



Short Communication

Effect of whole body cryotherapy interventions on health-related quality of life in fibromyalgia patients: A randomized controlled trial

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ABSTRACT

Introduction: Although fibromyalgia syndrome (SFM) affects 2–4 percent of adults, research has not identified a preferred therapeutic option for patients worldwide yet. Based on recent findings, it can be expected that whole body cryotherapy can improve health-reported quality of life by alleviating the symptoms of musculoskeletal pain and fatigue.

Objective: Our aim was to determine whether whole body cryotherapy only can result in improved perceived health and quality of life in fibromyalgia patients.

Methods: 24 patients with fibromyalgia diagnosis were randomized into 2 groups (n = 11 in the whole body cryotherapy group, n = 13 in the control group). In the whole body cryotherapy group, 10 sessions of whole body cryotherapy were performed (in addition to usual care) in a standard cryotherapy room over a duration of 8 days. Subjects in the control group did not change anything in their everyday activities. Quality of life was assessed just before and one month after treatment.

Results: Compared with the control group, patients in the whole body cryotherapy group reported significantly improved for health-reported quality of life. These effects lasted for at least one month following intervention.

Conclusion: Based on these findings, whole body cryotherapy can be recommended as an effective clinically adjuvant approach in the improvement of health-related quality of life in fibromyalgia patients.

1. Introduction

Fibromyalgia is characterized by persistent diffuse pain resulting from a central nervous system dysfunction due to neurochemical imbalances at the level of the brain.^{1–3} Associated symptoms include sleep disorders and severe fatigue, stiffness, digestive problems, urinary disorders, hypotension, headaches, depression, anxiety, and cognitive impairments.⁴ As a result, it is a physically and emotionally taxing disorder that has potentially devastating effects on patients' quality of life, limiting their daily life, as well as their social, professional and recreational activities.^{4,5}

As fibromyalgia patients do not die of their disease, health-related quality of life (QoL) is key in all patients. Crucial factors that can impede on QoL are pain and/or inflammatory processes.⁶

A variety of treatments are available for fibromyalgia,⁷ both medical and alternative.^{8,9} It seems that including patients in an organized and coordinated care plan is an especially effective option.¹⁰ Whole Body

Cryotherapy is a specific physical therapeutic supplement known to relieve pain and inflammatory symptoms of rheumatic diseases.¹¹ The main principle of whole body cryotherapy is to create a thermal stress that generates vasoconstriction^{10,12} and stimulation of the thermal receptors of the dermis by lowering skin temperature,¹³ mainly having an analgesic effect by slowing down nerve conduction.¹⁴ Combined treatment of cryotherapy and aerobic physical exercise has shown beneficial effects on health-reported quality of life in patients with fibromyalgia.¹⁵

In addition to these previous findings, and using a randomized controlled trial, the present objective is to highlight the possible cause-effect relationship that might exist between whole body cryotherapy only and health-reported quality of life improvement, evaluated and compared just before and one month post-treatment.

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2. Materials and methods

2.1. Ethical standards

Each participant was verbally provided with information regarding the study and the contents of the information sheet. In accordance with the Declaration of Helsinki, all participants were asked to sign a relevant consent form in which the study procedures were explained. This study was approved by the Ethical Committee of the University Hospital of Dinant-Godinne (Belgium) with the registration number 8039201629783.

2.2. Participants

A convenience sample of 24 female and male participants volunteered for this study. Patients who met the following inclusion criteria were retained: clinically diagnosed with Fibromyalgia using the American College of Rheumatology's standard criteria, and aged 18 years or older. Additionally, the following exclusion criteria were applied: modification of usual analgesic/anti-inflammatory treatments during the experimentation (with the exception of one subject (whole body cryotherapy group) without therapy, all the others kept their prescribed pharmacological therapy: antalgic for 18 of them, morphine for one (whole body cryotherapy group), opioid for one (whole body cryotherapy group), antidepressant for 3 of them (1 in whole body cryotherapy group)), recent history of whole body cryotherapy treatment, diagnosis of coexisting diseases, and potential contraindications for whole-body cryotherapy procedures. All participants were randomized by drawing lots using sealed envelopes either to whole body cryotherapy group (N = 11; 55 ± 10 y.o.; 8 females-3 males) or control group (N = 13; 50 ± 11 y.o.; 12 females-1male). The study flowchart is shown in Fig. 1.

2.3. Protocol

Both groups were all treated with physiotherapy during the test phase. At the same time, the experimental group followed cryotherapy sessions. The evaluation phase lasted 5 weeks. The participants in the whole body cryotherapy group were treated using a cycle of 10 visits to a cryogenic chamber over a period of 8 days (scheduled at the same time of day, one session per day for the first 4 and last 2 days, 2 sessions per day for days 5 and 6). They were subjected to the effects of extreme low temperature in a cryoair -110 °C Whole Body Cryotherapy

chamber (produced by MECOTEC, Pforzheim Germany) for 3 min. In order to protect the most sensitive body areas, all patients entering the rooms were dressed with swimsuits, face-mask to protect the nose and mouth, cotton socks, slippers and gloves, ear-protector and wooden shoes.

Participants were asked to complete twice the quality of life questionnaire Medical Outcome Study Short Form-36 (MOS SF-36)¹⁶ just before, and then 1 month following the end of the 8-days intervention. Each of the scores obtained (physical composite score "PCS" and mental composite score "MCS") had a maximum of 100 points.^{17,18}

2.4. Statistical analysis

The numerical data were first compiled by group (test group vs. control group participants) and by time of measurement (J1, J8 + 1 month). Within these 4 sets, the mean and standard deviation for each of our dependent variables (DV) were calculated. A Wilcoxon signed-rank test was conducted to examine the cold-induced changes within the control and whole-body cryotherapy groups. Then, we used a Mann-Whitney test to explore whether there were significantly between-group differences in terms of score change for self-rated physical and self-rated mental health. *P*-values less than 0.05 were considered statistically significant.

All analyses were carried out using the Statistica 8.0 software (Statsoft, France).

3. Results and discussion

In this study it was hypothesized that whole-body cryotherapy should alleviate pain and/or inflammatory processes in fibromyalgia patients, which should result in improved health-related quality of life (QoL). There were no significant differences in the age of participants between the two groups (whole body cryotherapy and control). Trends in the physical composite and mental composite scores of SF-36 are presented in Fig. 2 (results with significant value are marked with an asterisk (*) on each graph). Statistically significant improvements were found for both self-rated physical and self-rated mental health for the whole body cryotherapy group. Specifically, the physical score was increased from 21.3 ± 8.9 to 55.6 ± 27.8 ($z = 2.38$, $p = 0.017$), and the mental score was increased from 30.1 ± 22.4 to 60.4 ± 28.7 ($z = 2.38$, $p = 0.017$). There were no significant changes in any of these two scores for the control group. The magnitude of change was statistically larger in the whole body cryotherapy group compared to the control group for both health components ($z = 2.68$, $p = 0.007$ for self-rated physical health; and $z = 2.90$, $p = 0.004$ for self-rated mental health).

This observation of a beneficial effect of whole body cryotherapy might originate in the well-established effect of cryotherapy on the balance between pro-inflammatory and anti-inflammatory mediators, which have been found to influence pain modulation,¹⁴ and, consequently, quality of life. In addition, several authors mention an increase in cortisol levels linked to activation of the sympathetic nervous system by activation of the autonomic nervous system, a corticosteroid hormone and neuroendocrine stress marker in modulating pain and mood.^{19–21}

4. Conclusion

Because of the growing prevalence of fibromyalgia and its associated symptoms, therapeutic options are constantly evolving, and the advantages of a multimodal approach that would combine multiple therapies have been recognized in the last few years. Physiotherapy is one of the therapies proposed for the treatment of fibromyalgia, mainly for its contribution to joint and muscle maintenance, pain relief and psychological support. The present study provided support for the clinical relevance of Whole Body Cryotherapy in improving quality of

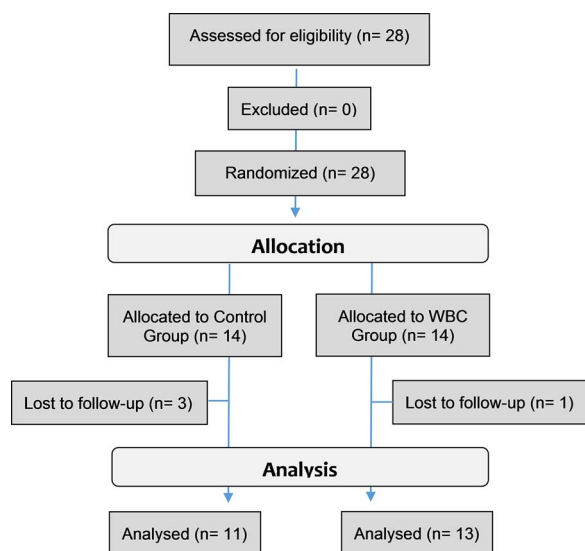


Fig. 1. Study flowchart.

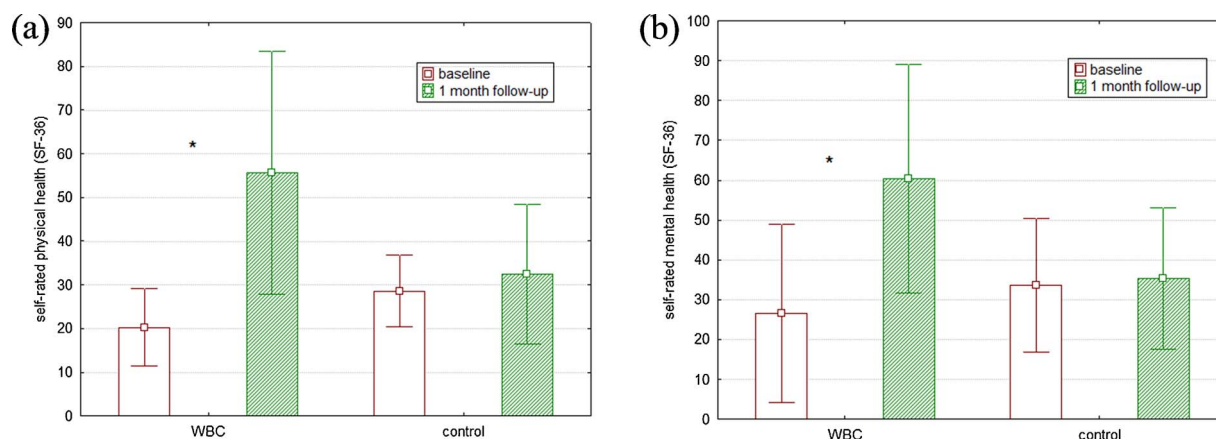


Fig. 2. Self-rated physical health (1.a) and mental health (1.b) as a function of group and time.

life in patients with fibromyalgia. With few whole body cryotherapy sessions, rapid improvements (i.e., within 1 month after whole body cryotherapy sessions) have occurred both in the mental and physical dimensions of patients' quality of life. In order to assess the stability of benefits over time, further studies including additional follow-up measures are required. In addition, since whole body cryotherapy has also proved to be an effective strategy against sleep disorders,²² further research should be conducted to determine whether it enhances fibromyalgia patients self-rated quality of life through improved sleep patterns.

Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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