions (n=50) and a control group (n=50) that did not receive cryotherapy (Bettoni et al. 2013). Each group continued their prescribed pharmacological therapy (analgesics and antioxidants) during the study. A range of disease specific and general measures were collected at baseline and after treatment. The intervention group saw a greater reduction in pain intensity score and general health status (low being better) as well as the group fatigue severity score.

Ongoing research

We identified two ongoing trials, which have yet to have their results published.

Areas of uncertainty

Currently there are no large-scale randomised control trials reporting on the efficacy of full body cryotherapy for the reduction of fibromyalgia symptoms.

Across the identified studies, there was a high level of Heterogeneity in study design and an inconsistency in the intervention structure. The session duration, temperature, frequency of sessions and length of treatment course varied across studies. Whilst there were broadly positive findings associated with the use of cryotherapy in this patient group, the duration of treatment effect is uncertain.

There were no studies identified that assessed the cost effectiveness of full body cryotherapy.

Conclusions

Currently there is a low level of published evidence from a small number of trials which suggest that full body cryotherapy offers a beneficial impact on a range of fibromyalgia symptoms when compared to standard care. There is significant uncertainty as to the optimal use of cryotherapy in this patient group and the treatment effect duration.

Brief literature search results

Resource	Results
HTA organisations	
Healthcare Improvement Scotland	We did not identify any evaluations of cryotherapy as a treatment for fibromyalgia from this source.
Health Technology Assessment Group	We did not identify any evaluations of cryotherapy as a treatment for fibromyalgia from this source.
Health Information and Quality Authority	We did not identify any evaluations of cryotherapy as a treatment for fibromyalgia from this source.
EUnetHTA https://www.eunetha.eu/rapid-reas/	We did not identify any evaluations of cryotherapy as a treatment for fibromyalgia from this source.
International HTA Database	We did not identify any evaluations of cryotherapy as a treatment for fibromyalgia from this source.
UK guidelines and guidance	
SIGN	We did not identify any relevant guidance
NICE	We did not identify any relevant guidance
Secondary literature and economic evaluations	
https://www.epistemonikos.org/en/	We did not identify any relevant evidence from this source
https://www.tripdatabase.com/	We did not identify any relevant evidence from this source
Cochrane library	We did not identify any relevant evidence from this source
Medline (via Ovid or Pubmed)	We did not identify any relevant evidence from this source
Primary studies	
https://www.epistemonikos.org/en/	We did not identify any relevant evidence from this source
https://www.tripdatabase.com/	We did not identify any relevant evidence from this source
Cochrane library	<p>Rivera, J., Tercero, M. J., Salas, J. S., Gimeno, J. H., & Alejo, J. S. (2018). The effect of cryotherapy on fibromyalgia: a randomised clinical trial carried out in a cryosauna cabin. <i>Rheumatology international</i>, 38(12), 2243-2250.</p> <p>Sundaram, V. M. (2015). To compare the effectiveness of whole body cryotherapy against steam therapy in patients with Chronic Fibromyalgia. <i>Physiotherapy</i>, 101, e988-e989.</p> <p>Bettoni, L., Bonomi, F. G., Zani, V., Manisco, L., Indelicato, A., Lanteri, P., ... & Lombardi, G. (2013). Effects of 15 consecutive cryotherapy sessions on the clinical output of fibromyalgic patients. <i>Clinical rheumatology</i>, 32(9), 1337-1345.</p> <p>Vitenet, M., Tubez, F., Marreiro, A., Polidori, G., Taiar, R., Legrand, F., & Boyer, F. C. (2018). Effect of whole body cryotherapy interventions on health-related quality of life in fibromyalgia patients: A randomized controlled trial. <i>Complementary therapies in medicine</i>, 36, 6-8.</p>

Medline	
Ongoing primary or secondary research	
PROSPERO database	We did not identify any relevant evidence from this source
Clinicaltrials.gov	<p>Trial Identifier: NCT03425903: Evaluate the Clinical Efficacy of Whole Body Cryotherapy in the Cryosense Cabin for the Treatment of Fibromyalgia</p> <p>Trial Identifier: NCT03466008: Whole-Body Cryotherapy (WBC) as an Adjunct Treatment on Pain in Fibromyalgia Persons: Short Time Effect.</p>

Date of search:	<i>April 2021</i>
Concepts used:	Fibromyalgia, Cryotherapy, Full body cryotherapy