The Additional Value of a Home Physical Therapy Regimen Versus Patient Education Only for the Treatment of Myofascial Pain of the Jaw Muscles: Short-term Results of a Randomized Clinical Trial

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Aims: *To compare the short-term efficacy of patient education only versus the combination of patient education and home exercises for the treatment of myofascial pain of the jaw muscles.* ***Materials and Methods:*** *Seventy myogenous temporomandibular disorder patients were assigned to 2 treatment groups. One group received patient education supplemented by general information about self-care of the jaw musculature. The other group received both education and a home physical therapy program. Treatment contrast, calculated from the mean normalized relative changes in anamnestic and clinical scores, was used to determine treatment success. Clinical outcome measures included pressure pain threshold (PPT) of the masseter, anterior temporalis, and Achilles tendon; pain-free maximal jaw opening; and pain on chewing, spontaneous muscle pain, and headache as rated on visual analog scales.* ***Results:*** *After 3 months the success rate was 57% for the group that received education only and 77% for the group that received both education and home physical therapy (*$P = .157$*). The patients were then redivided into 2 groups: successfully treated patients and unsuccessfully treated patients. In the unsuccessfully treated group, pain-free maximal jaw opening increased significantly more among those who had been in the education and physical therapy group than among those who had been in the education-only group (*$P = .019$*). The change in PPT was significantly greater in successfully treated patients than in unsuccessfully treated patients (*$.009 < P < .039$*), independent of the treatment modality, with higher PPTs among successful patients. There were no significant differences between the successfully and unsuccessfully treated groups or between treatment modalities for any other variable.* ***Conclusion:*** *Over a period of 3 months, the combination of education and a home physical therapy regimen, as used in this protocol, is slightly more clinically effective than education alone for the treatment of myofascial pain of the jaw muscles.* J OROFAC PAIN 2004;18:114–125.

Key words: myofascial pain, patient education, physiotherapy, pressure pain threshold, randomized clinical trial

Temporomandibular disorders (TMD) is a collective term embracing a number of clinical problems that involve the masticatory musculature, the temporomandibular joint (TMJ) and associated structures, or both.[1] The management of TMD includes several therapeutic protocols.

There is a growing consensus that treatment strategies should be reversible since the majority of patients suffering from TMD may achieve sufficient relief of symptoms with reversible therapy.[2–4] Indeed, long-term follow-up of TMD patients shows that 50% to

90% of the patients have few or no symptoms after reversible treatment.[1,5,6] For this reason reversible therapy is endorsed for the initial care of nearly all TMD.[2,3,7,8]

Behavioral therapy is generally considered first as a conservative approach for the treatment of TMD. The rationale for treating TMD with behavioral therapy includes the notion that parafunctional activity and psychosocial factors play a role in the pathogenesis of musculoskeletal pain.[9–13] The objectives of education are to reassure the patient; to explain the nature, etiology, and prognosis of the problem; and to control the amount of the masticatory activity.[14–17]

The use of physical therapy (PT) for the management of TMD has also been advocated.[18–22] The typical PT regimen for TMD includes several exercises that are widely prescribed by clinicians treating TMD because they encourage self-management of the condition and ameliorate the patient's coping ability. It has been suggested that these exercises help to relieve musculoskeletal pain and to restore normal function by reducing inflammation, decreasing and coordinating muscle activity, and promoting the repair and regeneration of tissue.[1,22,23] A meta-analysis of review articles and controlled clinical trials for TMD and other similar chronic musculoskeletal pain disorders carried out by Feine and Lund[24] showed that symptoms improved during treatment with most forms of PT, including placebo. PT was almost always better than no treatment, and efficacy increased in direct proportion to the amount of treatment the patient received.[24,25]

The scientific basis of treatment strategies for TMD needs to be improved. However, only a few randomized controlled trials (RCTs) are available.[26–29] Therefore, the aim of the present prospective RCT was to compare the efficacy of patient education only and the combination of patient education and a home PT regimen for the treatment of myofascial pain of the jaw muscles over a 3-month period.

A preliminary report of this study, which investigated a smaller sample of patients, was previously published.[30]

Materials and Methods

Subjects

Two hundred sixty-two consecutive patients seeking treatment for orofacial pain were referred to the TMD Center, University of Naples, over a 10-month period. The patients were subjected to a routine stomatognathic examination to diagnose a specific TMD. A dentist skilled in orofacial pain and TMD diagnosis performed a clinical and functional examination according to the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD) to diagnose myogenous patients.[31] A convenient sample size was estimated according to the data provided by Dao et al[32] and based on patients' pain ratings on a visual analog scale (VAS). Using their power analyses, setting the α error at 0.05 and the β error at 0.2 (ie, 80% power), and estimating a 45% to 60% decrease in pain intensity to be a clinically relevant improvement, we estimated that 42 to 72 patients would be needed (ie, 2 groups of 21 to 36 patients).

Inclusion criteria were:

- Pain recurrent or constant for more than 3 months
- Spontaneous pain in the last week of $>$ 30 on a 100-mm VAS

Exclusion criteria were:

- Objective evidence of TMJ pathology or dysfunction
- Arthrogenous TMD with pain or radiographic alterations in the TMJs (RDC/TMD diagnostic categories II and III)
- Other orofacial pain conditions
- Other TMD treatments within the last 3 months
- Neurologic or psychiatric disorders
- A history of pain medication abuse or current abuse

Seventy consecutive myogenous TMD patients who met the criteria specified were assigned to 2 treatment groups using balanced block randomization. One group, which consisted of 34 patients (3 men and 31 women from 16 to 66 years old; mean ± SD 31.8 ± 13 years), received only the education treatment program. The other group, which consisted of 36 patients (5 men and 31 women from 15 to 52 years old; mean ± SD 28.2 ± 8.8 years), received a combination of education and home PT (Fig 1). The baseline characteristics of the 2 groups are presented in Table 1. Written informed consent was obtained from all patients prior to participation in the study.

Treatment

Education-Only Group. The education-only group received patient education supplemented by general information about self-care of jaw musculature

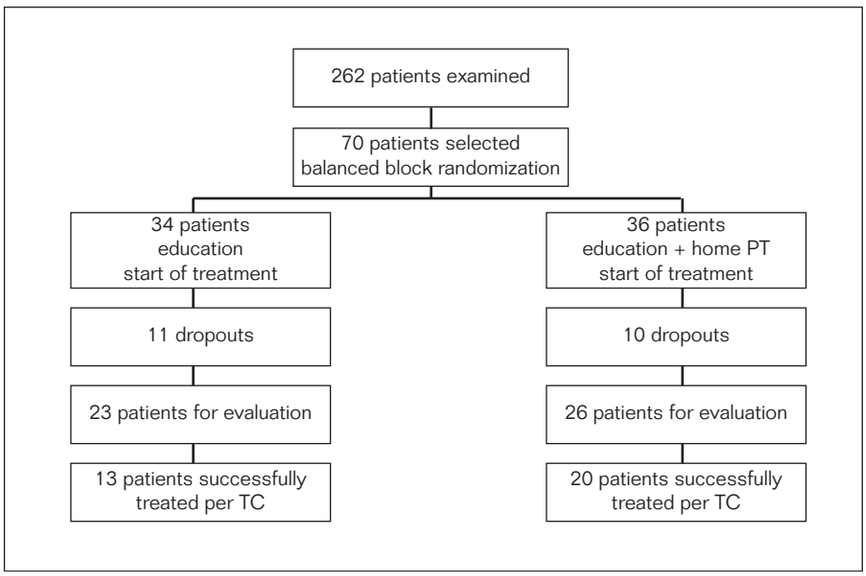

Fig 1 Study design. TC = treatment contrast; PT = physical therapy.

Table 1 Pretreatment Data (Mean ± SD) of All Patients

	Completers (n = 49)	Dropouts (n = 21)	*P**	Education alone (n = 34)	Education + home PT (n = 36)	*P**
Age (y)	29.3 ± 11.5	30.9 ± 10.9	NS	31.8 ± 13.0	28.2 ± 8.8	NS
Sex (M/F)	7/42	1/20	NS	3/31	5/31	NS
No. of sites tender to palpation	14.8 ± 4.3	15.9 ± 3.4	NS	15.4 ± 4.5	14.8 ± 3.7	NS
Pain intensity (100-mm VAS)	25.4 ± 20.9	33.1 ± 27.8	NS	21.6 ± 19.4	26.0 ± 26.0	NS
Duration of symptoms (mo)	25.1 ± 30.5	21.6 ± 19.9	NS	22.7 ± 26.9	25.5 ± 24.8	NS
Pain-free maximum opening (mm)	42.4 ± 6.9	38.6 ± 10.6	NS	41.1 ± 7.6	39.9 ± 9.2	NS
Pain on chewing (100-mm VAS)	34.1 ± 24.3	27.2 ± 31.2	NS	28.6 ± 27.3	26.3 ± 25.5	NS
Headache (100-mmVAS)	28.7 ± 25.3	27.7 ± 29.8	NS	17.5 ± 22.0	34.1 ± 32.3	.017
PPT (kPa)						
Masseter	141.7 ± 46.5	131.6 ± 39.8	NS	136.2 ± 34.5	139.6 ± 56.3	NS
Temporalis	155.6 ± 47.4	144.4 ± 37.6	NS	149.3 ± 41.5	150.8 ± 45.1	NS
Achilles tendon	270.2 ± 90.8	230.8 ± 60.3	NS	241.6 ± 72.1	268.6 ± 95.4	NS

*Mean values were compared by means of an unpaired Student *t* test. Ratios were compared by means of the Fisher exact test.
NS = not significant.

delivered by a dentist (AM). The patients were reassured by the dentist, who explained the problem, the suspected etiology, and the good prognosis of this benign disorder. The dentist explained normal jaw muscle function and stressed that overuse of these muscles could be the major cause of their complaints. The patients were told to pay close attention to their jaw muscle activity, to avoid oral habits and excessive mandibular movement, and to keep to a soft diet. They were instructed to keep the jaw muscles relaxed by holding the mandible in its postural position (teeth apart) and not in occlusion, which requires "unintentional" muscle contraction.[33] The dentist asked the patients to pronounce the letter "N" several times and to maintain the tongue behind the upper incisor teeth, with the lips in slight contact, to determine mandibular rest position. The patients were requested to practice what they learned at home with the help of feedback (ie, stickers). The patients were also informed about the relationship between chronic pain and psychosocial distress.

Education + Home PT Group. The education + home PT group received the same general information as the education-only group from the same dentist (AM), supplemented by a self-supportive

exercise program. This program included self-relaxation exercises with diaphragmatic breathing, self-massage of the masticatory muscles, application of moist heat pads on the painful muscles, stretching, and coordination exercises.

To learn normal diaphragmatic breathing, the patients exhaled fully with 1 hand on the chest and the other on the abdomen. They were trained to become aware of the respiratory mechanism by feeling the position and movement of the hands. Diaphragmatic breathing had to be performed for 5 minutes every 2 hours. The patient was also encouraged to use diaphragmatic breathing as much as possible throughout the day.

Self-massage was limited to the painful or tense masseter and temporalis muscle because both of these muscles are easily accessible for self-palpation. The patients were carefully instructed about the anatomic location of the affected muscle and were asked to exert an amount of pressure slightly higher than the pressure at which a pain sensation was initially felt; the pressure had to be modulated proportionally to the level of pain experienced. The masseter muscle was massaged by slight rolling movements performed with the index, middle, and ring fingers placed extraorally over the masseter area; the thumb was placed intraorally and exerted counterpressure during massage. The right masseter muscle was massaged by the left hand and vice versa. The left and right temporalis muscles were massaged by slight rolling movements performed with the ipsilateral index, middle, and ring fingers.

The patients were asked to apply moist, moderately warm heat pads (approximately 40 to 50°C) bilaterally once a day for 10 minutes.

In order to stretch the muscles, the patients were asked to slowly open the mouth until they experienced an initial pain sensation. Thereafter, they were invited to open the mouth a little bit more with the aid of either their thumb and index fingers or a number of tongue-blades piled together, as a reference for the amount of jaw opening. They then had to hold the stretch for 1 minute. The mandible stretch was repeated 6 times. This exercise had to be performed every day, every 2 hours. Coordination exercises were performed by the patient 3 times daily. These consisted of opening and closing the mouth slowly 20 times and maintaining the lower dental midline parallel to a vertical line traced on a small mirror.

Procedure

All the patients received written instructions about the treatment programs and they were told to continue the prescribed therapy for 3 months even if they were pain-free. Patients assigned to the education + home PT group were also invited to indicate on a daily diary the times when scheduled exercises were performed; patient compliance was ranked by the examiner as good (exercises performed more than two thirds of the time), medium (exercises performed between one and two thirds of the time), or poor (exercises performed less than one third of the time).

At the end of the first visit, which was performed by a trained examiner and had a duration of almost 1 hour, myogenous patients were selected, the therapeutic protocol was randomly assigned, and baseline data were collected by a different examiner who was blind to the treatment group assignment. Each patient was evaluated every 3 weeks during the 3-month treatment period. During these visits signs and symptoms of TMD were clinically and anamnestically investigated for both groups by the same clinician who performed the first visit. The length of each control visit was about 15 minutes. In the education-only group, after the clinical and anamnestic investigation, the patients were asked about their compliance to the prescribed program, and the clinician reinforced the patient's motivation. Compliance was ranked as good, medium, or poor on the basis of a subjective evaluation by the examiner. In the education + home PT group, after the clinical and anamnestic investigation, the clinician reinforced the patient's education and checked that the exercises were being performed correctly. No additional TMD treatments, such as splints, drugs, or occlusal corrections, were provided to patients in either group during the treatment period. Data were collected again 3 months after the start of treatment. Patients whose treatment had not been successful received other conventional TMD treatments (splints, drugs, or for the education group, home PT) or were reevaluated in collaboration with other clinicians.

Assessments

The following outcome measures were collected by an examiner who did not provide any treatment to the patients and who was blind to the treatment group assignment.

Treatment Outcome (Treatment Contrast). Treatment contrast (TC) was used as an a priori outcome measure. TC is the mean normalized difference of the relevant scores of pain intensity and limitation of oral function. On the basis of TC, patients were divided into 2 groups, successfully treated and unsuccessfully treated.[34,35]

Table 2 Example of Anamnestic and Clinical Scores of Treatment Contrast (TC) Values in a TMD Patient

	Final score	Initial score*	Treatment contrast
A. VAS spontaneous pain	0	50	–1.000
B. Joint pain	1	2	–0.333
C. Muscle stiffness	1	3	–0.500
D. Limited function	1	3	–0.500
E. Hard food chewing	1	3	–0.500
F. Yawning	1	2	–0.333
Active range of motion			
G. Opening right	1	2	–0.333
G. Opening left	1	2	–0.333
H. Closing right	1	3	–0.500
H. Closing left	1	3	–0.500
I. Right movement right	0	3	–1.000
I. Right movement left	0	3	–1.000
J. Left movement right	0	2	–1.000
J. Left movement left	1	2	–0.333
K. Protrusion right	0	2	–1.000
K. Protrusion left	0	2	–1.000
L. Retrusion right	0	0	
L. Retrusion left	0	0	
Passive range of motion			
M. Opening right	1	3	–0.500
M. Opening left	0	3	–1.000
N. Right movement right	0	2	–1.000
N. Right movement left	0	2	–1.000
O, Left movement right	0	2	–1.000
O. Left movement left	0	2	–1.000
Traction			
P. Right TMJ right	0	1	
P. Right TMJ left	0	0	
Q. Left TMJ right	0	0	
Q. Left TMJ left	1	1	
R. Superficial masseter right	2	3	–0.200
R. Superficial masseter left	1	3	–0.500
S. Deep masseter right	1	3	–0.500
S. Deep masseter left	3	3	
T. Anterior temporalis right	0	2	–1.000
T. Anterior temporalis left	0	3	–1.000
U. Posterior temporalis right	0	1	
U. Posterior temporalis left	0	2	–1.000
V. Sternocleidomastoid right	1	3	–0.500
V. Sternocleidomastoid left	1	2	–0.333
W. Occipitalis muscles	0	2	–1.000
X. Right bruxoprovocation right	0	0	
X. Right bruxoprovocation left	0	0	
Y1. Left bruxoprovocation right	0	0	
Y1. Left bruxoprovocation left	0	0	
Y2. Anterior bruxoprovocation right	0	0	
Y2. Anterior bruxoprovocation left	0	0	
Z. Intercuspal position right	0	0	
Z. Intercuspal position left	0	0	

*Scores were considered relevant if the initial score was ≥ 2 on a 5-point scale (0 to 4).
TC_{pb} = –3.166/6 = –0.527; TC_{cb} = –18.532/25 = –0.741; TC_{total} = –21.698/31 = –0.700.

TC was based on scores from the baseline and 3-month examinations. Briefly, the following were used to calculate the TC:

Patient-based Parameters—Subjective

1. Spontaneous pain as measured on a 100-mm VAS from 0 = "no pain/headache at all" to 100 = "worst pain/headache imaginable"
2. Joint pain, muscle stiffness, functional limitation, and pain during chewing of hard food and/or during yawning

Clinician-based Parameters—Objective

3. The presence of pain on either side during either active movements (ie, opening, closing, right and left lateral excursion, protrusion, retrusion) and/or passive movements (opening, right and left lateral excursion)
4. The presence of pain on either side during TMJ traction
5. Pain on either side during palpation of the following muscles: superficial and deep masseter, anterior and posterior temporalis, sternocleidomastoid, occipital
6. Pain during anterior bruxoprovocation
7. Pain on either side during clenching in the intercuspal position for 30 seconds

Parameters 2 through 7 were evaluated by asking the patients, "Do you have pain...?" Pain was scored on the following scale: 0 = not at all; 1 = mild; 2 = moderate; 3 = severe; 4 = very severe.

The parameters were used to calculate the TC. A patient-based TC (TC_{pb}) was calculated using the mean scores of parameters 1 and 2 (A to F in Table 2) as follows:

$$TC_{pb} = \frac{\sum_{i=A}^{F} \left(\frac{F_{sc} - I_{sc}}{F_{sc} + I_{sc}} \right)}{n}$$

where F_{sc} is the final score, I_{sc} is the initial score, and n is the number of relevant changes of TC. A clinician-based TC (TC_{cb}) was calculated using the mean scores of parameters 3 through 7 (G to Z in Table 2) as follows:

$$TC_{cb} = \frac{\sum_{i=G}^{Z} \left(\frac{F_{sc} - I_{sc}}{F_{sc} + I_{sc}} \right)}{n}$$

A total TC (TC_{total}) was calculated using the mean scores of all the parameters as follows:

$$TC_{total} = \frac{\sum_{i=A}^{Z} \left(\frac{F_{sc} - I_{sc}}{F_{sc} + I_{sc}} \right)}{n}$$

If the TC was ≤ –0.379 (ie, scores improved an average of 55% over the 3-month period, with the majority of items given scores of < 2 on the 0-to-4 scale at the 3-month evaluation) the treatment was considered successful. An example of TC calculation for a patient is given in Table 2.

Pressure Pain Threshold

Algometric measurements were made using an electronic algometer (Somedic) at sites on the right and left masseter muscles, on the right and left anterior temporalis muscles, and at a control site on the Achilles tendon. The procedure has been described in detail elsewhere.[36] Briefly, the pressure pain threshold (PPT) was determined as the point at which a pressure stimulus applied to the skin changed from a sensation of pressure to pain. The algometer had a tip with a rubber surface 1 cm^2. The tip was applied to the site at a consistent pressure of approximately 20 kPa/s. The site chosen on the masseter was located over the most bulky part of the muscle, as determined by palpation during voluntary contraction. For the temporalis, a site was chosen on the line between the upper orbital margin and the upper point of the outer ear, 2 cm behind the anterior border of the muscle.

The sites were tested in a random order with an interval of approximately 5 seconds between measurements. Four PPT measurements were made at each recording site, with a 2-minute rest interval between trials. Since the first PPT assessment has been shown as being highly variable, it was discarded, and PPT was defined by the mean of the 3 subsequent trials. To ensure precise relocation of these sites in each session, a transparent pliable plastic template was aligned with the ear, with the corner of the mouth, and with the eye, and the locations of the sites were marked.

Pain on Chewing

Pain during chewing was rated on a 100-mm horizontal VAS scale, with "no pain at all" at the left endpoint of the scale (0) and "worst pain imaginable" at the right endpoint (100). The patients were asked to chew bilaterally for 60 seconds a stick of chewing gum (Gnammy; Sperlari) and rate their pain on the scale immediately afterward.

Pain-free Maximal Jaw Opening

"Pain-free maximal jaw opening" was defined as the maximum distance the patient could open his or her jaw without experiencing any pain or discomfort. The distance between the upper and lower incisal edges was measured; overbite was added.

Statistical Analyses

All data collected were preliminarily analyzed with the Kolmogorov-Smirnov test. Because this test failed to show normality for VAS scores, they were analyzed using the nonparametric Mann-Whitney test. The parametric Student *t* test was used for the analysis of TC and PPT data. Proportions were compared using the Fisher exact test. All tests were 2-tailed. The α error was set at 0.05. A 55% change of clinical measurements was considered a clinically relevant difference for use in statistical comparisons. All calculations were performed with SPSS 8.0 for Windows statistical software.

Results

At baseline, no significant differences were found between the 2 groups, with the exception of headache scores, which were significantly higher in the education + home PT group (Table 1).

Twenty-one patients (30%) dropped out of the study—11 (16%) from the education-only group and 10 (14%) from the education + home PT group ($P > .05$). Hence, the education-only group included 23 completers, and the education + home PT group included 26 completers (Fig 1). The baseline characteristics of completers and dropouts have been summarized in Table 1.

Patients dropped out at different times throughout the study, but all patients (100%) were evaluated more than 1 time after the start of treatment. Fourteen patients (8 from the education-only group and 6 from the education + home PT group) dropped out after the second visit. The remaining 7 dropouts (3 from the education-only group and 4 from the education + home PT group) dropped out after the third visit.

Additional information from the dropouts was obtained by a brief telephone interview. The patients were asked "Why did you not come back

Table 3 Pretreatment and Posttreatment Data (Mean ± SD) of the Patients Who Completed the Study

	Pretreatment		Posttreatment		
	Education only (n = 23)	Education + home PT (n = 26)	Education only (n = 23)	Education + home PT (n = 26)	*P**
Age (y)	32.6 ± 13.7	26.4 ± 8.4			
Sex (M/F)	2/21	5/21			
No. of sites tender to palpation	15.2 ± 3.8	15.0 ± 4.1	8.78 ± 5.34	8.27 ± 4.84	NS
Pain intensity (100-mm VAS)	21.6 ± 19.5	29.3 ± 21.6	10.8 ± 13.1	8.1 ± 14.4	NS
Pain-free maximum opening (mm)	43.2 ± 6.4	41.3 ± 7.5	47.4 ± 6.2	50.7 ± 4.8	.017
Pain on chewing (100-mm VAS)	24.9 ± 23.3	23.3 ± 25.6	17.8 ± 24.5	10.8 ± 19.7	NS
Headache (100-mm VAS)	13.3 ± 19.7	26.1 ± 29.7	12.1 ± 17.0	11.2 ± 17.4	NS
PPT (kPa)					
Masseter	139.7 ± 37.6	141.5 ± 58.3	138.1 ± 34.1	138.5 ± 44.6	NS
Temporalis	152.8 ± 44.7	152.1 ± 46.6	154.9 ± 45.0	161.4 ± 55.5	NS
Achilles tendon	257.0 ± 75.7	276.2 ± 102.2	242.4 ± 69.2	270.6 ± 86.8	NS

*Mean values were compared by means of an unpaired Student *t* test.
NS = not significant.

to our clinic?" and "How is your current facial pain; is it unchanged, reduced, or increased?"

Twelve patients (5 from the education-only group and 7 from the education + home PT group) reported that they did not come back for evaluation because of practical problems (eg, the distance to the clinic, job or family conflicts) and that their pain was reduced.

Five patients (3 from the education-only group and 2 from the education + home PT group) reported that they had changed dentists and that their pain was increased. Three patients (2 from the education-only group and 1 from the education + home PT group) could not be reached by phone. One patient from the education-only group reported that she did not return to the clinic because of pregnancy and that her pain was unchanged.

Comparisons of clinical measurements between the 2 treatment regimens are summarized in Table 3. Pain-free maximal jaw opening was significantly greater (P = .017) in the education + home PT group than in the education-only group. No significant differences were found between treatment modalities in any of the other outcome measurements (Table 3). The power (1-β) of statistical comparisons between subjects for VAS scores was determined by setting the β error at 0.2, estimating the pooled SD as 24 mm and considering a 55% change in VAS score to be clinically relevant. The power of these tests ranged from 0.62 to 0.8.

The TC scores for the 2 treatment groups are summarized in Table 4. Based on TC score, patients were split into successfully treated and unsuccessfully treated groups. Baseline characteristics of successfully treated patients as compared to unsuccessfully treated patients are given in Table 5. The success rate based on TC was 13 out of 23 (57%) patients for education-only group and 20 out of 26 (77%) for the education and home PT group. This difference was not statistically significant (P = .157). Best-case and worst-case scenarios were also determined by considering the dropouts either successfully or unsuccessfully treated patients. The outcomes were still not significant in either case. The compliance of patients assigned to the education + home PT group was good or medium in 73% of the patients and was poor in 27%. The compliance of patients assigned to the education-only group was good or medium in 91% of the patients and was poor in 9%. TC_{pb}, TC_{cb}, and TC_{total} scores as related to the treatment outcome (successful versus unsuccessful) are given in Fig 2. The TC_{pb} of unsuccessful patients was significantly higher (P =.048) in the education-only group (signifying worse results) than in the education + home PT group.

Table 4 TC Values (Mean ± SD) of the Patients Who Completed the Study

	Education only (n = 23)	Education + home PT (n = 26)	*P**
TC_{pb}	–0.392 ± 0.342	–0.511 ± 0.285	NS
TC_{cb}	–0.511 ± 0.274	–0.560 ± 0.281	NS
TC_{total}	–0.432 ± 0.307	–0.536 ± 0.248	NS

TC_{pb} = patient-based treatment contrast; TC_{cb} = clinician-based treatment contrast; TC_{total} = total treatment contrast (ie, treatment contrast based on all 7 parameters measured).
*Mean values were compared by means of an unpaired Student *t* test. Ratios were compared by means of the Fisher exact test.
NS = not significant.

Table 5 Pretreatment Data (Mean ± SD) of Patients as Related to Their TC

	Successfully treated (n = 33)	Unsuccessfully treated (n = 16)	*P**
Age (y)	26.6 ± 8.4	34.3 ± 14.8	.025
Sex (M/F)	5/27	2/15	NS
No. of sites tender to palpation	14.7 ± 4.3	14.9 ± 4.5	NS
Pain intensity (100-mm VAS)	27.2 ± 20.6	19.4 ± 18.1	NS
Duration of symptoms (mo)	21.0 ± 27.3	31.9 ± 34.9	NS
Pain-free maximum opening (mm)	41.2 ± 6.8	41.6 ± 6.4	NS
Pain on chewing (100-mm VAS)	33.8 ± 27.1	15.5 ± 18.0	NS
Headache (100-mm VAS)	12.4 ± 17.7	18.9 ± 26.4	NS
PPT (kPa)			
Masseter	137.7 ± 33.3	149.2 ± 65.3	NS
Temporalis	154.8 ± 44.1	157.4 ± 54.6	NS
Achilles tendon	261.3 ± 88.7	287.1 ± 95.3	NS

*Mean values were compared by means of an unpaired Student *t* test. Ratios were compared by means of the Fisher exact test.
NS = not significant.

The relative changes in PPT were not significantly different between the 2 treatment modalities. A significant difference was found between the relative changes of PPT of successfully treated patients as compared to unsuccessfully treated patients ($.009 < P < .039$) in both the masticatory muscles and the Achilles tendon, with higher PPTs in the successful patients (Fig 3).

Changes in VAS scores for spontaneous pain, headache, and chewing pain did not differ significantly between the 2 treatment modalities in the successfully treated group ($P > .05$; $0.50 <$ power < 0.64). In the unsuccessfully treated group, VAS scores after the gum-chewing test were significantly lower ($P = .035$) in the education + home PT group than in the education-only group (Fig 4).

Pain-free maximal jaw opening was not significantly different between treatment groups for the successfully treated patients ($P > .05$; power = 0.55), whereas there was a statistically significant difference ($P = .019$) between the 2 treatment modalities in the unsuccessfully treated patients. Pain-free maximal jaw opening was greater in the education + home PT group than in the education-only group (Fig 5).

Discussion

The present trial lacks a nontreatment control group, and therefore the possibility that a natural healing of the disease occurred in some patients cannot be discarded.[37] Nevertheless, the authors emphasize that all the patients reported ongoing chronic pain (> 3 months; > 30 mm VAS). These selection criteria lower the chances of spontaneous recovery.[38]

In the present study, 30% of patients did not complete the study and the scheduled therapeutic protocol. This percentage of dropouts is similar to other clinical studies.[39] The interviews of dropout patients revealed that the majority of dropouts claimed that they had dropped out for practical reasons but admitted the improvement of their symptoms. In some of the patients the symptoms appear to have improved to such a degree during the treatment period that the last visits were considered "unnecessary," indicating that the success rate of the present clinical trial may be underestimated. During the first examination and throughout the study, extensive education was given to the patients. The benign nature of the disorder and the high possibility of a positive treatment outcome were explained to the patients in detail. Education and reassurance are powerful tools for the remission of this type of chronic disorder.

The literature on patient education (eg, self-care) compared to other treatment modalities in rehabilitation (eg, physiotherapy) shows that enforcing patient responsibilities and thereby addressing psychosocial factors (eg, coping, locus of control) can be a powerful tool.[40] This has been found in TMD research as well. Indeed, Dworkin et al[26,27] concluded that carefully structured minimal interventions emphasizing self-management of TMD may offer real benefit to a significant number of TMD patients. Addressing both dental and psychologic

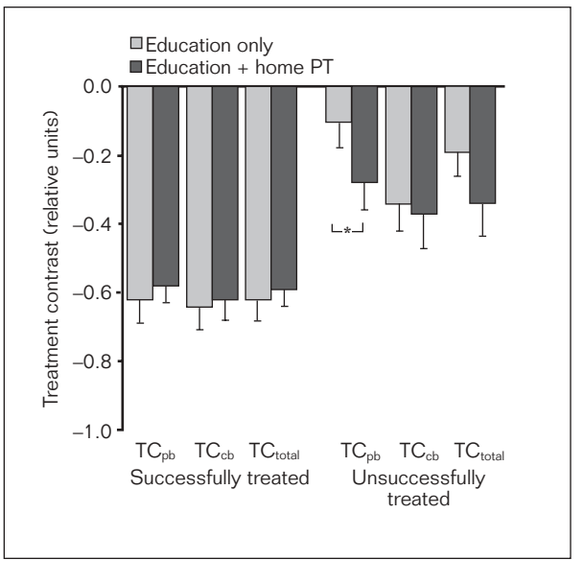

Fig 2 TC_{pb}, TC_{cb}, TC_{total} scores as related to the treatment outcome and the treatment modalities. Columns indicate means, with standard error of the mean shown. A 2-tailed Student *t* test was used to determine significance. $*P < .05$.

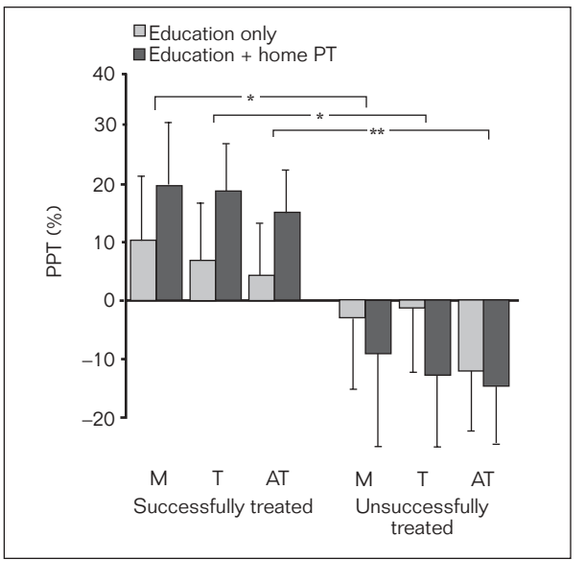

Fig 3 Relative changes of algometric measurements of PPT for the masseter, temporalis, and Achilles tendon in the education-only and education + home PT groups. Columns indicate mean change, with standard error of the mean indicated. Significant differences were found between successfully and unsuccessfully treated patients for the 3 measurement sites. A 2-tailed Student *t* test was used to determine significance. $*P < .05$; $**P < .01$. M = masseter, T = temporalis, AT = Achilles tendon.

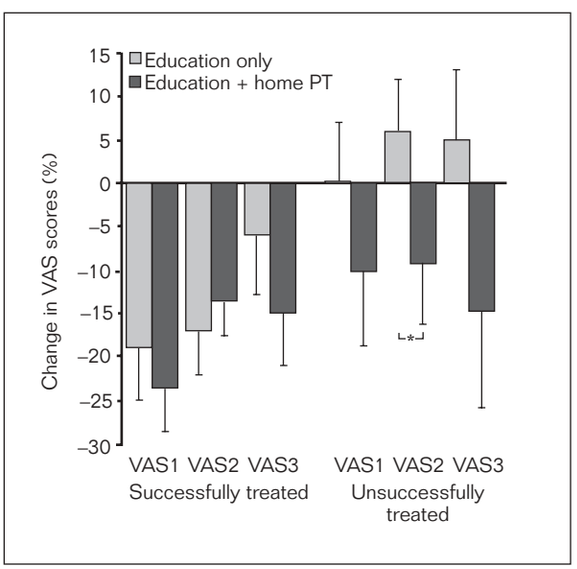

Fig 4 Changes of VAS scores for spontaneous pain (VAS 1), pain on chewing (VAS2), and headache (VAS 3) in the education-only and the education + home PT groups. Columns indicate mean change, with standard error of the mean indicated. A significant difference was found between treatment modalities only for pain on chewing in unsuccessfully treated patients. A 2-tailed Mann-Whitney test was used to determine significance. $*P < .05$.

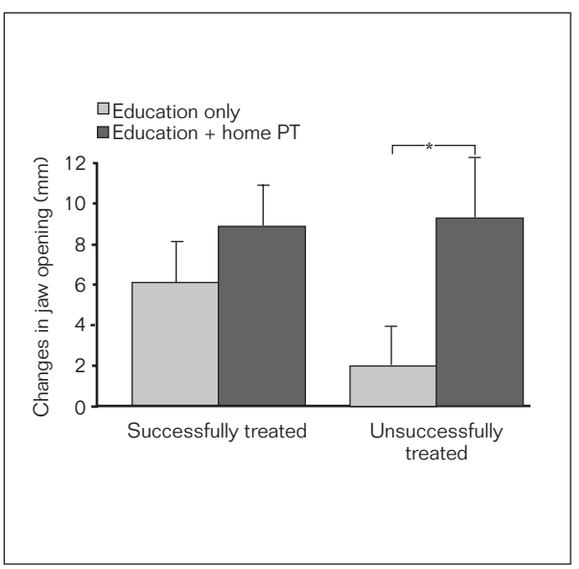

Fig 5 Pain-free maximal jaw opening. A significant difference was found between the 2 treatment modalities for the unsuccessfully treated patients. A 2-tailed Student *t* test was used to determine significance. $*P < .05$.

factors by using an intraoral appliance, biofeedback training, and stress management resulted in a better long-term outcome than either the intraoral appliance or biofeedback/stress management alone.[27] In arthrogenous TMD patients (ie, patients with disk displacement without reduction) the benefits of the use of a flat occlusal splint over nontreatment (the control) could not be identified; this stresses the view that other modalities are equally effective.[26]

The present RCT tested the hypothesis that a combination of education and home PT is associated with a better outcome than education alone. It was found that treatment outcomes and other parameters evaluated were generally not different between the education-only group and the education + home PT group, with the exception of pain-free maximal jaw opening. Pain-free maximal jaw opening differed significantly between the 2 treatment modalities; the difference was clinically significant (> 5 mm, which is the smallest detectable difference on repeated measurements according to Kropmans et al[41]). The greater increase in the range of motion in the education + home PT group is probably mostly attributable to the stretching exercises. The effectiveness of techniques that elongate the muscle and restore it to full stretch length has been suggested for other chronic musculoskeletal pain conditions.[42]

Data were further analyzed by calculating TC scores and splitting the patients into successfully and unsuccessfully treated groups. According to this analysis, pain-free maximal jaw opening differed significantly between the 2 treatment modalities only in the unsuccessfully treated group. Other significant differences were found for pain during chewing and patient-based treatment outcome in the unsuccessfully treated group. In other words, after 3 months, the unsuccessfully treated patients who received a combination of education and home PT perceived significantly less pain while chewing a standard bolus than patients who received only education. This finding might be explained by an improvement of blood flow in the masticatory muscles following light exercises, hot pads, and relaxation.[43,44] An alternative explanation for some positive effects of physiotherapy may be related to psychophysiological and central mechanisms mediated by the patient's coping skills, mood, and emotional state.[45] Due to the many statistical tests used in the analysis, it may be also possible that differences demonstrated in several measures could have occurred by chance.

Comparison of TCs did not show significant differences between the 2 treatment modalities. The lack of statistical significance may result from the limited power of several statistical tests used in the study. The power of the study was also limited by the 30% dropout rate and by the fact that majority of patients had poor or medium compliance (27% and 46% respectively) with the home PT regimen. The failure of several patients to maintain good compliance may have been due to the long duration of the home PT program, which was rather time-consuming.

It must be stressed, however, that a success rate of 77% for the education + home PT group compared to 57% for the education-only group may be considered clinically relevant.[46] Roberts et al described nonspecific effects (including the placebo effect) as accounting for between 30% to 66% of a treatment's "therapeutic effect."[47] This includes persuasion and the doctors' and patients' expectations and beliefs. These effects are quite likely to have appeared in our treatment regimens. The 77% success rate for the education + home PT regimen seems to be beyond this range, and thus the regimen may be advisable from a clinical viewpoint.

Among the unsuccessfully treated patients, TC_{pb} was significantly lower in the education + home PT group than in the education-only group (ie, the education + home PT group fared better). More specifically, the unsuccessfully treated patients assigned to the combination of education and home PT felt subjectively better than patients assigned to education alone. This finding is probably related to the greater "dose" of care received by the education + home PT group. This is also consistent with the conclusions of a meta-analysis that found that patients receiving more treatment modalities seem to do better than those receiving fewer modalities.[24] It is also possible that several patients in the education-only group were disappointed to receive only verbal instructions. It is remarkable, however, that the education alone led to a positive outcome of 57%. This observation supports the idea that education can be considered a good start in treatment of myofascial pain of the jaw muscles.

In order to be included in this clinical trial, patients had to report spontaneous pain greater than 30 mm at baseline on an anamnestic VAS. Therefore, the findings cannot be inferred to a general TMD population. It is possible that the effect of education or the combination of education and home PT would be different in a TMD patient with slight pain.

PPT change did not differ between the 2 treatment modalities, but it differed significantly

between successfully and unsuccessfully treated patients. Interestingly, significant PPT change was not restricted to the masticatory muscles but was also evident at the Achilles tendon. One explanation may be that a positive outcome is associated with better coping, a higher level of self-esteem, and general improvement of one's quality of life, while a negative outcome is associated with poor coping and a higher level of distress.[48]

Experimental evidence suggests that mood states may play an important role in affecting pain sensitivity in human subjects.[49–51] Recent research also suggests that pressure pain sensitivity of the masticatory muscles may be lowered during a prolonged, naturally stressful condition.[52]

The relationship between pain responses and psychological states is complex and only poorly understood. A large number of physiologic responses including peripheral as well as neural factors and neuroendocrine mechanisms are probably implicated. The last 2 systems could account for the simultaneous increases of pain sensitivity at the masticatory muscles and the Achilles tendon.

In conclusion, the combination of education and home PT is slightly more effective than education alone in the short-term, particularly because a wider range of jaw movement and a better subjective feeling of recovery were found in the unsuccessfully treated patients. Although there are some tendencies toward home PT being a little more effective in some of the outcome measures, we cannot make a conclusion about what a first-choice clinical approach should be. The limited power and the high dropout rate of this study should also be taken into consideration before drawing conclusions. The long-term effects of both treatments also need to be evaluated and will be the topic of future research.

Acknowledgments

A special thanks to Dr Anton de Wijer for his valuable advice, criticism, and helpful comments in preparing this manuscript.

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