ORIGINAL PAPER

Does addition of 'mud-pack and hot pool treatment' to patient education make a difference in fibromyalgia patients? A randomized controlled single blind study

Ali Osman Bağdatlı $^1\cdot$ Arif Donmez $^2\cdot$ Rıza Eröksüz $^2\cdot$ Güler Bahadır $^3\cdot$ Mustafa Turan $^4\cdot$ Nergis Erdoğan 2

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Abstract The aim of this randomized controlled single-blind study is to explore whether addition of mud-pack and hot pool treatments to patient education make a significant difference in short and mild term outcomes of the patients with fibromyalgia. Seventy women with fibromyalgia syndrome were randomly assigned to either balneotherapy with mud-pack and hot pool treatments (35) or control (35) groups. After randomization, five patients from balneotherapy group and five patients from control group were dropped out from the study with different excuses. All patients had 6-h patient education programme about fibromyalgia syndrome and were given a home exercise programme. The patients in balneotherapy group had heated pool treatment at 38 °C for 20 min a day, and mud-pack treatment afterwards on back region at 45 °C. Balneotherapy was applied on weekdays for 2 weeks. All patients continued to take their medical treatment. An investigator who was blinded to the intervention assessed all the patients before and after the treatment, at the first and the third months of follow-up. Outcome measures were FIQ, BDI and both patient's and physician's global assessments. Balneotherapy group was significantly better than control

Arif Donmez donmeza@istanbul.edu.tr

- ¹ Optimed Medical Center, Department of Physical Therapy and Rehabilitation, Salih Omurtak Caddesi No. 58, Çorlu, Tekirdağ, Turkey
- ² Istanbul Medical Faculty, Department of Medical Ecology and Hydroclimatology, Istanbul University, Istanbul, Turkey
- ³ Istanbul Medical Faculty, Department of Psychiatry Capa, Istanbul University, Istanbul, Turkey
- ⁴ Department of Medical Ecology and Hydroclimatology, Gulhane Military School of Medicine, Etlik, Ankara 06018, Turkey

group at after the treatment and at the end of the first month follow-up assessments in terms of patient's and physician's global assessment, total FIQ score, and pain intensity, fatigue, non-refreshed awaking, stiffness, anxiety and depression subscales of FIQ. No significant difference was found between the groups in terms of BDI scores. It is concluded that patient education combined with 2 weeks balneotherapy application has more beneficial effects in patients with fibromyalgia syndrome as compared to patient education alone.

Keywords Balneotherapy \cdot Mud pack \cdot Hydrotherapy \cdot Fibromyalgia syndrome \cdot Chronic pain \cdot Patient education

Introduction and aim of the study

Fibromyalgia syndrome is a chronic pain syndrome. The most prominent symptoms include widespread musculoskeletal pain, fatigue, stiffness, anxiety, depression, difficulties in the daily living activities and sleep disturbances. Its prevalence in the overall population is 2 %; it is more common in women with a prevalence rate of 3.4 % where it is only 0.5 % in men (Wolfe et al. 1995).

Several medications and non-pharmacological approaches are used to relieve the symptoms of fibromyalgia syndrome; however, its radical treatment is not known to date. Pharmacological treatment alternatives include analgesics, non-steroidal anti-inflammatory drugs, antidepressants and anti-epileptics. Patient education, exercise, hot and cold applications and balneotherapy are commonly used non-pharmacological, complementary treatments (Oral et al. 2013; Carville et al. 2008). Patient education (Eich et al. 2012) and exercise (Busch et al. 2007) are highly recommended nonpharmacological modalities in fibromyalgia. The results of recently published studies indicate that balneotherapeutic applications, such as immersions and mud-pack applications, are effective on the symptoms of fibromyalgia syndrome (Buskila et al. 2001; Evcik et al. 2002; Donmez et al. 2005; Ozkurt et al. 2012; Kesiktas et al. 2011; Fioravanti et al. 2007).

The aim of this study is to find out whether addition of mudpack and hot pool treatments to patient education would be more beneficial for fibromyalgia patients in short and mild term.

Patients and methods

The study was designed as a single blind, randomized controlled study. The study was conducted at İstanbul University, İstanbul Medical Faculty, Department of Medical Ecology and Hydroclimatology. Two hundred and fifty-two fibromyalgia patients, who were registered at the outpatient clinic, were constituted the universe of the study. All registered patients were informed about the study and invited to participate in the study through telephone call. Three of the authors (AD, RE and NE) evaluated the volunteered patients regarding the study criteria and enrolled seventy female fibromyalgia patients conforming the inclusion criteria and gave their informed consent.

Inclusion criteria The female patients should meet the American College of Rheumatology criteria for fibromyalgia and between 20 and 65 years of age (Wolfe et al. 2010). They should have had their usual treatment for at least2 months, without any modification. Participants have received sufficient explanation on the objectives, method and meaning of this study and grant their voluntary consent in writing.

Exclusion criteria The patients should not have any medical condition that may prevent them from having balneotherapy and have had balneotherapy within past 1 year. The study project was approved by the local ethical committee of Istanbul Medical Faculty on 9th of February 2011.

All patients underwent physical examination. A series of laboratory tests including complete blood count, ESR, hepatic and renal function tests, thyroid hormone levels and urine analysis were ordered to reveal an additional pathology that may require to exclude the patients from the study.

One of the authors (AD) randomized the patients, by using SPSS software generated randomization table, into two groups as balneotherapy group (35 patients) and controls (35 patients). Five patients in the balneotherapy group (3 of them because of time management problems, 1 of them because of her spouse's illness, and 1 of them declared no reason) and 5 patients in the control group (4 of them declared that they wanted to go to the spa centre immediately, and 1 of them declared no reason) left the study after randomization.

A 6-h patient education programme on fibromyalgia syndrome was provided to all patients participating in the study. Patient education programme was delivered in 2 days, three interactive classes each day. First day's programme included theoretical information on symptoms of fibromyalgia syndrome and prescription of individualized exercise programmes which includes stretching, relaxing, and posture exercises. At the second day, a psychologist thought the patients how stressing conditions may affect the disease and trained them how to coping with stress and on the use of relaxation techniques. Patient education programme was performed by two doctors, one physiotherapist and one psychologist.

Thirty-five patients in balneotherapy group had 10 heated pool baths and 10 mud-pack applications at the Department of Medical Ecology and Hydroclimatology. Temperature of the heated pool was 38 °C, and the duration of baths was 20 min. Immediately after the immersion, peloid packs at 45 °C were applied to backs of the patients for 20 min. The mud-pack used for application was a ready to use, single-use clay. Total mineralization of the mud was 3406 mg/L. The applications were performed for 2 weeks in weekdays.

Thirty-five patients at the control group were continued to have their treatment programme previously prescribed for their pain complaints due to fibromyalgia.

The same physician (RE), who was blinded to the treatment arms, evaluated all patients included in the study for four times: before the treatment, immediately after the treatment, and at the end of the 1st and the 3rd months after the treatment.

Evaluation parameters were Patient's Global Assessment (PGASc) Investigator's Global Assessment Score (IGASc), Fibromyalgia Impact Questionnaire (FIQ), pain, fatigue, nonrefreshing sleep, stiffness, anxiety, depression and Beck Depression Index (BDI) (Burckhardt et al. 1991; Beck et al. 1961).

Statistical methods

Statistical evaluations were performed on intention-to-treat basis. Statistical calculations are performed using commercially available statistical software (SPSS ver.11.5, SPSS Inc., Chicago, USA). Assignment of the patients into the treatment arms is done by random assignment of patient admission numbers into two groups equally using the software's grouping function. Demographic data are expressed as the mean and SD. Distribution of the data was evaluated using Shapiro-Wilk test. Normally distributed data were compared using Student's *t* test. Friedman test and Mann Whitney *U* tests were used for multiple comparisons and two group comparisons, respectively, where the data distribution was non-parametric. Degree of freedom for alpha was set to 0.05 in all calculations. Calculated *p* values less than 0.05 were accepted as statistically significant.

Results

Seventy women with fibromyalgia who met the criteria according to the American College of Rheumatology were included in





the study. Ten patients left the study after randomization (Fig. 1). The study was performed between February and December

2011. Balneotherapy and control groups were similar in terms of demographic features at the beginning of study (Table 1).

Table 1Demographiccharacteristic of the patients

	Balneotherapy group $(n=35)$	Control group ($n=35$)
Sex	35 Women	35 Women
Age (years) (mean±SD)	45.17±9.09	42.77 ± 9.59
Durations of symptoms (years) (mean±SD)	$8.83 {\pm} 4.74$	8.37±5.49
Height (cm) (mean±SD)	161.88 ± 6.63	159.65 ± 5.69
Weight (kg) (mean±SD)	69.46±13.32	$63.31 {\pm} 10.19$
BMI	26.62 ± 5.59	24.82 ± 3.69
Education duration (years) (mean±SD)	$9.77 {\pm} 4.48$	8.83 ± 3.82
Married	30	31
Divorced or single	5	4
Occupational status	25 Housewife	25 Housewife
	10 Employed	10 Employed
Number of patients under antidepressant therapy	14	12
Amitriptyline	8	6
Escitalopram oxalate	2	2
Fluoxetine hydrochloride	1	—
Sertraline hydrochloride	1	—
Paroxetine hydrochloride	-	1
Venlafaxine hydrochloride	1	2
Duloxetine hydrochloride	1	1

	Before treatment mean±SD	After treatment mean±SD	At the end of 1st month mean±SD	At the end of 3 months mean±SD	x ^{2 a}	р
Balneotherapy group (35)						
Pain	6.60 ± 1.85	4.25±2.16	4.71±2.12	4.97±2.24	29.30	< 0.001
IGASc	$4.74 {\pm} 0.98$	5.82±1.63	5.40 ± 1.94	5.91±1.75	17.42	0.001
PGASc	4.28 ± 1.36	6.20 ± 1.96	5.71 ± 2.32	5.82 ± 2.06	28.84	< 0.001
FIQ	51.20 ± 10.35	31.62±14.29	37.91±15.71	40.18 ± 14.46	33.26	< 0.001
Fatigue	$7.48 {\pm} 2.04$	$4.80{\pm}2.45$	5.22 ± 2.64	$5.97 {\pm} 2.56$	27.87	< 0.001
Non-refreshing sleep	$7.88 {\pm} 1.56$	$4.74{\pm}2.47$	$4.82{\pm}2.81$	$5.80 {\pm} 2.28$	34.86	< 0.001
Stiffness	$6.00{\pm}2.97$	$3.34{\pm}2.56$	3.97±2.79	4.57±2.97	25.51	< 0.001
Anxiety	$7.28 {\pm} 1.91$	$4.11 {\pm} 2.70$	$4.77 {\pm} 2.98$	4.62 ± 2.72	27.17	< 0.001
Depression	$5.65 {\pm} 2.58$	3.25 ± 2.38	$3.57{\pm}2.58$	3.91±2.83	18.81	< 0.001
BDI	16.60 ± 6.85	12.80 ± 8.13	12.65 ± 8.18	11.97 ± 8.06	16.45	< 0.001

 Table 2
 Comparison of the evaluation results before, after completion, after 1 month, and after 3 months of intervention in balneotherapy group

IGASc Investigator's Global Assessment Score, PGASc Patient's Global Assessment Score, FIQ Fibromyalgia Impact Questionnaire, BDI Beck's Depression Inventory

^a Friedman test

Significant improvements persisted up to the end of the 3rd month assessments in patient's and investigator's global assessment scores, total FIQ score, and pain intensity, fatigue, non-refreshed awaking, stiffness, anxiety and depression subscales of FIQ and BDI as compared to baseline values in balneotherapy group (Table 2).

Control group showed significant improvements in similar outcome measures except in patient's global assessment scores and stiffness parameters (Table 3).

The differences from the baseline were calculated for each study variable in both groups. It was found that observed differences from the baseline are greater in balneotherapy group in pain, FIQ, tiredness, non-refreshing sleep, stiffness, anxiety, depression patient's and investigator's global assessment scores at the 15th day and at the end of the 1st month evaluation. No significant difference was found in BDI score (Table 4).

None of patients experienced thermal crisis that would require the cease of treatment. No side-effect was observed during treatment.

Discussion

The present study is a randomized controlled trial performed in an outpatient hospital setting using balneotherapy including

Table 3	Comparison	of the e	evaluation	results	before,	after co	npletion	, after	1 month,	and after	3 months	s of inte	rvention	in contr	ol grou	p
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Week 0 mean±SD	Week 2 mean±SD	At the end of 1st month mean±SD	At the end of 3rd months mean±SD	x ^{2 a}	р
6.22±1.75	5.45±1.96	$6.00{\pm}1.59$	4.97±1.87	9.58	0.023
5.17±1.20	4.31±1.62	$4.94{\pm}1.47$	5.68±1.64	14.69	0.002
4.74±1.44	4.54±1.85	$5.14{\pm}1.76$	5.62±1.75	4.78	0.188
49.83±13.51	47.06±13.03	45.81±11.44	42.34±14.24	15.55	0.001
6.91±2.02	6.71±1.65	6.45 ± 1.66	$5.80{\pm}1.96$	15.27	0.002
$7.02{\pm}2.14$	6.45±2.16	6.42±1.66	$6.11{\pm}2.08$	8.17	0.043
$4.76 {\pm} 2.80$	4.67±2.70	4.58±2.43	4.58±2.51	0.46	0.926
6.71±2.37	5.42 ± 2.81	5.31±2.48	5.22 ± 2.48	17.96	< 0.001
5.45 ± 2.46	5.00 ± 3.06	4.57±2.64	4.57±2.72	9.66	0.022
15.60 ± 7.07	14.71 ± 7.36	13.74 ± 7.06	11.31 ± 5.42	19.95	< 0.001
	Week 0 mean±SD 6.22±1.75 5.17±1.20 4.74±1.44 49.83±13.51 6.91±2.02 7.02±2.14 4.76±2.80 6.71±2.37 5.45±2.46 15.60±7.07	Week 0 mean \pm SDWeek 2 mean \pm SD 6.22 ± 1.75 5.45 ± 1.96 5.17 ± 1.20 4.31 ± 1.62 4.74 ± 1.44 4.54 ± 1.85 49.83 ± 13.51 47.06 ± 13.03 6.91 ± 2.02 6.71 ± 1.65 7.02 ± 2.14 6.45 ± 2.16 4.76 ± 2.80 4.67 ± 2.70 6.71 ± 2.37 5.42 ± 2.81 5.45 ± 2.46 5.00 ± 3.06 15.60 ± 7.07 14.71 ± 7.36	Week 0 mean \pm SDWeek 2 mean \pm SDAt the end of 1st month mean \pm SD 6.22 ± 1.75 5.45 ± 1.96 6.00 ± 1.59 5.17 ± 1.20 4.31 ± 1.62 4.94 ± 1.47 4.74 ± 1.44 4.54 ± 1.85 5.14 ± 1.76 49.83 ± 13.51 47.06 ± 13.03 45.81 ± 11.44 6.91 ± 2.02 6.71 ± 1.65 6.42 ± 1.66 7.02 ± 2.14 6.45 ± 2.16 6.42 ± 1.66 4.76 ± 2.80 4.67 ± 2.70 4.58 ± 2.43 6.71 ± 2.37 5.42 ± 2.81 5.31 ± 2.48 5.45 ± 2.46 5.00 ± 3.06 4.57 ± 2.64 15.60 ± 7.07 14.71 ± 7.36 13.74 ± 7.06	Week 0 mean \pm SDWeek 2 mean \pm SDAt the end of 1st month mean \pm SDAt the end of 3rd months mean \pm SD 6.22 ± 1.75 5.45 ± 1.96 6.00 ± 1.59 4.97 ± 1.87 5.17 ± 1.20 4.31 ± 1.62 4.94 ± 1.47 5.68 ± 1.64 4.74 ± 1.44 4.54 ± 1.85 5.14 ± 1.76 5.62 ± 1.75 49.83 ± 13.51 47.06 ± 13.03 45.81 ± 11.44 42.34 ± 14.24 6.91 ± 2.02 6.71 ± 1.65 6.42 ± 1.66 5.80 ± 1.96 7.02 ± 2.14 6.45 ± 2.16 6.42 ± 1.66 6.11 ± 2.08 4.76 ± 2.80 4.67 ± 2.70 4.58 ± 2.43 4.58 ± 2.51 6.71 ± 2.37 5.42 ± 2.81 5.31 ± 2.48 5.22 ± 2.48 5.45 ± 2.46 5.00 ± 3.06 4.57 ± 2.64 4.57 ± 2.72 15.60 ± 7.07 14.71 ± 7.36 13.74 ± 7.06 11.31 ± 5.42	Week 0 mean±SDWeek 2 mean±SDAt the end of 1st month mean±SDAt the end of 3rd months mean±SD x^{2a} 6.22 ± 1.75 5.45 ± 1.96 6.00 ± 1.59 4.97 ± 1.87 9.58 5.17 ± 1.20 4.31 ± 1.62 4.94 ± 1.47 5.68 ± 1.64 14.69 4.74 ± 1.44 4.54 ± 1.85 5.14 ± 1.76 5.62 ± 1.75 4.78 49.83 ± 13.51 47.06 ± 13.03 45.81 ± 11.44 42.34 ± 14.24 15.55 6.91 ± 2.02 6.71 ± 1.65 6.42 ± 1.66 5.80 ± 1.96 15.27 7.02 ± 2.14 6.45 ± 2.16 6.42 ± 1.66 6.11 ± 2.08 8.17 4.76 ± 2.80 4.67 ± 2.70 4.58 ± 2.43 4.58 ± 2.51 0.46 6.71 ± 2.37 5.42 ± 2.81 5.31 ± 2.48 5.22 ± 2.48 17.96 5.45 ± 2.46 5.00 ± 3.06 4.57 ± 2.64 4.57 ± 2.72 9.66 15.60 ± 7.07 14.71 ± 7.36 13.74 ± 7.06 11.31 ± 5.42 19.95

IGASc Investigator's Global Assessment Score, PGASc Patient's Global Assessment Score, FIQ Fibromyalgia Impact Questionnaire, BDI Beck's Depression Inventory

^a Friedman test

mud packs, heated pool treatment and patient education in patients with fibromyalgia. In this study, balneotherapy group was found to be superior at the 15th day and at the end of the first month assessments regarding pain intensity, patient's and investigator's global assessment, fatigue, non-refreshing sleep, stiffness, anxiety, depression and FIQ scores. This superiority continued until the end of the third month assessment in non-refreshing sleep.

Randomized controlled trials and recent systematic review and meta-analysis reports indicate that balneotherapy has positive effects in fibromyalgia syndrome patients in terms of pain intensity, FIQ scores, patients' and investigator's global assessment (Falagas et al. 2009; Mc Veigh et al. 2008; Langhorst et al. 2009; Fraioli et al. 2013). However, authors of these studies are anonymously agreed that there is a need for more randomized controlled trials focused on this subject.

Patient education, heated pool treatment, balneotherapy and therapeutic exercises are advised in the section of nonpharmacologic treatment of FMS in the Guidelines for Fibromyalgia Treatment (Carville et al. 2008; Buckhardt et al. 2005; Arnold et al. 2012; Häuser et al. 2010). Therefore, these therapeutic approaches are included in the present study.

Our study results are in agreement with the findings stated in systematic reviews. As distinct from the other balneological studies on fibromyalgia, the present study is carried out at outpatient basis at the tertiary hospital environment rather than a spa centre. Therefore, the patients didn't have to change their daily living routines. Both patient groups included in the study

	Group	Weeks 0-2	Week 0-1 month	Week 0-3 months
Pain	Balneotherapy	2.34±2.11	1.89±2.36	1.63±2.65
	Control	0.77±2.24	0.23±1.86	1.26±2.34
	р	0.002**	0.002**	0.525
IGASc	Balneotherapy	-1.09 ± 1.65	-0.66 ± 1.80	-1.17 ± 1.84
	Control	0.86 ± 1.63	0.23±1.68	-0.51 ± 1.98
	р	<0.001**	0.046*	0.223
PGASc	Balneotherapy	-1.91 ± 1.88	-1.43 ± 2.10	$-1.54{\pm}1.85$
	Control	0.20 ± 1.86	$-0.40{\pm}2.02$	-0.89 ± 2.05
	р	<0.001**	0.030*	0.116
FIQ	Balneotherapy	19.58±13.62	13.29 ± 15.90	11.02 ± 15.45
	Control	2.77±9.39	4.03±11.15	7.49±13.95
	р	<0.001**	0.006**	0.455
Fatigue	Balneotherapy	2.69 ± 2.73	2.26 ± 3.05	1.51±2.44
	Control	0.20±1.35	0.46±1.82	1.11 ± 1.78
	р	<0.001**	0.007*	0.423
Non-refreshing sleep	Balneotherapy	$3.14{\pm}2.68$	3.06 ± 3.18	2.09 ± 2.88
	Control	$0.57 {\pm} 1.87$	$0.60{\pm}2.00$	0.91 ± 1.95
	р	<0.001**	<0.001**	0.051
Stiffness	Balneotherapy	2.66 ± 2.78	2.03 ± 3.50	1.43 ± 2.58
	Control	0.09 ± 2.36	0.17±2.23	0.17±2.65
	р	<0.001**	0.008**	0.058
Anxiety	Balneotherapy	3.17±2.71	2.51 ± 3.48	2.66 ± 3.47
	Control	1.29 ± 2.58	$1.40{\pm}2.59$	$1.49{\pm}2.50$
	р	0.003**	0.092	0.192
Depression	Balneotherapy	2.40 ± 3.17	2.09 ± 3.82	1.74 ± 3.76
	Control	$0.46 {\pm} 2.72$	$0.89{\pm}2.61$	$0.89 {\pm} 2.70$
	р	0.005**	0.103	0.336
BDI	Balneotherapy	$3.80{\pm}7.47$	$3.94{\pm}6.74$	4.76±7.83
	Control	1.20 ± 5.72	2.17±6.99	4.29±6.56
	р	0.133	0.296	0.873

p*<0.05, *p*<0.01

IGASc Investigator's Global Assessment Score, *PGASc* Patient's Global Assessment Score, *FIQ* Fibromyalgia Impact Questionnaire, *BDI* Beck's Depression Inventory

Table 4Comparisons ofbalneotherapy and control groupsin terms of differences from thebaseline (Mann Whitney U test)

had similar patient education and home exercise programmes. We believe that observed improvements in control group are related to patient education and exercise programme. Additionally, the patients in balneotherapy group had heated pool treatment and mud pack applications.

Multidisciplinary treatment programmes including different types of non-pharmacological therapies are accepted more effective for fibromyalgia. Combination of spa therapy and patient education improves symptoms and quality of life patients with fibromyalgia (Zijlstra et al. 2005).

The effects of mud packs and heated pool help to relieve muscle spasm with thermal stimuli. Application of mud pack and heated pool decrease the muscle tone and increase the pain threshold at the nerve endings accordingly. Gate-control theory may explain pain-relieving effect of balneotherapy. Body surface of the patient is stimulated during immersion by temperature and hydrostatic pressure of hot water and sensation of pain decrease because of these stimuli, according to the theory. In addition to these effects, hot mineral water baths and mud-pack therapy increases plasma endorphin and cortisol levels, activation of the diencephalicpituitary-adrenal axis, and decreases in plasma levels of several inflammatory mediators (IL-1, IL-6, PGE2, LTB4, TNF- α) (Fraioli et al. 2013; Cozzi et al. 1995; Ardiç et al. 2007; Fioravanti et al. 2011)

Considering both groups continued to live in their usual environment, observed superiority of the balneotherapy group in pain intensity, FIQ scores, patients' and physicians' global assessment may not be attributed to rest and environmental changes. It is better to argue that observed superiority may be due to heated pool and peloid pack applications. In the literature, it was frequently discussed whether environmental changes contribute to the positive effects of balneotherapy. Fibromyalgia patients may felt relaxed simply because they are away from their usual environment. Tubergen suggested that certain nonspecific variables of the spa environment such as environmental change, pleasant scenery, being in a non-competitive atmosphere with fellow patients, and the absence of work duties may be beneficial for patients with fibromyalgia (van Tubergen and Hidding 2002).

The present study has few limitations. The main limitation is the small number of patients included in the study, and one may criticize the short duration of follow-up period. Our budget hindered us from including more patients and to limit the follow-up period with 3 months.

In conclusion, balneotherapy with mud-pack and hot pool treatments is found to be effective in treating patients with fibromyalgia. Beneficial effects are observed both in short and mid-terms. Further randomized controlled studies should be designed to verify these results and to identify whether balneotherapy is cost-effective in fibromyalgia treatment.

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