Controlled Trial of Hypnotherapy in the Treatment of Refractory Fibromyalgia

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Abstract. **In a controlled study, 40 patients with refractory fibromyalgia were randomly allocated to treatment with either hypnotherapy or physical therapy for 12 weeks with followup at 24 weeks. Compared with the patients in the physical therapy group, the patients in the hypnotherapy group showed a significantly better outcome with respect to their pain experience, fatigue on awakening, sleep pattern and global assessment at 12 and 24 weeks, but this was not reflected in an improvement of the total myalgic score measured by a dolorimeter. At baseline most patients in both groups had strong feelings of somatic and psychic discomfort as measured by the Hopkins Symptom Checklist. These feelings showed a significant decrease in patients treated by hypnotherapy compared with physical therapy, but they remained abnormally strong in many cases. We conclude hypnotherapy may be useful in relieving symptoms in patients with refractory fibromyalgia.** (*J Rheumatol 1991;***18:72–5)**

Key Indexing Terms:
FIBROMYALGIA HYPNOTHERAPY PHYSICAL THERAPY TENDER POINTS

Fibromyalgia is a syndrome (FS) characterized by diffuse widespread musculoskeletal aching and stiffness, multiple tender points and sleep disturbances[1]. Recently the American College of Rheumatology (ACR) 1990 criteria for the classification of fibromyalgia were published including (1) widespread pain in combination with (2) tenderness at 11 or more of the 18 specific tender point sites[2]. The etiology and pathogenesis of fibromyalgia are not understood. It is suggested that fibromyalgia is a disorder in pain perception. An etiologic role of psychological factors has also been suggested[3]. A successful therapy is not known, although tricyclic antidepressant agents[4,5] and fitness training[6] may be of some help.

Hypnotherapy has been found to be useful in the treatment of chronic asthma[7], irritable bowel syndrome[8] and peptic ulcer disease[9]. In these diseases psychological factors are thought to contribute to the pathogenesis. We executed a randomized controlled trial to ascertain the value of hypnotherapy in the treatment of refractory fibromyalgia.

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MATERIALS AND METHODS

Forty patients with refractory fibromyalgia for at least 6 months (38 women and 2 men; aged 30–65 years) were included in the study. The trial was carried out in 1988. The criteria used for the diagnosis of fibromyalgia were those proposed by Smythe and Moldofsky[1] and included each of the following: (1) widespread aching of more than 3 months duration, (2) local tenderness at 12 of 14 specified sites, (3) disturbed sleep with morning fatigue and stiffness, (4) absence of traumatic, neurologic, muscular, infectious, osseous, endocrine or other rheumatic conditions, and (5) normal blood sedimentation rate, Latex fixation test, antinuclear antibody factor, creatinine kinase and thyroid function (as measured by the thyroid stimulating hormone level).

The mean duration of fibromyalgia in these patients was 8.5 years (range: 1.5–40 years). Previous therapies consisted of physical therapy (massage and training in relaxation) combined with analgesic drugs (usually acetaminophen, paracetamol).

After informed consent was given, the patients were randomly allocated to receive either hypnotherapy or physical therapy. At the start of the study the patient's rheumatologist and the observer had neutral expectations of the results of the trial. Hypnotherapy was carried out by HTWH and consisted of 8 1-h sessions in decreasing frequency over a 3-month period. After the 3rd session a cassette tape of 30 min duration for daily autohypnosis was given to the patient to be used at home. A standardized technique of hypnosis was used, comparable to that of others[8]. Briefly, hypnosis was induced by an arm levitation technique. Depending of the patient's dominant sensory perception abilities, hypnotic suggestions were given to deepen the hypnosis. After standard ego strengthening suggestions, attention was directed to the control of muscle pain, general relaxation and improvement of sleep disturbance. The cassette tape for daily autohypnosis contained a text with the same suggestions. No assessments of susceptibility to hypnosis were done.

Seventeen patients completed the hypnotherapy program; 3 patients were dissatisfied with treatment and withdrew after 3 sessions. According to the intention-to-treat principle, they remained in the study. Physical therapy

consisted of massage and training in muscle relaxation by means of the Mensendieck method, 1 to 2 h/week, for a period of 12 weeks carried out by a physical therapist. After 12 weeks the prolongation of the treatment was facultative. At the beginning of the trial all analgesics except paracetamol were stopped. At any time during the trial patients were permitted to take paracetamol.

All participants were assessed at baseline and at the 12th and 24th week by an independent observer (HCMH) who was unaware of the treatment the patient was receiving. Patient's assessment included (1) duration of morning stiffness (in min), (2) muscle pain, (3) fatigue on awakening, (4) sleep disturbance and (5) global assessment. Assessments 2–5 were done using visual analog scales (VAS) of 10 cm without markings (0 = no complaint, 10 = extreme complaint).

To estimate somatic and psychic discomfort, the Hopkins Symptom Checklist (HSCL-90) was used[10]. The HSCL-90 is designed for measuring changes in subjective feelings of illness and is thus especially suited for the purpose of evaluating treatment results. The patients were asked to complete the Dutch translation of the HSCL-90 at each assessment. The Dutch HSCL consist of 3 scales: psychical complaints (Psych), somatic complaints (Somat) and total score[11]. Physician's assessment included (1) measurements in duplicate of point tenderness with the aid of a dolorimeter (a spring loaded gauge with a range of 12 kg, 1.0 kg marks and a pressure area of 3.1 cm^2 made by the Department of Medical Instruments Making of the St. Antonius Hospital). Eight (4 paired) spots were measured: the midpoint of the upper fold of the trapezius muscle; the second costochondral junction; a point 2 cm distal to the lateral epicondyle and a point on the medial fat pad of the knee. The individual scores were added up to give the total myalgic score (TMS)[4]. The mean values of the duplicate measurements were recorded. (2) The presence of tender points at 30 anatomic spots[12] was determined by simple pressure of the thumb, together with 5 control points: forehead, mid-upper arm and mid-forearm (bilaterally), which are regarded as not tender in primary FS[13]. (3) Overall assessment by means of a VAS (0 = no pain, 10 = extremely painful). Because the diagnosis of FS is completely dependent on patient's symptoms, the overall assessment by the patient at 12 and 24 weeks was considered as the primary outcome measure in this trial.

Statistical methods. Mean (SD) is given when data were normally distributed, otherwise the median (range) is used. Outcome measures at Weeks 12 and 24 were evaluated by repeated measures analysis of variance (RmANOVA)[14], while allowing for the baseline measurement in each instance. VAS data and duration of morning stiffness were logarithmically transformed to obtain approximate normal distributions. In all cases it was verified that the effects of treatment, if any, did not significantly differ between Weeks 12 and 24. Other statistical methods used are given in the text. P = 0.05 (2-sided) was considered the limit of statistical significance.

RESULTS

The randomization resulted in 2 comparable groups (Table 1).

Of the total group 25 patients were on sick leave or were incapacitated because of fibromyalgia and 6 were unemployed, with equal distribution over both groups.

By RmANOVA, taking into account the baseline values at Week 0, significantly lower, i.e., more favorable, values were observed in the hypnotherapy group compared to the physical therapy group for the assessments of muscle pain ($p = 0.004$), fatigue on awakening ($p = 0.003$), sleep disturbance ($p < 0.001$), patient's overall assessment ($p = 0.04$) and HSCL total score ($p = 0.02$). No significant differences between both groups were found for morning stiffness, physician's overall assessment and TMS. The multivariate analysis showed for all variables no significant differences between Week 12 and 24 for both treatment groups. Therefore, for each patient the mean values of the variables at Week 12 and 24 were used to calculate the percentage change relative to the baseline value. In Table 2 the median values of these changes for each variable for both treatments are given.

Only 2 patients in the hypnotherapy group and 1 patient in the physical therapy group did not complain of pain at the end of the study.

Median (range) analgesic drug use at the initiation of the study (mostly paracetamol) was in the hypnotherapy group 3.0 (0–42) tablets/week and in the physical therapy group 4.5 (0–21)/week. At Week 12 this was 1.0 (0–21) tablets/week and 1.0 (0–20) tablets/week and at Week 24 1.0 (0–21) tablets/week for the hypnotherapy group and 7.0 (0–34) tablets/week for the physical therapy group. At the end of the study, 10 of 12 patients in the hypnotherapy group

Table 1. *Demographic and clinical measurements of patients with FS at entry to the study*

	Physical Therapy (n = 20)	Hypnotherapy (n = 20)	p* Value
Age (years)	45.5 (7.4)	44.6 (9.5)	0.8
Sex (F/M)	19/1	19/1	
Duration of FS (years)	5.5 (1.5–40)	6.0 (1.5–20)	0.7
Morning stiffness (min)	30.0 (5–360)	25.5 (0–720)	0.3
Muscle pain (VAS)	9.5 (3.4–9.8)	9.3 (4.5–9.9)	0.5
Fatigue on awakening (VAS)	9.4 (0.1–9.8)	9.3 (4.5–9.8)	0.9
Sleep disturbance (VAS)	8.7 (0.3–9.3)	8.6 (0.5–9.8)	0.7
Overall assessment (patient)	9.0 (5.0–9.9)	9.2 (2.9–9.9)	0.9
(VAS) (observer)	6.2 (3.3–9.3)	7.0 (5.4–8.9)	0.2
Number of tender points (0–30)	21.6 (8.5)	24.7 (4.0)	0.5
Total myalgic score (kg/3 cm^2)	36.4 (14.8)	35.3 (10.4)	0.9
Hopkins symptom checklist	61.6 (23.6)	60.7 (27.2)	0.8

Except for sex, data given are mean (SD) or median (range). No significant differences were found between the 2 groups.

* Mann-Whitney U test.

Table 2. *Morning stiffness, VAS and clinical measurements at 12 and 24 weeks and change (%) as compared to Week 0*

Week	Physical Therapy 12	24	Change (%)*	Hypnotherapy 12	24	Change (%)*
Morning stiffness (min)	22.5 (0–240)	30.0 (7–720)	0.0	15.0 (0–720)	17.5 (0–90)	−25.0
Muscle pain (VAS)	9.3 (3.9–9.9)	8.8 (0.5–9.8)	−6.8	6.0 (0.2–9.8)	7.1 (0.3–9.7)	−10.2**
Fatigue on awakening (VAS)	9.2 (0.5–9.9)	9.1 (0.4–9.9)	−0.3	6.0 (0.4–9.5)	7.1 (0.3–9.6)	−16.7**
Sleep disturbance (VAS)	7.1 (1.5–9.9)	8.4 (0.4–9.8)	−1.0	4.3 (0.0–9.3)	4.9 (0.3–9.5)	−23.1**
Overall assessment (VAS)						
patient	6.8 (4.3–9.9)	5.7 (0.2–9.7)	−8.4	4.9 (0.1–9.3)	5.1 (0.3–9.6)	−33.2**
physician	8.0 (1.0–9.6)	7.9 (0.3–9.5)	+5.7	7.0 (0.2–9.3)	7.4 (0.3–9.6)	−3.2
TMS (kg/ 3 cm^2)	30.0 (10.9)	32.2 (14.4)	−11.1	32.4 (15.1)	34.2 (15.0)	−2.4
HSCL total score	62.7 (29.0)	63.4 (31.0)	−0.9	52.8 (28.1)	49.8 (30.2)	−13.0**

* Median change (%) as compared to value at Week 0 (see text). See Table 1 for definitions and values Week 0. Except for TMS, a decrease is improvement.
** Significant differences between treatment groups (RmANOVA, see text).

and 3 of 12 patients in the physical therapy group had reduced their paracetamol use (Fisher exact test: $p = 0.006$).

Coupled with the decrease of the patient's overall assessment the total number of tender points decreased, regardless of the treatment received. As measured by a dolorimeter the costochondral junction and the trapezius muscle point were far more tender than the elbow and knee points: mean values 3.3 and 3.8 kg/3.1 cm^2 vs 4.5 and 6.0 kg/3.1 cm^2. There was no significant left-right difference. The TMS had not changed significantly at Weeks 12 and 24 in either group.

In 44% of the patients, the control points were also tender as measured by pressure of the thumb. Of the patients with tender control points, all but 2 had more than 22 tender points. Tender control points were not a constant finding over time, as most patients showed this in one or 2 of the 3 assessments. Only 12 of 40 patients had consistently nontender control points, 4 in the hypnotherapy group and 8 in the physical therapy group. They responded no differently to the treatment compared to the other patients in their group.

No relation was found between the initial HSCL total score and the changes in the other variables studied.

DISCUSSION

In this controlled therapeutic trial in patients with refractory fibromyalgia hypnotherapy was more successful than physical therapy in improving complaints. The assessment of fatigue on awakening, sleep disturbance, muscle pain, the patient's overall assessment and the total score of the HSCL showed a significant decrease in the hypnotherapy group at the end of the hypnotherapy at 12 weeks. This decrease persisted for 3 months after finishing the hypnotherapy. The variables studied in the physical therapy group had not changed significantly at 12 and 24 weeks.

However, the patients in the hypnotherapy group improved only subjectively. This improvement was not seen via more objective variables (TMS and number of tender points), in accordance with others[4]. This suggests that coping with the disease may be positively influenced by hypnotherapy though the underlying disorder is still present.

Correction of the sleep disturbance by hypnotherapy was the most consistent finding and possibly played an important role in the subjective improvement of fibromyalgia. This phenomenon has also been noticed during treatment with tricyclic antidepressants[5]. It is possible that at least part of the change simply reflects patients' suggestibility and expectations. This is a major difficulty in interpreting the contribution of hypnosis to therapeutic response[15].

The mean initial total score of the HSCL in both groups was extremely high: 61.6 (SD 23.6) for the hypnotherapy group and 60.7 (SD 27.2) for the physical therapy group. In comparison the mean HSCL total score in an average Dutch population was 22.3 (SD 16.5, N = 406), in psychosomatic patients 37.4 (SD 23.5, N = 551) and in psychiatric patients 64.8 (SD 31.4, N = 1390)[11]. The Psych and Somat scales of the HSCL were also within the pathologic range (data not shown). Thus, in our study, patients with longstanding fibromyalgia often showed pathological feelings of discomfort. In the hypnotherapy group the total score of the HSCL decreased significantly, suggesting that the psychical disturbance may be secondary to longstanding fibromyalgia. It is worth noting that only 3 of the 57 questions on the HSCL-90 concern fibromyalgia.

Our data do not support the concept of differentiating between fibromyalgia and so called psychogenic rheumatism by nontender control points in fibromyalgia and tender con-

trol points in psychogenic rheumatism[13,16]. Most patients in our study had variable tender control points. The finding of tender control points in fibromyalgia is consistent with others[2,17]. Also we found a positive correlation between the number of tender points and the presence of tender control points. Therefore it seems more likely that there is a fairly large overlap between fibromyalgia and psychogenic rheumatism (tender all over).

During our study there were no planned cointerventions and no known treatment contaminations. Although the idea of hypnotherapy frightened some patients, only 3 withdrew after 3 sessions because of dissatisfaction. The compliance to the physical therapy was not recorded. All patients were treated with some kind of physical therapy in the past, therefore the physical therapy group could be regarded as a control group.

The selection of patients with refractory fibromyalgia introduces a bias in favor of hypnotherapy because a new treatment is compared with a previously unsuccessful treatment. Our patients showed pathological feelings of discomfort as measured by the HSCL that could have influenced the response to the hypnotherapy. However, we chose this design to ascertain the value of hypnotherapy in a group of patients with severe and refractory fibromyalgia. Therefore, further studies of hynotherapy should be done in patients with recently developed fibromyalgia, who received no physical therapy.

Hypnotherapy seems to be effective in relieving complaints in some patients with refractory fibromyalgia. In professional hands it is a safe and inexpensive mode of treatment.

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