Phytothermotherapy: a possible complementary therapy for fibromyalgia patients

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ABSTRACT

Objective. *It is a traditional practice in the Alpine region of Trentino and Alto Adige (Italy) to use phytothermotherapeutic treatment with fermenting grass ("hay baths") for rheumatic diseases. However, despite its long history and popularity, a clinical validation of the efficacy and tolerability of the treatment has yet to be found in current literature. Fibromyalgia syndrome (FMS) is characterized by generalised musculoskeletal pain, high tender point counts, sleep disturbance, fatigue, headaches, irritable bowel syndrome, frequent psychological distress and depressed mood. There is no standard therapy regime for FMS and the variety of medical treatments used have given limited benefits. The aim of this study was to assess the efficacy and tolerability of a cycle of phytothermotherapy through a single-blind, controlled, randomized trial, in patients with primary FMS.*

Methods. *Fifty-six patients with primary FMS according to the ACR criteria were randomly allocated to two groups: 30 were submitted to phytothermotherapy at the thermal resort of Garniga Terme (Trento, Italy) and the other 26 were considered as controls. All patients were evaluated by FIQ, Tender Points Count, HAQ and AIMS1 at baseline, after 10 days, then after 12 and 24 weeks.*

Results. *Patients submitted to phytothermotherapy showed visible and significant improvement of all evaluation parameters at the end of the treatment, which persisted during the follow-up period. No significant difference was found in the control group. Regarding the tolerability, none of the patients presented side effects.*

Conclusion. *Our results suggest the efficacy and the tolerability of phytothermotherapy in patients with primary FMS.*

Introduction

Fibromyalgia syndrome (FMS) is characterized by generalised musculoskeletal pain, high tender point counts, sleep disturbance, fatigue, headaches, irritable bowel syndrome, frequent psychological distress and depressed mood (1). A variety of medical treatments (antidepressants, opioids, analgesics, sedatives, muscle relaxants, antiepileptics) have been used to treat FMS with little benefit (1). Patients often resort to complementary or alternative therapies (2).

It is a traditional practice in the Alpine region of Trentino and Alto Adige (Italy) to use phytothermotherapeutic treatment with fermenting grass ("hay baths") for rheumatic diseases (3).

The efficacy of phytothermotherapy in rheumatic diseases has been bolstered by ancient tradition. However, despite its long history and popularity, there is a marked lack of clinical validation of its efficacy and tolerability in current literature.

The aim of this study was to assess the efficacy and tolerability of a cycle of phytothermotherapy through a single-blind, controlled, randomized trial in patients with primary FMS.

Materials and methods

Fifty-six females with primary FMS who met the ACR criteria (4) and were aged between 33 and 67 years, with FMS duration of 11-45 months, were included in the study (Table I). All patients had been taking pharmacological therapy for at least 3 months, with poor results, and at baseline they had at least 11 of the 18 tender points specified in the ACR criteria (4).

Exclusion criteria were FMS associated with other diseases and severe co-morbidity of the heart, lung, liver, cerebrum, or kidney, acute illness, juvenile diabetes, varices, systemic blood diseases, asthma or allergies to herbal products, neoplasms, pacemaker, pregnancy or nursing. Patients already submitted to

Table I. Demographic and baseline clinical characteristics of FMS patients subjected to phytothermotherapy (Group I) and control group (Group II) (mean±SD).

	Group I	Group II
N° of patients	30	26
Age (years)	53.20 ± 8.26	48.62 ± 9.37
Sex (F/M)	30/0	26/0
Weight (kg)	66.09 ± 12.13	69.46 ± 6.61
Height (m)	1.65 ± 0.10	1.59 ± 0.09
Disease duration (years)	2.2 ± 1.5	2.51 ± 1.52
FIQ	60.40 ± 8.31	64.89 ± 12.97
Tender points count	14.40 ± 2.03	14.92 ± 1.72
HAQ	0.972 ± 0.342	1.219 ± 0.501
AIMS1	2.32 ± 0.47	2.57 ± 0.82

phytothermotherapy in the year preceding the start of the trial were also excluded.

After confirming fulfilment of the screening criteria as defined above and after obtaining written informed consent, patients were randomized and allocated to two groups: group I (30 patients) submitted to phytothermotherapy at the thermal resort of Garniga Terme (Trento, Italy) and group II, of controls (26 patients).

Group I patients were submitted to 10 generalized daily immersions of 20 min each in warm (50-58°C) hay. The grass used was grown 1200-1500 m above sea level, on Monte Bondone (Trento, Italy). The grass is cut, gathered and transported before it dries to the spa of Garniga Terme, according to traditional methods. At the spa, a 50 cm layer of hay is placed in baths, where fermentation produces heat that reaches a temperature of approximately 60°C in the deepest layers after 1-2 days. The patients are immersed in this fermenting hay and covered with a layer 10-20 cm thick. The cycle comprises 10 baths, with a day of rest after the fifth bath.

Group II continued the pharmacological treatment alone.

All the patients selected came from the area near Garniga Terme and continued to live at home and carry out their daily routines.

All patients were examined and evaluated by an investigator who was not a member of the spa staff and who was blind to the mode of treatment. At baseline, after 10 days, then after 12 and 24 weeks, patients were evaluated using the Fibromyalgia Impact Questionnaire (FIQ) (5), Tender Points Count (determined by digital pressure) (4), Health Assessment Questionnaire (HAQ) (6) and Arthritis Impact Measurement Scales (AIMS1) (7).

Patients were recommended not to modify their pharmacological treatment during the study period, and only paracetamol was administered orally when necessary.

All adverse events were recorded, whether reported spontaneously by the patients or observed by the physicians at the spa, noting the severity and any possible correlations with the therapy. If serious adverse events occurred the patient was excluded from the study.

The study protocol followed the Principles of the Declaration of Helsinki and was approved by the Ethics Committee of the Azienda Ospedaliera Universitaria Senese.

Statistical analysis

Demographic and clinical characteristics are expressed as mean and standard deviation, whereas efficacy evaluation parameters are expressed as the median and interquartile range. In all the hypotheses tested, a *p*-value of less than 0.05 was considered statistically significant.

The comparison between the FIQ, Tender Points Count, HAQ and AIMS1 scores of Group I versus Group II at baseline was performed using the Mann-Whitney W test. For these variables the Friedman test for repeated measures was applied to the two groups, to compare values between each time point. When significant differences were found, the Dunn's post hoc test was performed for multiple comparison between the baseline values and the time point values.

SPSS14.0 software (SPSS Inc. Chicago, Illinois USA) and GraphPad Prism 5.0 software was used.

Table II. Evaluation parameters (median-interquartile range) in FMS patients submitted to phytothermotherapy (Group I) and control group (Group II) during the study.

		Baseline	10 days	Week 12	Week 24	Friedman test
FIQ	Group I	60.86 (53.23-65.37)	43.10 (41.13-48.53)***	47.53 (37.71-58.21)***	44.83 (42.93-49.24)***	$p<0.001$
	Group II	62.38 (56.76-73.99)	67.23 (58.33-71.73)	71.25 (52.07-81.25)	66.01 (52.08-76.28)	
Tender points count	Group I	14 (13-16)	11 (9-14)***	10 (8-14)***	10 (7-12)***	$p<0.001$
	Group II	14 (13.75-16)	16 (14-18)	16 (14-18)	16 (14-18)	
HAQ	Group I	0.870 (0.870-1.120)	0.50 (0.25-0.75)***	0.62 (0.37-0.87)***	0.62 (0.25-0.87)***	$p<0.001$
	Group II	1.25 (0.87-1.50)	1.25 (0.9675-1.403)	1.25 (0.8075-1.593)	1.12 (0.84-1.495)	
AIMS1	Group I	2.22 (2-2.67)	1.78 (1.44-2.11)***	1.78 (1.44-2.11)***	1.44 (1.22-1.89)***	$p<0.001$
	Group II	2.44 (2.053-3.468)	2.66 (2.19-2.883)	2.66 (1.77-3.358)	2.77 (1.88-3.44)	

***$p<0.001$ Dunn's post hoc test.

Results

The primary aim of this study was to evaluate the effects of a cycle of phytothermotherapy in primary FMS.

Data at baseline demonstrated that the clinical pictures were similar in the two groups of patients and no significant differences were observed in the evaluation parameters (Table I).

Patients submitted to phytothermotherapy showed an evident improvement at the end of the cycle of the therapy and all evaluation parameters were significantly reduced in comparison to the baseline (Table II). The improvement remained significant ($p<0.001$) after a follow-up period of 24 weeks (Table II).

No significant changes in the evaluation parameters were observed in the control group: FIQ, Tender Points Counts, HAQ and AIMS1 score remained unchanged throughout the whole follow-up period (Table II).

Regarding the secondary aim of the study – to ascertain the tolerability of phytothermotherapy – no patient reported any exacerbation of symptoms and the hot applications were well tolerated in all cases. None of the patients had localized or generalized intolerance reactions to the grasses contained in the baths.

Discussion

We performed a randomized clinical trial in primary FMS using phytothermotherapeutic treatment with fermenting grass.

Our results show the beneficial effects of a cycle of phytothermotherapy in a group of patients with FMS, who are poor responders to pharmacological treatment. All evaluation parameters were significantly reduced at the end of the treatment cycle and remained stable after 24 weeks in comparison to the baseline. The favourable effects extended to several domains, including pain, fatigue, general health and physical functioning.

The results of our study are in agreement with other trials previously performed with spa therapy and hydrokinesitherapy (8-11), but it is important to underline that a randomized trial on the effects of phytothermotherapy has never before been performed in FMS.

The mechanisms of action of phytothermotherapy are not known, although it is recognised that the effects of phytothermotherapy are, in part, related to temperature. Hot stimuli may influence muscle tone and pain intensity, helping to reduce muscle spasm and to increase the pain threshold in the nerve endings. It has been reported that thermal stimulation increases extensibility of collagen-rich tissues and improves the range of motion of joints (12). Furthermore, thermal stress brings about a significant increase in the serum levels of pituitary hormones and opioid peptides such as endorphins (13). Pituitary activation could be particularly useful in FMS, in which an altered reactivity of the hypothalamic-pituitary-adrenal axis has been observed (14).

These effects of phytothermotherapy on muscle tone, joint mobility and pain intensity may be effective in all the rheumatic diseases characterized by painful symptoms and prolonged muscle tension.

Other effects of phytothermotherapy may be due to the active ingredients contained in the fermenting grasses, which are rich in aromatic species that, aided by vasodilatation, are able to enter the organism in the form of essential oils, terpenes and other aromatic substances (15).

Other specific factors may also contribute to the clinical improvement observed after phytothermotherapy, including the changes in environment, pleasant scenery and the absence of work duties (12). In an attempt to eliminate these factors from our study, however, all patients were resident in areas surrounding the spa and continued their work activities without modifying their lifestyles.

Another aspect that often contributes to amplifying the effect of phytothermotherapy is its frequent association with physio-kinesitherapy. Such treatments were excluded from the protocol of this study.

Finally, despite the poor tolerance of physical treatments by FMS patients, phytothermotherapy was well tolerated in our study and none of the patients withdrew from this therapy.

In conclusion, our results show the beneficial effects of a cycle of phytothermotherapy in a group of patients with FMS, who are poor responders to pharmacological treatments. Phytothermotherapy can therefore represent a useful aid alongside the usual pharmacological and physio-kinesitherapy in FMS patients.

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