The effect of a strict, low-salt, uncooked vegan diet rich in lactobacteria on symptoms in 18 fibromyalgia patients during and after a 3-month intervention period in an open, non-randomized controlled study was evaluated. As control 15 patients continued their omnivorous diet. The groups did not differ significantly from each other in the beginning of the study in any other parameters except in pain and urine sodium. The results revealed significant improvements in Visual analogue scale of pain (VAS) \((p \approx 0.005)\), joint stiffness \((p \approx 0.001)\), quality of sleep \((p \approx 0.001)\), Health assessment questionnaire (HAQ) \((p \approx 0.031)\), General health questionnaire (GHQ) \((p \approx 0.021)\), and a rheumatologist’s own questionnaire \((p \approx 0.038)\). The majority of patients were overweight to some extent at the beginning of the study and shifting to a vegan food caused a significant reduction in body mass index (BMI) \((p \approx 0.0001)\). Total serum cholesterol showed a statistically significant lowering \((p \approx 0.003)\). Urine sodium dropped to 1/3 of the beginning values \((p \approx 0.0001)\) indicating good diet compliance. It can be concluded that vegan diet had beneficial effects on fibromyalgia symptoms at least in the short run.

Key words: fibromyalgia, vegan, pain, fatigue, sleep, symptom alleviation

Fibromyalgia (FM) is a chronic pain disorder (1), the diagnostic criteria of which were formulated in 1990 by The American College of Rheumatology (2). Clinical manifestations of FM also include generalized weakness with normal muscle strength, myalgias, nonrestorative sleep, fatigue, and stiffness (3). Despite the increasing interest in fibromyalgia, the etiology and pathophysiology are still poorly known (4,5). Muscle metabolism disorder (6,7), connective tissue disorder (8), hormonal disorders (9 – 11) as well as central vascular etiology (12,13) have also been suggested as etiological factors.

There have been several treatment trials in order to find better ways to treat fibromyalgia including medical and non-medical interventions. Promising short term results have been reported from the combination of carisoprodol, paracetamol, and caffeine (14). Amitriptylin and cyclobentsaprine (15 – 18) have been helpful at least in the short term. The most promising non-medical treatments have included cardiovascular fitness training (19), cognitive behavioural treatment (20), electroacupuncture (21), and cold therapy (22), but only cognitive behavioural treatment has shown effectiveness also in the long term (23).

A number of studies have reported the effects of food on the symptoms of rheumatic diseases and the possible beneficial effect of vegetarian food (24 – 30), but almost all of them have dealt with rheumatoid arthritis so very little information on fibromyalgia is available. However, some indications of the diet’s role in fibromyalgia exist. According to the questionnaire based survey by Haugen et al. (28), 42 % of the fibromyalgia patients reported aggravation of disease symptoms after intake of certain food. The food most frequently reported to cause aggravation included meat, wine, alcohol, coffee, sweets, sugar, chocolate, and citrus fruits and apples. A very small study by Hostmark et al. (31) revealed increased subjective well-being among some fibromyalgia patients after a three week vegetarian diet although the aim of the study was to investigate plasma fibrinogen, serum peroxides, lipids, and apolipoproteins which all were reduced significantly.

One form of vegan diet “living food” was previously studied quite thoroughly (29,32 – 41). The content of a living food diet is described by Hanninen et al. (42). The basic idea is to serve all food uncooked and it consists of fruits, berries, vegetables, mushrooms, nuts, seeds, and legumes and cereals. It contains very small amounts of vitamin B12, so a supplement is advised. The daily calory intake is approximately 1829 kcal, protein intake 71 g (16%-E), carbohydrate intake 276 g (53%-E), fat intake 63 g (31%-E), and it contains no cholesterol. The purpose of the present study was to evaluate the effects of this strict vegan diet on the symptoms of fibromyalgia.

Subjects and methods

Subjects: Finnish female fibromyalgia patients \((n=28)\) were divided into two groups. Because of the complicated nature of the preparation of the diet...
their wishes were respected in the group division. Informed consent was obtained from each participant, and the study protocol was accepted by the Ethical Committee of Tampere University and Central Hospital. The intervention group (n=18) was instructed to prepare the living food before the intervention started. During the test period they had a possibility of being in contact with the instructor in case of problems. The control group (n=15) consisted of fibromyalgia patients who continued their normal omnivorous diet regimen. The basic demographic data of the two groups are shown in Table I. Only nine patients had a BMI under 25, and thus the majority were to some extent overweight. Only one person in the control group was smoking. A rheumatologist clinically assessed the subjects before the test began and confirmed that the participants fulfilled the 1990 ACR criteria of fibromyalgia. The intervention group ate living food for three months. Later everybody could continue on which diet they wanted for five months. All medications were otherwise kept stable during the study but the patients were allowed to change the amount of pain-killers according to their own will. The use of medication was reported regularly. Three members of the intervention group discontinued the intervention, one before the start and two early in the beginning for family reasons. Two members of the control group discontinued because of family reasons and difficulties with transport to check-ups. None discontinued because of unsuitability of living food.

Health assessment: All subjects underwent a clinical assessment by a rheumatologist before, during, and after the intervention period. Blood and urine chemistry (b-hematocrite, b-ESR, s-cholesterol, and u-sodium) were collected four times. To evaluate the FM symptoms the participants fulfilled Health assessment questionnaires, Beck’s depression inventories, General health questionnaires, and questionnaires dealing with the quality of sleep, morning stiffness, and pains at rest. Quality of sleep was measured using a questionnaire with seven questions dealing with sleeping problems (difficult to go to sleep, daily fatigue, use of sleeping pills, use of pain-killers in order to sleep etc.). The answers were stated as never (0 point), sometimes (1 point), often (2 points), and always (3 points) and the amount of points were added. The higher the value the poorer the quality of sleep. They also filled in an overall questionnaire made by the rheumatologist, dealing with subjective feelings. Furthermore the intervention group members were asked to report on the compliance to the vegan diet. The physical condition was evaluated by using a 2 km walking test before and at the end of the intervention period. The subjects were asked to walk as quickly as they could and the time as well as the heart beat were measured at the end of the test. The exercise index was calculated using a standardized formula (43). Also handgrip powers of both hands were measured before, at the end, and after the intervention period, using the Martin vigorimeter with standardized positioning and instructions.

Dietary assessment: Dietary information was obtained using 5-d food records. Nutrient intakes were calculated by the Nutrica Computer Program (Social Insurance Institution, Finland) using the Finnish nutrient database (44), supplemented with nutrient values of the vegetable food commonly used by the vegetans. Food records were collected four times.

Biochemical measurements: Blood samples were collected by venopuncture after an overnight fast and cholesterol and urine samples were analyzed using the Progress analyzer, (Kone Oy, Finland). Daily urine samples were collected in plastic containers and kept cool until delivery to the laboratory. Hematocrite was analyzed using a Coulter Counter M530 analyzer, (Coulter corp. Miami, Fl) and ESR was measured according to the Westergren adaptation. Blood samples were stored frozen until all samples could be analyzed at the same time.

Table I. Basic demographic data of the 28 fibromyalgia patients.

<table>
<thead>
<tr>
<th></th>
<th>intervention group</th>
<th>control group</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>18</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Age: average (range)</td>
<td>51 years (34 – 62)</td>
<td>52 years (37 – 59)</td>
<td>0,8</td>
</tr>
<tr>
<td>Weight: average (range)</td>
<td>74 kg (55 – 111)</td>
<td>73 kg (55 – 89)</td>
<td>0,8</td>
</tr>
<tr>
<td>Height: average (range)</td>
<td>164 cm (154 – 179)</td>
<td>163 cm (150 – 180)</td>
<td>0,8</td>
</tr>
<tr>
<td>BMI: average (range)</td>
<td>26 kg/m2 (20 – 40)</td>
<td>28 kg/m2 (22 – 32)</td>
<td>0,3</td>
</tr>
<tr>
<td>Duration of disease: average (range)</td>
<td>4,8 years (2 – 5)</td>
<td>4,8 years (1 – 11)</td>
<td>0,7</td>
</tr>
<tr>
<td>HAQ: average (range)</td>
<td>8,1 (2 – 15)</td>
<td>5,3 (0 – 13)</td>
<td>0,5</td>
</tr>
<tr>
<td>Beck’s depression inventory: average (range)</td>
<td>9,7 (2 – 21)</td>
<td>7,9 (0 – 18)</td>
<td>0,6</td>
</tr>
<tr>
<td>Tender fibromyalgia points: average (range)</td>
<td>16,2 (12 – 18)</td>
<td>15,4 (4 – 18)</td>
<td>0,7</td>
</tr>
<tr>
<td>VAS pain: average (range)</td>
<td>6,0 (2,9 – 9,3)</td>
<td>5,8 (4,9 – 7,5)</td>
<td>0,04</td>
</tr>
</tbody>
</table>
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Statistical analyses: The SPSS/PC computer program was used in the statistical analyses. Statistical significances of the differences between the intervention group and the control group were assessed by ANOVA for repeated measures. The difference between the basic demographic data (age, disease duration, smoking, height) were assessed by oneway ANOVA. One non-parametric parameter was evaluated by Chi-Square test.

Results

The intervention group reported several other diseases as well as fibromyalgia, the control group had less other diagnoses. The medication was kept unchanged except for pain-killers during the intervention period. The need for them was reduced during the intervention, but there was no statistical significance between the two groups (p=0.053). Basic characters of the groups are shown in Table I. The results are shown in Figure 1. All members of the intervention group added gradually fish and/or meat to their diet after the intervention period and none continued on the living food diet alone. Also the results show that most of the parameters are approaching the start values towards the end of the observation time (Fig. 1).

The laboratory parameters showed significant improvement in total serum cholesterol (p=0.003) in the intervention group. Urine sodium dropped nearly to one third of the start values indicating good diet compliance in the intervention group (p=0.0001). Four members of the intervention group reported they had eaten fish occasionally at the end of the study, but otherwise adherence was strict. No significant changes were detected in ESR (p=0.154) or hematocrite (p=0.184) between the two groups.

In the beginning of the study 66% of all fibromyalgia patients were overweight (BMI in both groups=28) and there was a significant decrease in weight and thus in BMI in the intervention group at the end of the test period (p=0.0001). BMI in the intervention group was within normal values at the end of the study (BMI=24) and there was a clear improvement in the intervention period. BMI in the control group remained the same during the whole study.

Based on Beck’s depression inventories and clinical check-ups, a few patients were mildly depressive in both groups, but there was no significant difference between the two groups during the study (p=0.112). Scores zero to nine are judged normal, ten to 18 mild depression, 19 to 29 moderate, and 30 to 63 severe depression (47).

Both groups reported having quite a lot of pain at rest in the beginning of the study, but there was a significant decrease in the intervention group during the living food diet period (p=0.005). The positive result disappeared gradually after shifting back to the omnivorous diet. Also significant changes were found in other parameters describing the symptoms of fibromyalgia such as improvement in the quality of sleep (p=0.0001), reduction of morning stiffness (p=0.00001), improvement in the General health assessment questionnaire (p=0.02) as well as in the Health assessment questionnaire (p=0.03), and in the rheumatologist’s overall questionnaire (p=0.038), which dealt with subjective feelings. The only parameter that showed only tendency was the number of tender fibromyalgia points (p=0.07).

The handgrip pressure power was also tested during the study, but there was no significant change. Pressure test was carried out for both hands.

The exercise test was also done in the beginning of the study and at the end of the intervention. No statistically significant change was revealed. The exercise index showed that both groups were of average class in their physical condition in the beginning, but at the end of the study the control group was less than average. The test consisted of a two kilometre walk with maximum speed and the index was then calculated (43). Index less than 70 is considered considerably below average, 70– 89 less than average, 90–110 average, 111–130 better than average, and over 130 considerably better than average.

Discussion

The participants were allowed to choose either the intervention or the control group according to their own will. Nevertheless the groups did not differ significantly from each other in any other parameters except in pain and urine sodium in the beginning of the test. The difference in pain led to the conclusion that the patients with more difficult symptoms were more interested in trying a new diet. Because of the totally different way of eating, it was more likely to achieve better compliance by letting the participants

Fig. 1. The results of the clinical and laboratory tests of the intervention and control groups. Data were collected before the intervention period (= before), in the middle of the intervention period (= middle), in the end of the intervention period (= end), two months after the intervention period (= after I) and five months after the intervention period (= after and II). Data are given as average and 95% confidence interval (95% CI). Statistical significance is given as p values for effects of division to intervention vs. control groups/or effects of time alone. Morning stiffness was evaluated by Chi-Square test and thus the p values are given separately for each point. ● Intervention group. ■ Control group.
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choose their own group rather than dividing them randomly. Although none discontinued because of the unsuitability of the living food, it was clearly seen that the patients did not continue only with the intervention diet after the scheduled period. One reason surely was the approaching Christmas time and its' influence on diet in general. Also the totally different way of making food and eating might have tired the patients and led to including parts of the normal diet in the living food, despite of the favourable effects of the intervention diet. It must be remembered that since living food was not available in the restaurants in general, all food had to be prepared and brought in case of family celebrations, trips etc. This sort of experiment is impossible to carry out blindly because of the nature of the study. A crossover design would have probably increased the value of the study.

The difference in urine sodium in the beginning was not clear, but most likely it was due to an enthusiasm to start a little before the official schedule. The total serum cholesterol improvement was as expected based on previous studies (31,33). The case with ESR was as expected as fibromyalgia is not associated with hypersedimentation (2).

The changes in weight and BMI were as expected based on the previous study with rheumatoid patients (29). Vegetarians tend to have a lower body weight in general and the prevalence of obesity is also lower among them (45).

In general, major depression is present in fibromyalgia patients in approximately 18% at any visit and a median of 58% in their lifetime (46). A few patients were mildly depressive in our study, but there was no significant change between the two groups. Smoking has been reported to be more frequent for women with fibromyalgia (51,52) and this could be partially due to anxiety and depression related to the initial disease (53). On the other hand, a Finnish study of the prevalence of fibromyalgia found no correlation between smoking and fibromyalgia's prevalence (54). Our patients were only mildly depressive, which in turn could explain the low amount of smokers.

Both groups had clearly less force in their hands, when compared to normal healthy individuals (49). This is in line with previous findings (50).

There is very little information available on whether diet and specifically vegetarian diet influences the symptoms of fibromyalgia. According to a questionnaire based Norwegian study, 42% of the fibromyalgia patients reported aggravation of disease symptoms after the intake of certain food and 23% had tried different diets in the attempt to alleviate disease symptoms (28). The effect of nutritional supplements (aloe vera extract, freeze-dried fruit and vegetables, saccharides and vitamins) resulted in a remarkable reduction in initial symptom severity with continuous improvement in the follow-up (48). Thus, our study is the first to evaluate the effectiveness of the vegetarian food on the symptoms of FM. It seems that vegan diet alleviates the symptoms of fibromyalgia at least in the short run. Further studies are needed to verify these results and especially in crossover design. The effectiveness of the vegan diet in the long run should also be studied.

References

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