Treatment of fibromyalgia at the Maharishi Ayurveda Health Centre in Norway. A six-month follow-up study

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ABSTRACT

Background. Treatments offered at the Maharishi Ayurveda Health Centre in Norway are based on Maharishi Vedic medicine, which is also known as Maharishi Ayurveda. It is a consciousness based revival of the ancient Ayurvedic medicine tradition in India and is established by Maharishi Mahesh Yogi, the founder of the Transcendental Meditation (TM) technique.

Objective. To conduct a pilot study of the effect of the treatment program at the Health Centre on fibromyalgia patients.

Methods. Thirty-one women with diagnosed fibromyalgia received an individually designed Maharishi Vedic physiological purification therapy. All subjects received personal advice on diet based on Ayurvedic principles, including a novel approach to food intolerance, and daily routines. In addition they were offered instruction in TM (for stress and pain management and personal development) (four subjects started), and recommended Ayurvedic herbal food products for home treatment.

Main outcome measures: A modified Fibromyalgia Impact Questionnaire included a visual analogue scale for each of the seven outcomes: working ability, generalised pain, tiredness, stiffness, tiredness on arising, anxiety and depression. Pre-treatment scores were compared with scores at six-month follow-up for levels of statistical significance.

Results. Twenty-eight subjects (90%) completed the follow-up. The outcome measures were reduced by 25 to 46% by the study’s endpoint: working ability (p<0.002), pain (p<0.001), tiredness (p<0.001), morning tiredness (p<0.001), stiffness (p<0.005), anxiety (p<0.136), and depression (p<0.001). A group of five excellent responders including all four participants who started to practise TM, had almost no symptoms by the endpoint. Compared to the non-meditating control group the TM-subgroup showed statistically significant improvements for all outcome measures except depression.

Conclusions. In this pilot study fibromyalgia patients undergoing treatment at Maharishi Ayurveda Health Centre in Norway showed significant improvements six months post treatment. Because fibromyalgia is considered a treatment-resistant condition, these encouraging results warrant further research.

Introduction

Our goal was to study the effects of the treatment program for fibromyalgia (FM) that is offered at the Maharishi Ayurveda Health Centre in Norway. The treatment is based on Maharishi Vedic medicine (MVM), also known as Maharishi Ayurveda. MVM is a revival of the ancient tradition of Ayurvedic medicine of India, by Maharishi Mahesh Yogi, the founder of the Transcendental Meditation (TM) technique. MVM offers a range of treatment and life supporting modalities restored from the 40 branches of the Vedic literature, including Ayurveda. The strategies include TM and the TM-Sidhi program, Maharishi Vedic physiological purification program (Maharishi Panchakarma), Maharishi Vedic Vibration Technology, Maharishi Vedic sound therapy, Maharishi Light Therapy with Gems, Maharishi Vedic astrology, Maharishi Vedic architecture, Maharishi Vedic music and Maharishi Vedic Organic Agriculture (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 for the structure and functioning of the individual mind-body (2). The TM-technique is a strategy for development of consciousness and is considered the most significant of all the strategies of MVM, because it is said to provide the direct experience...
of pure consciousness. Since the teaching and the verification of the practice of the TM-technique is standardised world-wide, the technique has been subjected to extensive research (3). Maharishi Ayurveda Health Centres have been established in many countries around the world, and at the Maharishi Ayurveda Health Centre in Mesi
ali, Norway, much experience has been gained in treatment of FM-patients (4). The diagnosis of the FM-syndrome is based on a history of a minimum of three months of widespread pain with excessive tenderness in a minimum 11 of 18 discrete regions, as specified in the Boston criteria (5). The syndrome is complex and includes fatigue, un-refreshing sleep, depression and anxiety along with gastrointestinal and genitourinary problems (5, 6). More recent research indicates that sleep problems (7) and sexual dysfunction (8) is a part of the syndrome. It is a common disorder and in a US, Spanish and Norwegian general population its prevalence has been found to be 2%, 2.4% and 3.2% (9-11). Mostly women are affected. The patients are extensive users of medical care and account for the largest disability group of newly disabled women in Norway.

The treatment of FM is a rapidly growing area of research, covering a wide range of treatment modalities. Accumulating evidence suggests that aerobic exercise has a positive effect on FM (12). However, many patients report increased pain following high intensity aerobic exercise and problems with adherence to such an intervention (13). A recent study suggests that physical activity protects male patients with post-traumatic stress disorder from developing severe fibromyalgia (14). Another recent study indicates that exercise in warm water reduces pain and improves cognitive function in FM-subjects (15). Also, short-term studies indicate positive effects with new pharmacological approaches (13). As no major breakthrough in the treatment of FM so far has been found (13), we undertook this study.

At the health centre a novel approach to food intolerance is applied. This approach, which is a consciousness-based strategy, is believed to identify food items that have a negative effect on the health of a specific individual and thus incompatible with the mind-body. Incompatible items identified by this approach include foods processed in a particular way or foods that contain synthetics additives as well as pharmaceutical products, toothpastes (including Ayurvedic) 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 the vast number of chemical substances in spices.

Materials and methods

The participants underwent a Maharishi Vedic physiological purification program (Maharishi Panchakarma) that included a range of full body herbalised oil massages, “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 pulse. 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 a MVM-health education program along with instruction in the TM-technique (to be practised 20 minutes twice a day) for stress and pain management and personal development.

Prior to the commencement of the treatment program at the Maharishi Ayurveda Health Centre, all the participants underwent an individually prescribed pre-treatment program for seven to nine days at home that included the intake of clarified butter in the morning followed by a laxative treatment. This program is believed to increase the effect of the main treatment offered at the health centre. They also received guidelines for an easily digested diet (avoiding heavily digested substances such as red meat, raw vegetables and most milk products) and a stress reducing lifestyle, which were to be followed until two weeks post treatment. By the end of the treatment, participants received personalised advice on diet based on Ayurvedic principles, daily routines, and Ayurvedic herbal food products (including Triphala Plus, Livogard and Fibrozan), which was intended to be easily integrated into their daily lives on returning home. Each patient was advised to avoid specific food items 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 six month follow-up study. Participants were enrolled in the study between November 2005 and March 2006. Clinical examination was performed just prior to the start of the treatment by a rheumatologist (KM in most cases). 14 subjects were examined after six months follow-up. Two did not meet the requirements for a fibromyalgia diagnosis based on the Boston criteria and were excluded. The remaining 31 subjects were women aged 33 to 74 years with a mean age of 46 years. The disease duration was 3–42 years with a mean time of 16 years. They underwent treatment for three days (n=1), five days (n=11) or seven days (n=19). One subject had previously learned the TM-technique, but had not practised the technique for seven years prior to the onset of her FM-symptoms. She resumed the practice and four other subjects received instruction in the technique.

Three subjects dropped out of the study – all without giving any explicit reason. Two subjects completed the one month follow-up – the first reporting moderate improvement and the second a moderate worsening. This second drop out was the only subject who had only three days of treatment. She declined after having experienced mouth ulcers along with both mouth dryness and at times excessive salivation, most likely due to the herbal products she was using. The third drop out was one of the four participants who learned the TM-technique, but declined follow-up by returning home.
The Fibromyalgia Impact Questionnaire (FIQ) is not validated in the Norwegian language. The 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: working ability (limited by symptoms of FM), pain, tiredness, stiffness, tiredness on rising in the morning and 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 left of the scale indicated no problems and a mark to the extreme right indicated the worst imaginable condition. In addition the participants evaluated the performance of their daily activities by questions similar to the FIQ. The participants filled out the questionnaire in privacy just prior to the start of the treatment at the health centre. In addition questionnaires were filled out at home at one-, three- and six-month post treatment. Statistics were done for one (Table I) and six months (Table II) follow-up. The scores were measured from 0 to the mark in centimetres to an accuracy of one decimal place. The first three participants completed a questionnaire at entry, which was a copy of the American questionnaire. Their scores were later transferred to the 10 scale.

A paired sample t-test was used to compare the outcome measures at study entry and at the one month and the six month end point respectively. A Mann-Whitney test was used to analyse the differences in outcome measures between the TM-group and the non-TM-group. Responders were identified by hierarchical cluster analysis with square Euclidian distance. SPSS 15.0 was used for all the analyses.

**Results**

In this six-month follow-up study of the effect of the MVM-treatment a statistically significant reduction of all outcome measures except anxiety was found (25 to 46% reductions) at both the one-month and the six-month follow-up. One of the participants, however, reported highly increased anxiety due to worsening of her asthma. There was no significant difference in the outcome measures between the two groups, who were in for the five- and seven-day treatments. There was no significant change in reductions of outcome measures between the one- and the six-month follow-up. The total sum of all the outcome measures were 1112 (194 outcome measures) at the start compared to 630 (187 outcome measures) at the one-month follow-up and 701 (194 outcome measures) at the end-point.

A hierarchical cluster analysis using squared Euclidian distance with respect to improvement of scores (excluding “working ability” due to missing data) identified a fairly homogenous group of 12 subjects. They were classified as good responders showing improvements on all five body scales by at least 50% except one subject who showed improvements of 10% and 34% for two body scales.

A subgroup of five participants (18%) included all the four TM-practitioners, and these five were classified as excellent responders; they had end-point scores that were less than 1.0 cm. A Mann-Whitney test of the outcomes for this TM-subgroup showed statistically significant reductions for all outcome measures except depression compared to the non-meditating control group (Table II). The majority of the participants showed improvement in terms of a reduced total sum of all scores at the end of the study. However, three subjects reported a worsening of their condition of more than 5% of the total sum at end-point compared to entry: the increase of scores was 6.5, 6.2 and 12.7, respectively.

A number of food items were found to be incompatible with certain participants. These food items 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 adding turmeric in a small quantity during

**Table I.**

<table>
<thead>
<tr>
<th>Outcome measures of FIQ</th>
<th>Number</th>
<th>Mean value of outcomes at entry</th>
<th>Mean value of outcomes at one month</th>
<th>Difference of mean values</th>
<th>95% confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working ability</td>
<td>25</td>
<td>5.7</td>
<td>3.7</td>
<td>2.0</td>
<td>0.9</td>
<td>3.2</td>
</tr>
<tr>
<td>Pain</td>
<td>27</td>
<td>6.6</td>
<td>3.3</td>
<td>3.5</td>
<td>2.2</td>
<td>4.4</td>
</tr>
<tr>
<td>Tiredness</td>
<td>27</td>
<td>6.9</td>
<td>4.5</td>
<td>2.4</td>
<td>1.3</td>
<td>3.5</td>
</tr>
<tr>
<td>Morning tiredness</td>
<td>26</td>
<td>7.2</td>
<td>3.6</td>
<td>3.6</td>
<td>2.3</td>
<td>4.9</td>
</tr>
<tr>
<td>Stiffness</td>
<td>26</td>
<td>6.4</td>
<td>3.7</td>
<td>2.7</td>
<td>1.7</td>
<td>3.8</td>
</tr>
<tr>
<td>Anxiety</td>
<td>27</td>
<td>3.6</td>
<td>2.6</td>
<td>1.0</td>
<td>0.0</td>
<td>2.0</td>
</tr>
<tr>
<td>Depression</td>
<td>27</td>
<td>3.9</td>
<td>2.5</td>
<td>1.4</td>
<td>0.2</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Paired Samples Test for difference of mean values of outcome measures between entry and one month of follow-up.

**Table II.**

<table>
<thead>
<tr>
<th>Outcome measures of FIQ</th>
<th>Number</th>
<th>Mean value of outcomes at entry</th>
<th>Mean value of outcomes at one month</th>
<th>Difference of mean values</th>
<th>95% confidence interval</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Working ability</td>
<td>26</td>
<td>5.9</td>
<td>3.6</td>
<td>2.3</td>
<td>0.9</td>
<td>3.7</td>
</tr>
<tr>
<td>Pain</td>
<td>28</td>
<td>6.6</td>
<td>4.0</td>
<td>2.6</td>
<td>1.4</td>
<td>3.8</td>
</tr>
<tr>
<td>Tiredness</td>
<td>28</td>
<td>6.9</td>
<td>4.1</td>
<td>2.8</td>
<td>1.6</td>
<td>4.0</td>
</tr>
<tr>
<td>Morning tiredness</td>
<td>28</td>
<td>7.2</td>
<td>4.5</td>
<td>2.7</td>
<td>1.5</td>
<td>3.9</td>
</tr>
<tr>
<td>Stiffness</td>
<td>28</td>
<td>6.3</td>
<td>4.0</td>
<td>2.3</td>
<td>0.7</td>
<td>3.8</td>
</tr>
<tr>
<td>Anxiety</td>
<td>28</td>
<td>3.6</td>
<td>2.7</td>
<td>0.9</td>
<td>-0.3</td>
<td>2.0</td>
</tr>
<tr>
<td>Depression</td>
<td>28</td>
<td>3.7</td>
<td>2.0</td>
<td>1.7</td>
<td>0.7</td>
<td>2.6</td>
</tr>
</tbody>
</table>

Paired Samples Test for difference of mean values of outcome measures between entry and six months of follow-up.
Table III. Outcome measures before 3-6 days treatment at the Maharishi Ayurveda Health Centre, Norway, and after a six-month follow-up in a group learning and practicing TM and in a control group not learning or practicing TM.

<table>
<thead>
<tr>
<th>Outcome measures of FIQ</th>
<th>TM group (n=4)</th>
<th>Non-TM group (n=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>At entry</td>
<td>At six months</td>
</tr>
<tr>
<td></td>
<td>Median (range)</td>
<td>Median (range)</td>
</tr>
<tr>
<td>Working ability</td>
<td>6.1 (0.4-7.6)</td>
<td>0.1 (0.0-0.3) ***</td>
</tr>
<tr>
<td>Pain</td>
<td>6.5 (4.5-8.4)</td>
<td>0.1 (0.0-0.3) ***</td>
</tr>
<tr>
<td>Tiredness</td>
<td>7.4 (2.3-8.2)</td>
<td>0.6 (0.1-0.8) **</td>
</tr>
<tr>
<td>Morning tiredness</td>
<td>4.5 (0.1-8.8)</td>
<td>0.4 (0.0-0.4) **</td>
</tr>
<tr>
<td>Stiffness</td>
<td>8.4 (3.7-9.4)</td>
<td>0.6 (0.1-0.8) **</td>
</tr>
<tr>
<td>Anxiety</td>
<td>3.8 (0.1-5.9)</td>
<td>0.0 (0.0-0.8) *</td>
</tr>
<tr>
<td>Depression</td>
<td>3.1 (0.1-6.7)</td>
<td>0.1 (0.0-0.6)</td>
</tr>
</tbody>
</table>

Mann-Whitney test *p<0.05, **p<0.01 and ***p<0.001, TM group compared to the non-TM control group.

Discussion

In this six months follow-up study we showed that a treatment program offered at Maharishi Ayurveda Health Centre in Norway had beneficial effect on fibromyalgia symptoms (except anxiety), and that 18% of the patients had almost no symptoms at the endpoint. Four patients participated in the TM program. Although this number was too small to draw any firm conclusions on the effect of TM on FM, the better outcomes experienced by the TM-practitioners (around three-fold) are consistent with previous experience at the health centre (eight cases) (4) and is supported by research on the effects of TM with reference to FM. A recent study showed decreased pain perception amongst practitioners of the TM-technique (16). Studies on large groups of TM-practitioners suggest decreased usage of medical services (17, 18). Several controlled studies have shown reductions in depression, including two randomised studies that showed a statistically significant effect compared to other treatment modalities (19, 20). One meta-analysis showed reduction in trait anxiety and another showed an increase in self-actualisation with effects significantly larger than that for other relaxation and meditation programs (21, 22). Some subjects, who have undergone treatment at the health centre, have felt that the practice of TM made it easier to adopt the MVM-recommendations for healthy lifestyle.

A study on the Maharishi Vedic physiological purification therapy (n=142 consecutive) showed statistically significant improvement over a range of health scales including stamina, energy, mind/emotions and previous complaints one month post treatment, compared to a control group (n=60) that participated in a MVM-health education program (23).

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 that has been shown to be higher in FM-subjects reporting less pain and less physical impairment (24), and to be a predictor of positive outcome for FM-subjects undergoing rehabilitation (25).

Experimental design

The participants in this study were all self-selected and thus very motivated. The study was not controlled, but as FM is considered a treatment-resistant condition, each participant could act as her own control. Compliance with the home treatment, including the intake of herbal preparations and practice of TM, was not assessed, but by the study’s endpoint three of the four TM-practitioners reported that they had been meditating twice a day fairly regularly over the six-month period. The fourth had stopped after three months although she reported very good experiences with the practice, and her scores were the highest for all outcomes in the TM-subgroup. The entry scores for anxiety and depression were considerably lower compared to the other five outcome measures, thus making it more difficult to obtain statistically significant results. Seven subjects (25%) had entry scores for anxiety lower than 0.4.

Side effects

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

We want to comment on the three subjects who experienced a worsening of their state at the end-point of the study. The first was very satisfied with the improvements she experienced immediately after the treatment, but some days after returning home, there was a conflict in the family and she experienced a relapse. She did not present at the one-month follow-up, accounting for seven out of the nine missing outcome measures. She was one of the most enthusiastic about the treatment and the frustration she felt as a consequence of the relapse could have added to the worsening of her condition. The second participant reported very good improvements in telephone interviews both at the four-month follow-up and five months after the end-point of the study. This was in contrast to her scores which showed no improvements on any scale and a considerable worsening of her mental state at the end-point. She explained that the situation was due to a divorce that occurred around the end-point of the study. The third subject, who reported the most substantial worsening of her condition of all the subjects, was very disappointed with her results. However, a physical examination at the end-point (made by a different rheumatologist from the one at the start) revealed only eight exces-
sively tender points compared to 18 at entry, thereby no longer satisfying the diagnostical criteria for the FM-diagnosis. In the group of 12 good responders, four subjects including one TM-practitioner were taking regular analgesic medication at the start. By the end-point, three including the TM-practitioner had stopped all analgesics. Data was missing for one subject. No subjects reported increased use of analgesics or antidepressants (based on interview at the end-point). Two subjects started to exercise after they had experienced improvements following the treatment. The first was the subject that stopped practising TM, and the other was a non-responder.

Food incompatibility

LBR is the only one according to his knowledge, who makes use of such a strategy of identifying food incompatibilities and the spices to reverse these incompatibilities. The following clinical observations support the significance of this strategy for FM-patients: (i) the application of the strategy has improved long-term results for the management of this (and other) conditions at the health centre, (ii) most patients experience less postprandial discomfort, (iii) according to pulse diagnosis use of this strategy makes it easier to obtain an optimal treatment result, and (iv) some FM-patients who had experienced very good long-term effects of the treatment, reported almost full relapse of their condition when they had stopped complying with the dietary recommendations and considerable improvement after resuming the recommended diet (along with intake of herbal food supplements), and (v) certain individuals for whom food intolerance diagnosed by immunological methods was largely consistent with the diagnosis at the health centre, experienced immediate positive results from the treatment at the health centre when other strategies had failed (2). It is the first author’s experience, however, that food intolerances identified by this strategy are not necessarily consistent with food intolerances identified by IgE/IgM-testing or diagnosed as lactose intolerance or coeliac disease.

Conclusions

The results of this pilot study are encouraging and warrant further research using a stronger experimental design with all participants receiving full treatment including TM. The concept of food intolerance that is used in this study also warrants further study.

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