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ORIGINAL ARTICLE

Treatment of fibromyalgia at the Maharishi Ayurveda Health Centre in Norway II—a 24-month follow-up pilot study

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Abstract Treatments offered at the Maharishi Ayurveda Health Centre in Norway are based on Maharishi Vedic Medicine (MVM). MVM is a consciousness-based revival by Maharishi Mahesh Yogi, the founder of the Transcendental Meditation (TM) program of the ancient Ayurvedic medicine tradition in India. To extend from 6 to 24 months, a pilot study of the effects of the treatment program at the Health Centre on fibromyalgia. Retesting 2 years after a clinical trial. In this intention to treat study, 31 women with a diagnosis of fibromyalgia received an individually tailored program of (1) physiological purification therapy (Maharishi Panchakarma) and (2) Ayurvedic recommendations regarding daily routine and diet including a novel approach to food intolerance. Five subjects chose to learn TM for stress reduction, pain management and personal development. All were recommended Ayurvedic herbal products for follow-up treatment. A modified Fibromyalgia Impact Questionnaire (FIQ) that included seven dimensions. Scores at 24 months follow-up were compared with pre-treatment scores. At 24-months follow-up, there were significant reductions (26% to 44%) in six of the seven fibromyalgia dimensions: impairment of working ability, pain, tiredness, morning tiredness, stiffness and anxiety. The 7th, depression, decreased 32% (borderline significant). At 24 months, the four subjects who continued practising TM, had almost no symptoms and significantly lower FIQ change scores (−92% to 97%) than the non-meditators on all outcomes. This pilot study suggests that the treatments and health promotion programs offered at the Maharishi Ayurveda Health Centre in Norway lead to long-term reductions in symptoms of fibromyalgia, which is considered a treatment-resistant condition, and further studies are warranted.

Keywords Alternative treatment · Ayurveda · Complementary treatment · Fibromyalgia · Transcendental Meditation

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Introduction

Treatments offered at the Maharishi Ayurveda Health Centre in Norway are based on Maharishi Vedic Medicine (MVM; also known as Maharishi Ayurveda). MVM is a consciousness-based revival of the ancient Ayurvedic medicine tradition in India. MVM was established over the last

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50 years by Maharishi Mahesh Yogi, a Vedic scholar and the founder of the Transcendental Meditation (TM) program.

MVM offers a range of treatment and life-supporting modalities based on the 40 branches of the Vedic literature, including Ayurveda. Two of these strategies are the TM technique and the Maharishi Vedic physiological purification program (Panchakarma) [1]. MVM extends the frame of Ayurveda by recognising that the mind and body have their basis in a level of consciousness said to transcend time and space, a level known as pure consciousness. This level of consciousness is considered to be primary for all existence and thus it is primary for the structure and functioning of the individual mind–body [2]. The TM technique is a strategy for the development of consciousness. It is easy to learn and involves neither concentration nor contemplation. During the practice, the mind experiences a thought at more and more subtle levels until the subtlest level of the thought is experienced and transcended. The mind thereby gains the direct experience of pure consciousness. Since the teaching and the verification of the practice of the TM technique is standardised at TM Centres world-wide, the technique has been subjected to extensive research covering a wide range of health issues [3].

Maharishi Ayurveda Health Centres have been established in many countries around the world, and at the health centre in Mesnali, Norway, much experience has been gained in the treatment of fibromyalgia (FM) patients [4, 5].

The pathogenesis of FM is far from being understood and there has not yet been any breakthrough in the treatment of the condition, in spite of it being a rapidly growing area of research on a wide range of treatment modalities [6]. We recently reported the results of a 6-month follow-up study that showed statistically significant improvements in most outcome measures included in the Fibromyalgia Impact Questionnaire [5]. The aim of the present study was to evaluate the longer-term effects of the treatment program—after 24 months.

Materials and methods

Subjects participated in a purification program, the Maharishi Panchakarma program, that included a range of full body herbalised oil massages (abhyanga, vishesh, pizzichili), "swedana" (herbalised steam bath), "shirodhara" (the streaming of oil on the forehead) and the administration of "bastis" (Ayurvedic enemas).

An integral part of the program was the daily assessment of each participant's condition using Ayurvedic pulse diagnosis. According to MVM, a holistic understanding of the functioning of the mind–body is gained through the pulse reading technique known as "Maharishi Nadivigyan". The treatment program was adjusted daily, in accord with the pulse analysis (performed by LBR). During their stay, the participants were offered an MVM-based health education program along with instruction in the TM technique (to be practised twice a day for 20 min/session) for stress reduction, pain management and personal development.

Prior to the treatment program at the health centre, all the participants underwent an individually-tailored pre-treatment program for 7–9 days at home that included the intake of clarified butter in the morning for some days followed by a laxative treatment. They also received guidelines for establishing a diet of easily digested food and a stress reducing-lifestyle. These guidelines were to be followed for 2 weeks post-treatment. At the end of the treatment period, participants received personalised advice on (1) diet based on Ayurvedic principles, (2) daily routines and (3) Ayurvedic herbal products (including Triphala Plus, Livogard and Fibrozan (Table 1)) that was intended to be easily integrated into their daily lives on returning home.

At the health centre, a novel approach to food intolerance is used. This approach, which is also a consciousness-based strategy, is believed to identify food items that have a negative effect on the health of a specific individual and thus are incompatible with the mind–body. Incompatible items identified by this approach include foods processed in a particular way or foods that contain synthetic additives, as well as pharmaceutical products, toothpastes (including Ayurvedic ones) and herbal products. However, some of these foods have been found to become compatible either due to the treatment offered by the health centre or by adding specific spices in the cooking or baking process. The adding of specific spices is believed to transform the food items during the cooking process, due to the influence of chemical substances in the spices.

Patients were advised to avoid ingestion of specific foods or other products that were determined to be incompatible for them.

Thirty-three consecutive subjects seeking treatment at the Maharishi Ayurveda Health Centre for widespread, chronic pain volunteered to participate in a 24-month follow-up study. Participants were enrolled in the study between November 2005 and March 2006. A clinical examination was performed just prior to the start of the treatment by a rheumatologist (KM in most cases). Two did not meet the requirements for a FM diagnosis based on the Boston criteria [7] and were excluded. The remaining 31 subjects were women aged 33 to 74 years (mean, 46 years). Disease duration was 3–42 years (mean, 16 years). One subject underwent treatment for 3 days, 11 for 5 days and 19 for 7 days. One subject had previously learned the TM technique but had not practised it for 7 years prior to the onset of her FM symptoms. She resumed the practice during her stay at the clinic, and four other subjects received instruction in the technique.

Table 1 Content of some Maharishi Ayurveda herbal products

Name of ingredients contained in Livogard	Composition in %
Terminalia chebula	12
Andographis paniculata	9
Curcuma longa	8
Zingiber officinale	8
Trigonella foenum-graecum	8
Swertia chirata	8
Carum copticum	8
Piper longum	4
Myristica fragans	4
Lotus arabicus	4
Ferri oxidum	4
Boswellia serrata	4
Cypraea moneta	4
Terminalia belerica	4
Emblica officinalis	4
Excipients	7
Name of ingredients contained in Triphala Plus	
E. officinalis	35
T. chebula	35
T. belerica	19
Rosa centifolia	8
Excipients	3
Name of ingredients contained in Fibrozan	
B. serrata	11
Commiphora mukul	11
Asphaltum	9
Z. officinale	9
C. copticum	9
P. longum	9
Piper nigrum	9
Allium sativum	5
Hemidesmus indicus	5
Cinnamomum tamala	5
Carum carvi	5
F. oxidum	3
Mytilus margaritiferus	3
Piper chava	1
P. longum	1
Excipients	7

We used the intention to treat method to handle drop outs; the least registered value was used. Five subjects dropped out of the study—all without giving any explicit reason. Two of the five subjects completed the 1 month follow-up—the first reporting a moderate improvement and the second (after only 3 days of treatment) a moderate worsening. The latter dropped out after experiencing mouth ulcers along with both mouth dryness and at times excessive salivation. These symptoms ceased upon withdrawal of the herbal product that she was using and were experienced again when the product later was taken. The third drop out, was one of the five participants who started practising the TM technique, but declined any further follow-up after treatment. The 4th and the 5th drop-outs left the study after completing 6 months of follow-up (see Fig. 1).

The Fibromyalgia Impact Questionnaire (FIQ) is not validated in the Norwegian language. This American questionnaire includes a set of seven Visual Analogue Scales (VAS)—each scale represented by a line that is 9.3 cm long. Five scales relate to the body: limitations caused by FM on working ability, pain, tiredness, stiffness and tiredness on rising in the morning. Two scales relate to the mind: anxiety and depression. A modified questionnaire was designed with scales 10 cm in length. The VAS for pain was replaced with a new scale in order to differentiate between local and generalised pain—the latter being used as the outcome measure. The participants were asked to evaluate their condition as a whole for the last 7 days and indicate their score for each measure with a mark on the line. A mark to the extreme left of the scale indicated no problems at all and a mark to the extreme right indicated the worst imaginable condition. In addition, participants evaluated the performance of their daily activities by answering questions similar to those in the FIQ.

The participants filled out the questionnaires in private just prior to the start of the treatment at the health centre. Questionnaires were also filled out at home at one, 3 and 6 months post-treatment [5] and again at 24 months post-treatment. Scores were calculated by the distance, in centimetres (to an accuracy of one decimal place), from 0 to the participant's mark on the VAS. For four of the five drop-outs, the least score from each of the seven scales from at least one follow-up was taken as the outcome measure.

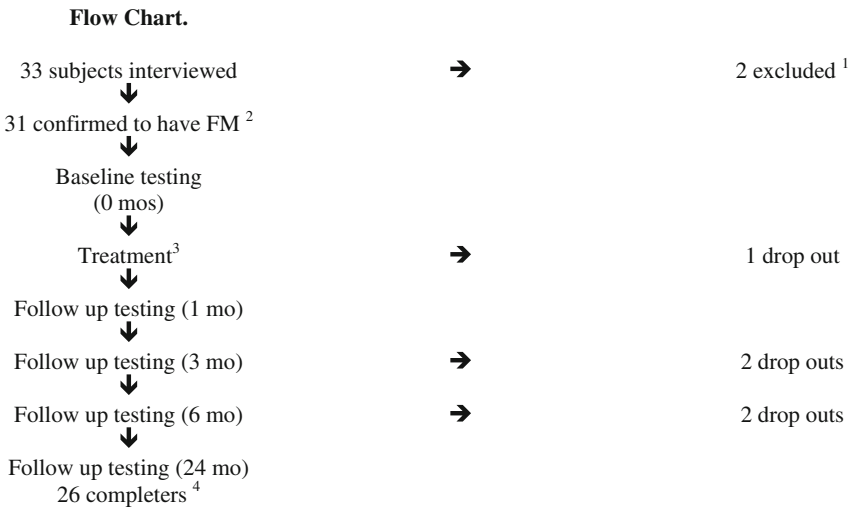
The first three participants to enrol completed a questionnaire at entry that was a copy of the American questionnaire. Their scores were later transformed to corresponding scores on the 10-cm scale.

A paired sample *t* test was used to compare outcome measures at study entry and at 24-month follow-up. A Mann–Whitney *U* test was used to analyse differences in outcome measures between the TM + Panchakarma group (n=4) and the Panchakarma-only group (n=26). Cluster analysis using the Square Euclidian Distance was used to identify a group of good responders. SPSS 15.0 was used for all analyses.

Results

1. Decreases in symptoms between baseline and 24 months ranged from −44% for pain to −26% for anxiety. Across

Fig. 1 Flow chart



[1] They did not meet clinical criteria for Fibromyalgia (FM). [2] Four subjects learned and practiced TM. One subject had learned TM previously but had not practiced it for years; she resumed practicing it at the beginning of the study. [3] Physiological purification treatments (Panchakarma [PK]) + recommendations regarding daily routine and herbs. [4] Of the 26 completers, 4 practiced TM and 22 did not.

the seven domains of the FIQ, the average decrease in scores was 33% (it had been 37% at the 6-month follow-up). All decreases were statistically significant compared with baseline (Table 2) except for depression. Depression had an effect size in the same range (−32%) but only borderline significance (p=0.062).

2. Changes in symptoms at the 24-month follow-up compared with scores at the 1-month follow-up showed non-significant increases on all subscales but one, ranging from 0% (depression) to +25% (morning tiredness) with an average increase of +11%. Changes in symptoms at the 24-month follow-up compared with scores at the 6-month follow-up showed both decreases and increases on the various FIQ subscales. The changes, which were non-significant, ranged from −8% (pain) to +14% (working ability) with an average increase of 5%.
3. A good responder was defined as a subject, who reported a minimum reduction of 50% on all five body scales. An excellent responder was defined as a subject who reported that all end point scores were less than 1.0. The two regular TM practitioners were classified as excellent responders reporting end-point scores that were all less than 0.3. One reduced her total sum of scores from 47.0 at baseline to 1.1; the other decreased from 11.9 to 0.8. The other two TM practitioners (one was irregular in practise and the other stopped after 3 months of practise) were almost excellent responders, reporting low end-point scores on all scales except for stiffness (which slightly exceeded 1.0). They reduced their total sum of scores from 42.5 to 3.8 and 50.8 to 3.9. These two subgroups experienced, at 24 months, a 92% to 98% decrease in total sum of scores (Table 3). No other participants improved to such a degree. A

Table 2 Pre-post-changes in fibromyalgia-related outcomes

Outcome measures of the FIQ	Number	Mean of outcomes at entry	Mean of outcomes at 24 months	Difference between means	95% confidence interval		p value
					Lower limit	Upper limit	
Working ability	28	5.9	4.2	1.7	0.5	3.0	0.008
Pain	30	6.6	3.7	2.9	1.8	4.0	0.000
Tiredness	30	6.9	4.9	2.0	0.7	3.2	0.003
Morning tiredness	30	7.2	4.8	2.4	1.2	3.7	0.001
Stiffness	30	6.2	4.0	2.2	1.0	3.5	0.001
Anxiety	30	3.9	2.9	1.0	0.0	2.0	0.043
Depression	30	3.7	2.5	1.2	−0.1	2.5	0.062

Paired samples tests were used to determine the difference in mean values of outcome measures between entry and 24 months follow-up

Table 3 Outcome measures before 3–6 days of treatment at the Maharishi Ayurveda Health Centre, Norway, and after 24 months follow-up in a group learning and practicing TM and in a control group not learning or practicing TM

Outcome measures of FIQ	TM group (n=4)		Non-TM group (n=26)	
	At entry median (range)	At 24 months median (range)	At entry median (range)	At 24 months median (range)
Working ability	6.1 (0.4–7.6)	0.2 (0.1–0.3)***	7.0 (0.1–9.7)	4.6 (0.2–10)
Pain	6.5 (4.5–8.4)	0.5 (0.1–0.7)***	6.7 (2.9–10)	3.6 (0.7–10)
Tiredness	7.7 (2.3–8.2)	0.3 (0.2–0.7)***	7.4 (1.2–10)	6.2 (0.2–9.9)
Morning tiredness	4.5 (0.1–8.8)	0.2 (0.1–0.5)***	7.5 (1.1–10)	6.3 (0.5–9.0)
Stiffness	8.4 (3.7–9.4)	0.6 (0.1–1.5)***	5.3 (2.9–9.3)	4.3 (0.5–10)
Anxiety	3.8 (0.1–5.9)	0.1 (0.0–1.0)*	4.1 (0–9.5)	3.9 (0.0–8.3)
Depression	3.1 (0.1–6.7)	0.1 (0.0–0.1)**	3.0 (0.0–8.4)	2.6 (0.0–9.0)

*p<0.05; **p<0.01; ***p< 0.005 (Mann–Whitney U test, TM group compared with the non-TM control group)

Mann–Whitney U test of the outcomes for this TM-subgroup of four subjects showed statistically significant reductions for all outcome measures compared with the non-meditating Panchakarma-only group.

4. Cluster analysis had clearly defined a group of 12 good responders at the 6-month follow-up [5], but the same analysis could not clearly define a group of good responders at the 24-months follow-up. Ten subjects, the four TM subjects and six other subjects, who were all categorised as good responders at the 6-month follow-up [5], still met the criteria for being good responders at the 24-month follow-up, except that three of the ten subjects reported increased tiredness compared to the 6-month follow-up. One more subject, who reported markedly less tiredness at 24 months compared to the 6-month follow-up, met the criteria for being a good responder.
5. The vast majority (26 of 31; 83%) of the participants showed improvement in terms of a reduced total sum of scores at the study's end (24 months). Four subjects (plus one dropout) had a worsening of their conditions in terms of an increased total sum of scores (ranging from +4% to +33%) at the study's end-point.
6. All participants were found to have intolerance to some foods. These foods included wheat (in 97% of the subjects), pork (97%), egg (94%) and spelt (13%). In all cases except one, the wheat incompatibility was found to be reversed by the addition of a small quantity of turmeric during cooking or baking, and the spelt incompatibility was found to be reversed in all cases by adding a small quantity of cinnamon.
7. Compliance with the home treatment, including the intake of herbal preparations and the practice of TM, was retrospectively assessed by telephone interviews at the study's end-point. Subjects evaluated their compliance in terms of very good (A), good (B) and bad (C) (Table 4). Most subjects (81%) were compliant (A + B) with dietary recommendations. Almost half of the subjects (42%) were compliant (A + B) with herbal recommendations.

Discussion

In this 24-month follow-up study, we found that the treatment program offered at the Maharishi Ayurveda Health Centre in Norway significantly reduced most FM symptoms that it did so in most FM patients and that these reductions were maintained for 24 months. These reductions were not significantly different than outcomes at 1- and 5-month follow-up.

At the end-point of the study at 24 months, the four subjects (13 %) who started to practise TM (one stopped after 3 months) had a substantially and significantly better response than the Panchakarma-only group. Indeed, the Panchakarma + TM group had almost no symptoms. Although this number of subjects is too small to draw any firm conclusions on the effect of TM on FM, the substantially larger outcomes experienced by the TM-participants (around sevenfold greater) are consistent with previous experience at the health centre (11 cases of individuals with FM who learned TM and had Panchakarma with a maximum follow-up time of 10 years) [4]. They are also supported by research on the effects of TM that are relevant to FM. One study showed decreased pain perception amongst practitioners of the TM technique [8]. Other studies of large groups of TM practitioners suggest decreased usage of medical services [9, 10]. Randomised, controlled studies on TM have shown statistically significant reductions in depression compared with control groups [11–16]. One meta-analysis showed a reduction in trait anxiety and another showed an increase in self-actualisation with effects significantly larger for TM than that for other relaxation and

Table 4 Compliance at 24 months follow-up assessed for months 18–24

	A	B	C
Herbs	27%	15%	58%
Diet	46%	35%	19%

A very good, *B* good, *C* bad

meditation programs [17, 18]. Self-actualisation, as measured by the Shostrom Personal Orientation Inventory, is a measure of overall mental health. One of the two major subscales of this inventory is a subscale of inner-directedness. This subscale corresponds to "locus of inner control" or self-efficacy, which has been shown to be higher in FM subjects reporting less pain and less physical impairment [19] and to be a predictor of positive outcomes for FM subjects undergoing rehabilitation [20]. Some subjects, who underwent treatment at the health centre, felt that the practice of TM made it easier to adopt the MVM recommendations for a healthy lifestyle.

A previous study on Maharishi Panchakarma (142 consecutive subjects) showed statistically significant improvements over a range of health scales including stamina, energy, mind/emotions and previous complaints 1 month post-treatment, compared with a control group (n=60) that only participated in an MVM-based health education program [21]. A case series of four subjects suffering from chronic diseases suggested substantial improvement after patients underwent a 3-week in-residence Maharishi Panchakarma treatment program and a home follow-up program [22].

Entry scores may have affected our findings for two outcomes, anxiety and depression. The entry scores for the two mental subscales were considerably lower compared with the other five outcome measures (seven subjects (23%) had entry scores for anxiety lower than 0.4, and four subjects (13%) had entry scores less than 0.2). The decrease in anxiety (−26%) was significant (p=0.043) at 24 months, but the decrease in depression, although a bigger absolute effect (−32%) was only borderline significant (p=0.062). This was the reverse of the 6-month data where the decrease in depressive symptoms (−46%) was significant (p<0.001) and the decrease in anxiety (−25%) was not (p=0.136) [5]. It is possible that the lack of significance in each instance was due to the already low baseline scores (floor effect) and a small sample size, causing the study to be underpowered for these variables.

Based on a retrospective interview at 24-months, compliance with using the herbal products seemed to be poor (Table 4). This could be mostly due to self-selection due to (i) the costs of the products, (ii) differing individual effects of the products.

Side effects

No participant reported a major complaint as a result of the Panchakarma treatment. Treatments were in general enjoyed and experienced as soothing and relaxing, even by the six participants who reported allodynia (experience of pain from normally non-noxious stimuli). Short periods of increased pain were experienced by some of the participants.

Other comments

Two of the four TM practitioners reported that they had been meditating twice a day fairly regularly during the 2-year post-treatment period. The third discontinued after almost 3 months of practice, and the fourth was irregular in her practise, both despite good experiences. The two regular TM practitioners maintained an excellent response at the study's end-point, and the other two slightly increased their responder scores.

In the group of 11 good responders, three subjects including one TM practitioner were taking regular analgesic medication at the start of the study. By 24 months, all three had stopped all analgesics. Data were missing for one of the 11 good responders. Two subjects started to exercise after they had experienced improvements following the treatment. Of these two, the first was the subject that stopped practising TM after 3 months, and the other was subject number two, who reported a worsening of symptoms (16%) at the 24-month end-point.

Limitations

Our study has limitations. First, the sample was small. Second, the study was not randomised—the participants in this study were all self-selected and thus very motivated. Third, the study was not controlled. Having said that, we felt that it was reasonable to allow each subject's baseline data to serve as the control. We felt that way because FM is considered a treatment-resistant condition, and most of our subjects had, according to their reports, severe symptoms for many years. This was confirmed by the fact that the total sum of their baseline scores for the five body scales averaged 32.4 (range, 11.8–48.4); only three subjects had a sum less than 20. It was also confirmed by the fact that they entered a rather costly treatment programme without any insurance compensation. The price for a 9-day residence treatment programme is, today, including instruction in the TM-technique US $5,780. The price for the TM course alone is US $1,830 (students US $915). The price for a residential treatment programme in Norway based on conventional medicine (Jeløy kurbad) is US $5,590. (US $1= 5.90 NOK) Fourth, the instrument we used to measure FM was not a very sharp one—especially on the anxiety and depression dimensions. Fifth, all data were self-reported.

Conclusions

The treatment offered at the Maharishi Ayurveda Health Centre in Mesnali can provide substantial and significant long-term benefits to FM patients. The results of this pilot study are encouraging and warrant further research using a

stronger experimental design (randomised and controlled), one with sufficient power for all variables (larger sample size) and one in which all participants receive 9 days of Panchakarma treatment plus TM. The concept of food intolerance that was used in our study also warrants further investigation.

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Conflicts of interests The first author is the administrative and medical director of the Maharishi Ayurveda Health Centre, Mesnali, Norway. Jeremy Z. Fields is Adjunct Research Professor at Maharishi University of Management, Fairfield, Iowa, USA. The rest of the authors declare no conflict of interest.

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