Treating Temporomandibular Disorders in Adolescents: A Randomized, Controlled, Sequential Comparison of Relaxation Training and Occlusal Appliance Therapy

Kerstin Wahlund, DDS, Odont Dr
Senior Consultant
Department of Stomatognathic Physiology
Kalmar County Hospital
Kalmar, Sweden

Ing-Marie Nilsson, DDS, Odont Dr
Senior Consultant
Department of Stomatognathic Physiology
Centre for Oral Rehabilitation
Norrköping, and
Department of Orofacial Pain and Jaw Function
Malmö University
Malmö, Sweden

Bo Larsson, MD
Professor
Regional Centre for Child and Youth Mental Health and Child Welfare – Central Norway, and
National Competency Centre for Complex Disorders
St Olav Hospital
Trondheim, Norway

Correspondence to:
Dr Kerstin Wahlund
Department of Stomatognathic Physiology
Kalmar County Hospital
SE-391 85 Kalmar, Sweden
Fax: + 46480448988
Email: Kerstin.Wahlund@ltkalmar.se

Aims: To compare the effects of occlusal appliance therapy (OA) and therapist-guided relaxation training (RT) on temporomandibular disorder (TMD) pain in adolescents, thereby replicating a previous randomized controlled trial, and to explore whether additional therapy administered in a crossover sequential design improves treatment outcomes. **Methods:** The study involved 64 adolescents, aged 12 to 19 years, experiencing TMD pain at least once a week and diagnosed with myofascial pain in accordance with the Research Diagnostic Criteria for TMD. For phase 1 of the study, subjects were randomly assigned to OA or RT; nonresponders were offered the other treatment in phase 2. Self-reports of TMD pain and clinical assessments were performed before and after treatment in each phase and 6 months after the last treatment phase. Differences in outcomes between treatment groups across the different phases were analyzed by analysis of covariance (ANCOVA), and for differences in proportions, the chi-square test was used. **Results:** After phase 1, a significantly higher proportion of adolescents treated with OA (62.1%) than those treated with RT (17.9%) responded to treatment, defined as a subjective report of "Completely well/Very much improved" or "Much improved." Similar differences in self- report of treatment effect occurred after phase 2. About two-thirds of all adolescents in both phases reported such an improvement level at the 6-month follow-up, including a somewhat higher proportion of phase 1 responders (79.2%) than phase 1 nonresponders (60%). **Conclusion:** The findings suggest that, for adolescents with TMD pain, use of standardized clinical treatment with OA is more effective than RT on self-evaluation of treatment improvement. For nonresponders, subsequent crossover treatment might be useful to improve subjective TMD pain. *J Oral Facial Pain Headache 2015;29:41–50. doi: 10.11607/ofph.1285*

Key words: *adolescence, occlusal appliance, randomized controlled trial, relaxation training, temporomandibular disorders*

Temporomandibular disorder (TMD) pain is a rather common health problem among adolescents that involves the masticatory muscles, temporomandibular joint (TMJ), and associated structures.[1–3] Approximately 2% to 7% of adolescents have reported TMD pain in general population–based studies.[2,4] A large epidemiologic study of 28,899 Swedish adolescents aged 12 to 19 years found an overall prevalence of 4.2% for self-reported weekly TMD pain, with prevalence rates increasing with age; this was especially evident in girls.[3] TMD pain has a substantial impact on adolescents, negatively affecting their emotions and behaviors, psychosocial functioning, and quality of life.[5–8] Other recurrent pain conditions, such as tension-type headache (TTH), are also commonly associated with TMD among young sufferers.[2,5,9] While about two-thirds (66%) of adolescents who reported having TMD pain at least once a week wanted professional help, only 34% had received any form of care in dental clinics.[3,9]

In recent decades, occlusal appliance therapy (OA) has been widely used in the treatment of TMD pain, and there is some evidence of its benefits.[10–13] Other treatments, such as behavioral approaches consisting of relaxation training, biofeedback, and cognitive behavioral therapy (CBT), have also successfully treated TMD pain in adult patients.[14–16]

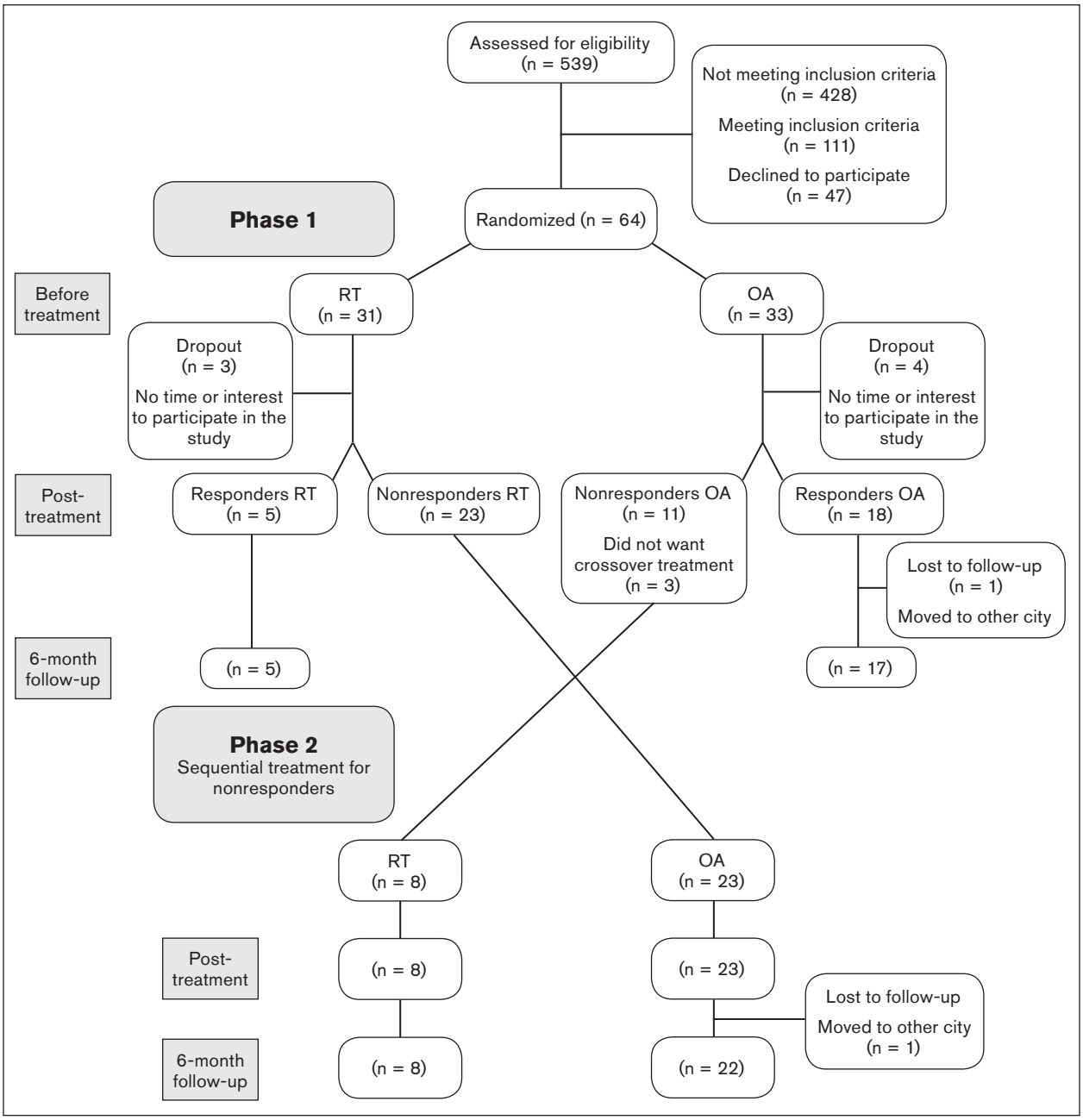

Fig 1 Flow diagram of the study. RT = relaxation training; OA = occlusal appliance therapy.

For example, one study found that a combination of splint and behavioral therapy improved pain complaints more effectively than either treatment given alone.[17] A recent systematic review of previous systematic reviews and meta-analyses of the management of TMD concluded that there is some evidence that conservative treatment, including OA and various types of behavioral interventions, can be effective in relieving TMD pain in adults.[18] They also reported that OA and behavioral therapies seem to have similar pain-reducing effects and are as effective as other forms of conservative TMD treatment. Additionally, a number of school- and clinic-based outcome studies have found that relaxation therapy is an effective treatment for adolescents suffering from frequent TTH or migraine headaches and that this improvement endured over various lengths of follow-up.[19–22]

The findings of a previous randomized controlled trial (RCT),[23] and the general lack of evidence on outcomes of TMD pain treatments in adolescents, highlight the necessity for further, systematic evaluations of TMD pain management in adolescents. Evidence on empirically based treatments for TMD pain is much greater for adults than for adolescents, and the

current use of OA in adolescents is primarily based on clinical experience and practice. In the earlier RCT of adolescents with TMD pain, a significantly higher proportion of patients treated with four sessions of OA and brief information achieved at least a 50% reduction in pain. Patients receiving the same number of therapist-based relaxation training (RT) sessions combined with brief information did not differ significantly from the control group (who received brief information only) and showed no improvement in TMD pain.[23] However, RT commonly lasts eight sessions and has been shown effective in numerous controlled studies of recurrent headaches among adolescents.[19–22] Therefore, to optimize treatment performance, it was decided to administer eight sessions of therapist-guided RT in this trial. The study aimed to compare the effects of OA and RT on TMD pain in adolescents, thereby replicating a previous randomized controlled trial, and to explore whether additional therapy administered in a crossover sequential design improves treatment outcomes.

Materials and Methods

Subjects

The study was conducted between September 2003 and January 2011, drawing subjects from the 539 adolescents referred to two specialist sites in Sweden for TMD treatment: the Department of Stomatognathic Physiology in Linköping and Norrköping (Fig 1). There were 111 patients who met the inclusion criteria and were invited to participate in the study. Of these 111 patients, 47 patients declined to participate, mainly due to distance and transportation problems. Consequently, the majority of the 64 study participants were recruited from the two cities.

Inclusion and Exclusion Criteria

The trial included patients: *(1)* aged 12 to 19 years; *(2)* experiencing TMD pain at least once a week for at least 3 months, as verified by a questionnaire and pain diary entries; *(3)* with a diagnosis of myofascial pain according to the Research Diagnostic Criteria for TMD (RDC/TMD)[24]; and *(4)* who wanted treatment. Patients excluded were those with no myofascial pain diagnosis and only a diagnosis of arthralgia and/or a disc displacement with reduction according to the RDC/TMD, as well as those with juvenile idiopathic arthritis, migraine, or ongoing orthodontic treatment that might interfere with OA.

All patients and their parents were informed about the study and signed a written consent form to participate. The Regional Ethics Committee of the Faculty of Health Sciences at Linköping University approved the study.

Randomization

Using a random number table, a secretary not otherwise involved in the study generated the allocation sequence to assign patients to a treatment, either OA or RT. The secretary put these assignments in sealed opaque envelopes. Before assignment, a trained nurse provided each patient with standardized information about TMD-related anatomy, TMD pain epidemiology, parafunction, and stress, as also provided in the previous RT.[23] After providing this information, the nurse opened the patient's envelope, randomly assigning the patient to one of the two treatment methods.

Trial Design

The study had two phases (see Fig 1). In phase 1, patients were randomly assigned to either RT or OA. Patients were evaluated before treatment (pre) and 3 months after treatment (post1). Phase 2 included only patients who did not respond to treatment in phase 1. These nonresponders were offered the alternate treatment method in a sequenced crossover design and were also reevaluated after 3 months (post2). All subjects were invited to participate in a 6-month follow-up after their final treatment phase.

Treatment

Occlusal appliance therapy (OA): A therapist with both theoretical and practical training for a year in occlusal appliance treatment administered the OA. The occlusal appliance was a stabilization splint placed in the maxilla. The splint surface was designed to produce maximum occlusal contact with canine guidance.[25] The therapist checked the splints after 2 weeks of use and adjusted them, if needed. The adolescents in the OA group were asked to use the splint every night until the posttreatment evaluation, and whenever they felt they needed it thereafter, until their 6-month follow-up. Adolescents in the OA group received treatment in four sessions of 30 minutes each, conducted every other week—a total of 2 hours of therapist time.

Relaxation training (RT): A trained and experienced therapist performed the RT procedures. Patients in this group received individual, clinic-based treatment for 8 weekly sessions of 45 minutes each, representing a total of 6 hours of therapist time. Each patient received a home-training program, including a manual and audio instructions, and was instructed to practice relaxation procedures at least once a day for 15 to 20 minutes.

The course of RT sessions was as follows:

- Sessions 1 and 2: Progressive muscle relaxation in a seated position focusing mainly on the upper part of the body, especially the muscles in the face and neck region
- Session 3: Progressive muscle contraction without tensing

- Session 4: Diaphragmatic breathing and the use of a cue-controlled word, "relax"
- Session 5: Relaxation during activities, eg, reading, standing, or walking
- Session 6: Short form of relaxation with breathing and activity
- Session 7: Application of relaxation at early signs of increased muscle tension or pain
- Session 8: Repetition

The main purpose of RT was to teach patients a quick coping method to use in everyday situations of increased bodily tension and at the onset of TMD pain.

Assessment

At each evaluation point, patients reported in a questionnaire the intensity, frequency, duration, unpleasantness, and location of their TMD pain; jaw function; tooth clenching and grinding; use of analgesics; and pain-related school absences. A dental assistant was present to review questionnaires for completeness and legibility and to answer questions, if needed. The patients also recorded their pain experiences in prospective daily diaries spanning 3 weeks each.

Clinical Examination

For diagnostic purposes, a clinical examination was performed in accordance with RDC/TMD examination guidelines and assessed pain site, mandibular movement capacity (mm), and associated pain, presence of joint sounds, and palpatory pain of the temporomandibular muscles and joints.[24] Two previously calibrated TMD specialists (KW and IMN), blinded to group assignment, performed the examination. The questionnaire and the clinical examination and diagnostic procedures have all shown acceptable reliability in adolescents with TMD.[26]

Treatment Evaluation

The outcome variables listed below were evaluated. For pain intensity, pain frequency, pain index, and unpleasantness, the highest scores reported for the temples, face, and jaws/jaw joints in the pre-, post-, and follow-up evaluations were used:

- *Pain intensity:* The average intensity of current pain was measured by using a 0 to 10 numeric rating scale (NRS), with 0 = "No pain" and 10 = "Worst pain imaginable" as endpoints.[26,27]
- *Pain frequency:* Patients reported their frequency of pain on a 5-point scale: "Never," "1 to 2 times a month," "Once a week," "Several times a week," or "Daily."
- *Pain index:* A pain index was calculated by multiplying the pain intensity score by the pain frequency score, with sum scores ranging from 0 to 50.[23]
- *Unpleasantness:* Adolescents were asked to rate the degree of unpleasantness due to TMD pain in the temples, face, and jaws/jaw joints on an 11-point NRS.
- *Clinical significance:* A pre-post reduction in the pain index of 50% or more was defined as clinically relevant pain improvement.[23] This is consistent with common use in headache outcome research as a benchmark for clinical significance and has been used extensively also among adolescents.[19,28]
- *Weekly pain diary:* Patients recorded TMD pain intensity and analgesic consumption in a pain diary four times daily: at breakfast, lunch, dinner (after school), and bedtime. Each diary spanned 3 weeks, with one completed before treatment, one immediately after treatment (post1 and post2), and one at the 6-month follow-up. Patients rated pain intensity on a 6-point behavioral rating scale with the following endpoints: 0 = "No pain," and 5 = "Very intense pain, totally handicapped, can't do anything."[29,30] Sum scores for this measure, here defined as weekly pain sum, ranged from 0 to 140.
- *Global improvement:* The Patient's Global Impression of Change Scale (PGIC)[31] was used to assess subjective improvement with treatment. This was the primary outcome measure. The PGIC is a 7-point scale with the following options: "Completely well/Very much improved," "Much improved," "Somewhat improved," "No change," "Somewhat worse," "Much worse," and "Very much worse." The PGIC was used to assess patients' response to treatment in phase 1. Adolescents reporting themselves "Completely well/Very much improved" or "Much improved" and requesting no further treatment were considered to be responders. Responders received no additional treatment and were evaluated at a 6-month follow-up. Patients who answered "Somewhat improved," "No change," "Somewhat worse," or "Much worse," or "Very much worse" were considered to be nonresponders. Nonresponders were offered subsequent treatment in phase 2 with the alternate treatment method, ie, OA treatment for phase 1 RT patients and vice versa.
- *Analgesic consumption:* Patients reported analgesic use on a 5-point scale: "Never or almost never," "1 to 2 times a month," "1 to 2 times a week," "3 to 4 times a week," or "Daily." They were also asked if these were prescription analgesics or over-the-counter medication.
- *School absence:* Patients reported the number of days of school missed during the last month because of TMD pain.

- *Maximum unassisted pain-free opening:* This distance was measured in millimeters with a ruler between the maxillary and mandibular central incisors, adding the vertical overbite.[26]

Classification

Because TMD and TTH have been found to coexist frequently, two complementary classification systems were used. The RDC/TMD allows multiple diagnoses to be set for a given patient. In addition to myofascial pain, the patient could also receive a diagnosis of disc displacement and/or arthralgia/arthrosis.[24] TTH was diagnosed as either episodic or chronic according to the International Headache Society (IHS) criteria.[32]

Treatment Motivation and Credibility

Before treatment, adolescents were asked to rate the following four questions on an 11-point scale:

1. "How motivated are you to begin this treatment?" [0 = "Not at all" and 10 = "Very much"]
2. "How much time and work are you willing to put into this treatment?" [0 = "None" and 10 = "Very much"]
3. "How good do you think this treatment is for the pain you have in your face and temples?" [0 = "Not good at all" and 10 = "Very good"]
4. "Would you recommend this treatment method to a friend with the same type of pain as you have?" ["No" or "Yes"]

Treatment Compliance

After treatment in both phases 1 and 2, and at the 6-month follow-up, patients treated with OA were asked to rate the frequency of their splint use on a 5-point scale: *(1)* "Every night," *(2)* "Several times a week," *(3)* "Once or twice a week," *(4)* "Occasionally," or *(5)* "Never." Patients in the RT group were asked to rate the frequency of training and their use of relaxation techniques for TMD pain on a similar 5-point scale: *(1)* "Daily," *(2)* "Several times a week," *(3)* "Once or twice a week," *(4)* "Occasionally," and *(5)* "Never."

Statistical Analyses

Based on the results of the previous RCT,[23] a power analysis was performed to determine the sample size necessary to detect a one-sided difference in pain improvement between the OA and RT treatment groups, with improvement defined as a 50% pre-post reduction in the pain index. It was estimated that 33 subjects per treatment group would be sufficient to detect this difference on a 5% alpha level with 80% power. Given an anticipated dropout rate of 10%, the target was a total sample size of approximately 75 subjects. However, due to the extended 7-year recruitment period and barriers to recruitment of patients, the final sample included only 64 subjects, representing 85% of the desired sample size.

Descriptive statistics included numbers and percentages of subjects, means, and SDs. Associations between categorical variables were analyzed by using the Pearson chi-square test or the Fisher exact tests, and agreement between categorical variables with Kappa coefficients. Student *t* test or analysis of covariance (ANCOVA) was used to assess mean differences between and within groups for parametric variables, and within-group change over time was measured with the dependent *t* test. In these analyses, effect size (ES) was estimated by using Cohen's eta square.[33] For ordinal variables and between-group differences, the Mann-Whitney test was used. The level of alpha was set to $P < .05$.

Results

Pretreatment Assessment

Table 1 shows the distribution of sex, age, dropouts, duration of TMD pain, and diagnosis. There was no significant difference between treatment groups in any of these variables. All subjects received a diagnosis of myofascial pain in the examination. The distribution of patients with a diagnosis of arthralgia or/and disc displacement with reduction is shown in Table 1. The majority of the patients reported episodic or chronic TTH as well.

During the phase 1 treatment period, three patients in the RT group (9.7%) and four in the OA group (12.1%) dropped out. Two of the patients in the RT group received two to three sessions before dropping out, while the remaining five dropouts did not undergo any treatment. All dropouts stated that they did not have time or were not interested in continuing participation in the study.

The analyses outlined below were primarily carried out in accordance with the protocol analyses excluding dropouts during treatment. The results were also contrasted to the more conservative intent-to-treat (ITT) analysis, in which dropouts were included in the primary outcome measures. In these ANCOVA analyses, imputation of posttreatment scores were based on percentages of pre-post changes observed in a control group in a previous RCT[23] having received the same amount of pedagogic information as in the present study.

Treatment Credibility and Motivation

The results of the independent *t* test showed that the two treatment groups were identical in their subjective evaluations of "Overall treatment credibility" (mean ± SD was 7.7 ± 1.8 for OA and 7.7 ± 1.7 for RT)

Table 1 Distribution of the Two Treatment Groups (RT=Relaxation training, OA= Occlusal appliance) by Sex, Age, Duration of TMD Pain, Dropout, and Diagnoses

	Treatment group		
Variable	RT (n=31)	OA (n=33)	All (n=64)
Sex			
Girls	30 (96.8%)	31 (93.9%)	61 (95.3%)
Boys	1 (3.2%)	2 (6.1%)	3 (4.7%)
Mean age ± SD (y)	16.5 ± 1.86	16.3 ± 1.91	16.4 ± 1.87
Duration of TMD pain (mo)			
Temple	23.8 ± 19.2	24.5 ± 25.9	24.7 ± 20.0
Face	20.0 ± 16.5	25.9 ± 19.3	23.1 ± 18.1
Dropout	3 (9.7%)	4 (12.1%)	7 (10.9%)
RDC/TMD			
Myofascial pain	31 (100%)	33 (100%)	64 (100%)
Disc displacement	8 (25.8%)	10 (30.3%)	18 (28.1%)
Arthralgia	17 (54.8%)	9 (27.3%)	44 (68.7%)
Episodic tension-type headache (ETTH)	17 (54.8%)	19 (57.6%)	36 (56.2%)
Chronic tension-type headache (CTTH)	13 (41.9%)	12 (36.4%)	25 (39.1%)

and for "Recommending treatment to someone else" (7.7 ± 2.2 and 7.6 ± 2.1 for OA and RT). While "Treatment motivation" was somewhat higher in the OA group than the RT group (8.6 ± 1.7 and 8.0 ± 1.8, respectively), this difference was not significant. However, the OA group reported significantly higher scores in "Time available for treatment" than the RT group (8.6 ± 1.7 and 7.7 ± 1.8, respectively), $t[62] = 2.06$, $P < .05$.

Phase 1: Randomized Treatment

Overall, 36% of all adolescents reported being "Completely well/Very much improved" or "Much improved," 34.4% were "Somewhat improved," and 29.6% were "Unchanged" or "Worse/much worse" at the end of phase 1. The results of the chi-square test showed that 62.1% of the adolescents treated with OA were "Completely well/Very much improved" or "Much Improved," while only 17.9% of those in the RT group reported such levels of improvement, a highly significant difference, χ^2 [1] = 11.57, $P < .001$. The proportion of subjects who had achieved a 50% reduction in the pain index was 33.1% in the OA group and only 17.2% in the RT group, but this difference was not significant.

In the analyses using ANCOVAs and posttreatment scores as outcome, there were no significant differences between treatment groups in the weekly pain sums from the composite pain index variable (frequency and intensity), pain intensity, and the prospective pain diaries (ES varied from 2.1% to 5%). Nor were any differences found for unpleasantness due to TMD pain, drug consumption, number of school absences, or maximum unassisted pain-free jaw opening (Table 2). In the ITT analyses, for TMD pain index, posttreatment scores were clearly lower in the OA than in the RT group, but the difference was not significant, F(1, 61) = 3.64, $P = .06$ (ES 6%). Pain intensity and weekly diary recordings were also not significant, with estimates of ES being 4.6% and less than 1%, respectively.

No patients in either treatment group reported any major adverse treatment effects.

Phase 2: Treatment of Nonresponders

At posttreatment evaluation after phase 1, two of the nonresponding patients in the OA group refused crossover-sequenced treatment in phase 2. They were evaluated further at a 6-month follow-up. One other nonresponding patient in the OA group was excluded from phase 2 due to increasing pain in the jaw joint; the patient was treated with an intra-articular cortisone injection.

After phase 2, 51.6% of phase 1 nonresponders reported being "Completely well/Very much improved" or "Much improved." A higher proportion of adolescents treated with OA (56.5%) than those treated with RT (37.5%) reported being "Completely well/Very much improved" or "Much improved," but this difference was not significant (total n = 31). Also, the proportion of adolescents treated with RT (43%) who achieved a 50% reduction in the pain index compared to those treated with OA (32%) was not significant. With nonparametric analyses (n = 22 vs 8, respectively, for OA and RT groups), again no significant differences occurred between treatment groups in gain scores across phase 2 for pain frequency, pain intensity, diary recordings, unpleasantness due to TMD pain, medication use, school absence, or maximum unassisted pain-free jaw opening (Table 2).

Table 2 Pain Variables, School Absences, Analgesic Consumption, and Mandibular Movement Capacity by Treatment Group from Pretreatment to Follow-up

	Phase 1						Phase 2			
	Pre		Post1		Follow-up[a]		Post2		Follow-up[b]	
Variable	OA (33)	RT (31)	OA (29)	RT (28)	OA (17)	RT (5)	OA (23)	RT (8)	OA (22)	RT(8)
Average pain intensity (NRS 0–10); mean ± SD	5.5 ± 2.0	5.4 ± 1.9	3.7 ± 2.0	4.4 ± 1.8	2.8 ± 1.6	2.8 ± 1.9	3.6 ± 1.8	4.6 ± 2.3	3.6 ± 2.2	4.0 ± 2.6
Pain frequency (0 to 5) median, IQR	4.0 (1.0)	4.0 (1.0)	4.0 (1.0)	4.0 (1.0)	3.0 (1.0)	2.0 (1.0)	4.0 (1.0)	4.0 (1.8)	3.0 (2.0)	3.5 (1.8)
Pain index (intensity × frequency); mean ± SD	23.4 ± 10.7	23.7 ± 10.6	14.7 ± 9.4	18.4 ± 9.5	8.4 ± 6.3	6.0 ± 3.7	13.4 ± 8.5	18.5 ± 0.7	12.1 ± 9.1	14.8 ± 11.0
Pain diary (0 to 140) mean ± SD	44.0 ± 23.6	42.9 ± 16.8	31.8 ± 24.5	35.6 ± 19.6	18.6 ± 19.4	13.7 ± 9.4	26.0 ± 18.2	31.0 ± 24.1	26.3 ± 21.1	24.7 ± 21.1
School absence (0 to 31 days); mean ± SD	0.3 ± 0.8	1.2 ± 2.1	0.2 ± 0.8	0.5 ± 1.0	0.2 ± 0.5	0.0 ± 0.0	0.2 ± 0.7	0.0 ± 0.0	0.5 ± 1.2	0.0 ± 0.0
Analgesic consumption (0 to 5); median, IQR	2.0 ± 2.0	2.0 ± 1.0	2.0 ± 2.0	2.0 ± 1.0	1.0 ± 1.0	2.0 ± 0.5	2.0 ± 1.0	1.0 ± 1.0	1.0 ± 1.0	1.5 ± 1.8
Unassisted pain-free jaw opening (mm); mean ± SD	40.2 ± 8.6	44.9 ± 10.9	43.1 ± 8.0	45.3 ± 9.2	46.4 ± 8.4	52.4 ± 7.8	49.0 ± 10.0	46.1 ± 7.2	46.1 ± 9.0	48.7 ± 6.9

RT = relaxation training; OA = occlusal appliance; NRS = numeric rating scale; IQR = interquartile range (q1–q3); [a]Six-month follow-up for responders after phase 1; [b]Six-month follow-up for nonresponders after phase 2.

Six-Month Follow-up

Six months after their last treatment phase, 68.5% of all adolescents had achieved a subjective improvement level of "Completely well/Very much improved" or "Much improved." A somewhat higher proportion of phase 1 responders (79.2%) than phase 1 nonresponders (60%) achieved these levels of improvement, but the difference was not significant. There was no difference between the various lines of patient allocation across time in any of the evaluated pain parameters.

Associations Between Global Improvement, Changes in Pain Index, and Diary Recordings

There were significant associations after phase 1 between the subjective improvement ratings on the PGIC and both a 50% reduction in pain index (χ^2 [1] = 13.30, $P < .001$) and prospective pain recordings (χ^2 [1] = 9.04, $P < .01$), as well as between pain index and prospective pain recordings (χ^2 [1] = 10.90, $P < .01$). However, the agreement was low to modest, as reflected by Kappa coefficients of 0.12, 0.09, and 0.44, respectively. At the 6-month follow-up, similar associations were found between improvement ratings and pre–follow-up changes in pain index and diary recordings (χ^2 [1] = 8.15, $P < .01$ and χ^2 [1] = 9.65, $P < .01$, respectively), and between pain index and diary recordings (χ^2 [1] = 7.89, $P < .01$), with Kappas of 0.16, 0.16, and 0.39, respectively.

Treatment Credibility, Compliance, and Patient Satisfaction Versus Outcome

Pretreatment credibility ratings including motivation were consistently higher among adolescents who were responders ("Completely improved" or "Much improved") and higher among subjects showing improvement in the pain index and in the diary after phase 1 than among subjects with lower credibility ratings. However, these differences were all not significant.

Treatment compliance in the OA group was acceptable, with 41.4% reporting use of their occlusal appliance every night and 48.3% reporting use several nights a week during phase 1, while just one adolescent reported only occasional use. At the 6-month follow-up, about two-thirds reported using their splint several times a week or more. However, training compliance in the RT group was low. Only 12% trained daily when instructed to do so, while 68% reported training at least once a week. By contrast, about three-quarters (78%) reported using the method at least several times a week when experiencing TMD pain. In the OA group, a significantly higher proportion of adolescents who used the method "daily or

almost daily" (70.4%) were responders to treatment than those who used it less frequently (29.6%); Fisher exact test, $P < .05$. Because only five adolescents were responders to RT, no such analysis was performed. In the OA group, treatment compliance correlated with improvement in pain index scores. While daily OA users improved more than less-frequent OA users, this difference was not significant ($t[28] = 1.96$, $P = .06$). A similar but not significant difference also occurred for treatment compliance in diary recordings, and there were no significant relationships between RT treatment compliance and outcome measures.

After phase 1, a significantly greater proportion of adolescents reported OA treatment to be "Very good" (55.2%) than RT (28.6%), while 24.1% and 60.7% in the respective groups reported treatment to be "Rather good" (χ^2 [2] = 7.82, $P < .05$). At the 6-month follow-up, 87% of all adolescents reported their overall treatment to be either "Very good" or "Rather good."

Discussion

This study used a two-phase, sequential, crossover design to compare the effects of OA and RT on TMD pain in adolescents. Given the positive findings of a previous RCT[23] and the paucity of evidence on the effectiveness of treatments for TMD pain among adolescents, the study aimed to replicate the previous study and to explore how to improve treatment outcomes. Overall, the attrition rates for this study were low (about 9% to 12% for phase 1 and an additional 10% during phase 2), somewhat lower than the previous study, in which 12% to 17% of adolescents with TMD pain in the same age range dropped out.[23] As in the previous RCT, the main causes of attrition were lost interest or insufficient time to continue participation in the study.

For PGIC, the primary outcome measure, a significant majority of adolescents treated with OA (62.1%) reported that they were completely recovered or much improved in phase 1 and did not want further treatment, while only 17.9% of those treated with RT procedures reported the same level of improvement. Although posttreatment pain index scores were lower in the OA than the RT group, the difference was not significant; the same was true for changes in the other pain-related measures. The findings for adolescents with TMD pain of both the previous RCT and the present trial showed statistical improvement only in subjective TMD pain measures and not in pure dental measures.[23] However, the finding of subjective improvement in the PGIC is even more important, given that it was the only measure used in the present study that reflects a personalized view of pain improvement and its meaningfulness, not only a normative or a statistical perspective on clinical change.[34]

Although treatment motivation was somewhat higher in the OA group than in the RT group and the OA group had significantly more "time available for treatment," the previous RCT showed similar results without these differences between the treatment groups in motivation and time available.

Further, the compliance rate in the present study varied greatly between the two treatments. More than three times as many subjects in the OA group reported using their treatment daily than in the RT group during phase 1. There was a positive relationship between splint usage and improvement in pain measures, while there was no such relationship for RT. The previous trial found similar results.[23]

Adolescents who used OA "daily or almost daily" during the first phase also responded to treatment significantly more often than those who used it less often. The lower training compliance in the RT group might be due to the fact that this treatment approach requires a greater active commitment from the adolescent during the training phase and systematic application in everyday life when TMD pain occurs. The unexpected poor outcomes of RT are likely due to adolescents spending less time in training, also reflected by a lower treatment satisfaction in their evaluations. However, the poor outcome of RT may also suggest that it is not an effective treatment for adolescents with TMD pain. This would be somewhat surprising, given that RT usually administered in eight to nine sessions has been found to be highly effective in treating recurrent and chronic headaches in adolescents.[19–22] For some young people, a more extended therapeutic support provided in a greater number of sessions may be helpful to improve their TMD pain.

Although the mechanisms of splint therapy are still unclear, its pain-relieving efficacy has often appeared to be similar to other treatments, such as acupuncture, biofeedback/stress management, visual feedback, and jaw exercises, as well as RT.[10–13,18] However, both the previous and present studies of adolescents with TMD pain found differential treatment effects, favoring OA treatment, and in both only small effects for RT.

While the present study used various types of pain-related measures to evaluate treatment outcomes, the primary outcome measure was a subjective assessment of improvement after treatment. The study also used a composite TMD pain index measure, which combined pain frequency and intensity and prospective entries in a standardized pain diary as secondary measures. Prospective diaries show the course of daily TMD pain in everyday life.

The global pain scale adds further depth to the other outcome measures; in addition to pain relief, it also captures other dimensions such as improved function, side effects, and treatment expectations. A measure of unpleasantness due to pain was also used to examine the affective component of the pain experience. Although the outcome measures were all strongly associated with each other, their agreement was low, suggesting that they reflect various dimensions of the TMD pain experience in adolescents. All in all, these measures were chosen to capture various aspects of TMD pain in adolescents in order to provide a more comprehensive picture of its change over time.

More than half of all patients experienced substantial subjective recovery after subsequent crossover treatment in phase 2, especially those treated with OA in phase 2. Improvement was well maintained for both in phase 1 and phase 2 responders at the 6-month follow-up. The overall findings suggest that combined treatment with OA and RT, given sequentially, may be of benefit to improve treatment outcomes for nonresponders with TMD pain. This conclusion is supported by the finding of small differences between the treatment lines, ie, for responders vs nonresponders, and added treatment at the 6-month follow-up.

The present study was somewhat limited by its sample size, which was smaller than the power analysis indicated as being sufficient to obtain significant outcomes. This might lead to a type II error and prevent the detection of real treatment effects. However, the significant differences in the PGIC indicate that OA was evaluated by the adolescents as a more effective treatment for TMD pain than RT. Additionally, because this study had no untreated control group, it is difficult to evaluate whether the influence of nontreatment factors or the mere passage of time over the extended 9-month evaluation period might have contributed to the observed improvement of TMD pain. Nevertheless, the previous RCT, which compared OA and RT of roughly the same duration as this study, observed only a minor improvement in a control group exposed to pedagogic information during one session, which was also provided to both groups in the present study. Thus, despite its limitations, the findings of the present study contribute to the empirical knowledge of the effects of RT and OA treatments and may help to guide future research to develop further more effective treatments of TMD pain in adolescents.

Conclusions

Overall, the findings of this study, as reflected by subjective and individual assessments, indicate that the use of standardized clinical treatment with OA for adolescents suffering from TMD pain was more effective than eight standardized sessions of RT. For nonresponders, subsequent treatment with the alternate treatment may be useful to improve subjective TMD pain. Importantly, OA appears to be a cost-effective clinical treatment in terms of therapist time. The results of the previous and present studies need to be replicated in other clinical settings and in larger samples. To further improve outcomes, other treatments should also be evaluated and compared to the standardized use of OA, preferably in both short- and long-term trials.

Acknowledgments

The authors thank research assistants Gun Hector and Christina Holmgren for their help in carrying out this study. This study was supported by the Swedish Dental Society; the Public Dental Service of Östergötland (Östergötland County Council), Sweden; and the Public Dental Service of Kalmar (Kalmar County Council), Sweden. The authors report no conflicts of interest related to this study.

References

1. Wänman A, Agerberg G. Recurrent headaches and craniomandibular disorders in adolescents: A longitudinal study. J Craniomandib Disord 1987;1:229–236.
2. List T, Wahlund K, Wenneberg B, Dworkin SF. TMD in children and adolescents: Prevalence of pain, gender differences, and perceived treatment need. J Orofac Pain 1999;13:9–20.
3. Nilsson IM, List T, Drangsholt M. Prevalence of temporomandibular pain and subsequent dental treatment in Swedish adolescents. J Orofac Pain 2005;19:144–150.
4. Drangsholdt M, LeResche L. Temporomandibular disorder pain. In: Crombie IK, Croft DR, Linton SJ, LeResche L, Von Korff M (eds). Epidemiology of Pain. Seattle: IASP Press, 1999: 203–233.
5. List T, Wahlund K, Larsson B. Psychosocial functioning and dental factors in adolescents with temporomandibular disorders: A case-control study. J Orofac Pain 2001;15:218–227.
6. Bonjardim LR, Gavião MB, Pereira LJ, Castelo PM. Anxiety and depression in adolescents and their relationship with signs and symptoms of temporomandibular disorder. Int J Prosthodont 2005;18:347–352.
7. Nilsson IM, Drangsholt M, List T. Impact of temporomandibular disorder pain in adolescents: Differences by age and gender. J Orofac Pain 2009;23:115–122.
8. Hirsch C, Türp JC. Temporomandibular pain and depression in adolescents—A case-control study. Clin Oral Investig 2010;14:145–151.
9. Nilsson IM, List T, Drangsholt M. The reliability and validity of self-reported temporomandibular disorder pain in adolescents. J Orofac Pain 2006;20:138–144.

10. Dao TT, Lavigne GJ. Oral splints: The crutches for temporomandibular disorders and bruxism? Crit Rev Oral Biol Med 1998; 9:345–361.
11. Forssell H, Kalso E. Application of principles of evidence-based medicine to occlusal treatment for temporomandibular disorders: Are there lessons to be learned? J Orofac Pain 2004;18:9–22.
12. Türp JC, Komine F, Hugger A. Efficacy of stabilization splints for the management of patients with masticatory muscle pain: A qualitative systematic review. Clin Oral Investig 2004;8: 179–195.
13. Al-Ani MZ, Davies SJ, Gray RJ, Sloan P, Glenny AM. Stabilisation splint therapy for temporomandibular pain dysfunction syndrome. Cochrane Database Syst Rev 2004;1: CD002778.
14. Okeson JP, Moody PM, Kemper JT, Haley JV. Evaluation of occlusal splint therapy and relaxation procedures in patients with temporomandibular disorders. J Am Dent Assoc 1983;107:420–424.
15. Crider AB, Glaros AG. A meta-analysis of EMG biofeedback treatment of temporomandibular disorders. J Orofac Pain 1999; 13:29–37.
16. Liu HX, Liang QJ, Xiao P, Jiao HX, Gao Y, Ahmetjiang A. The effectiveness of cognitive-behavioural therapy for temporomandibular disorders: A systematic review. J Oral Rehabil 2012; 39:55–62.
17. Turk DC, Zaki HS, Rudy TE. Effects of intraoral appliance and biofeedback/stress management alone and in combination in treating pain and depression in patients with temporomandibular disorders. J Prosthet Dent 1993;70:158–164.
18. List T, Axelsson S. Management of TMD: Evidence from systematic reviews and meta-analyses. J Oral Rehabil 2010;37: 430–451.
19. Larsson B, Carlsson J, Fichtel Å, Melin L. Relaxation treatment of adolescent headache sufferers: Results from a school-based replication series. Headache 2005;45:692–704.
20. Trautmann E, Lackschewitz H, Kröner-Herwig B. Psychological treatment of recurrent headache in children and adolescents—A meta-analysis. Cephalalgia 2006;26:1411–1426.
21. Palermo TM, Eccleston C, Lewandowski AS, Williams AC, Morley S. Randomized controlled trials of psychological therapies for management of chronic pain in children and adolescents: An updated meta-analytic review. Pain 2010;148: 387–397.
22. Eccleston C, Palermo TM, de C Williams AC, et al. Psychological therapies for the management of chronic and recurrent pain in children and adolescents. Cochrane Database Syst Rev 2012;12:CD003968.
23. Wahlund K, List T, Larsson B. Treatment of temporomandibular disorders among adolescents: A comparison between occlusal appliance, relaxation training, and brief information. Acta Odontol Scand 2003;61:203–211.
24. Dworkin SF, LeResche L. Research diagnostic criteria for temporomandibular disorders: Review, criteria, examination and specifications, critique. J Craniomandib Disord 1992;6: 301–355.
25. Clark GT. Interocclusal appliance therapy. In: Mohl ND, Zarb GA, Carlsson GE, Rugh JD (eds). A Textbook of Occlusion. Chicago: Quintessence, 1988:271–284.
26. Wahlund K, List T, Dworkin SF. Temporomandibular disorders in children and adolescents: Reliability of a questionnaire, clinical examination, and diagnosis. J Orofac Pain 1998;12:42–51.
27. Seymore RA, Simpson JM, Charlton JE, Phillips ME. An evaluation of length and end-phrase of visual analogue scales in dental pain. Pain 1985;21:177–185.
28. Blanchard EB, Andrasik F, Evans DD, Neff DF, Appelbaum KA, Rodichok LD. Behavioral treatment of 250 chronic headache patients: A clinical replication series. Behav Ther 1985;16: 308–327.
29. Blanchard EB, Andrasik F, Neff DF, Jurish SE, O'Keefe DM. Social validation of the headache diary. Behav Ther 1981;12: 711–715.
30. Larsson B, Melin L. The psychological treatment of recurrent headache in adolescents—Short-term outcome and its prediction. Headache 1988;28:187–195.
31. Farrar JT, Young JP, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001;94:149–158.
32. Headache Classification Committee of the International Headache Society. Classification and diagnostic criteria for headache disorders, cranial neuralgias and facial pain. Cephalalgia 1988;8:1–96.
33. Cohen J. Statistical Power Analysis for the Behavioral Sciences. Hillsdale, NJ: Lawrence Erlbaum Associates, Publishers, 1988.
34. Birnie KA, McGrath PJ, Chambers CT. When does pain matter? Acknowledging the subjectivity of clinical significance. Pain 2012;153:2311–2314.