

# Effect of Therapeutic Jaw Exercises in the Treatment of Masticatory Myofascial Pain: A Randomized Controlled Study

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**Aims:** To study the effect and cost-effectiveness of jaw exercise treatment in patients with masticatory myofascial pain. **Methods:** A total of 97 patients with myofascial pain according to the RDC/TMD were randomized into three groups: (1) jaw exercises; (2) stabilization appliance; or (3) no treatment. After 3 months, the patients were evaluated according to the following instruments: pain intensity according to a visual analog scale (VAS); global improvement according to the Patient Global Impression of Change scale (PGIC); depression and anxiety according to the Hospital Anxiety and Depression Scale (HADS); jaw function according to the Jaw Functional Limitation Scale (JFLS-20); consumption of analgesics; and frequency of tension-type headache. **Results:** Pain intensity during jaw movement decreased significantly more in the jaw exercise group compared to the no treatment group ( $P < .001$ ). There was no statistically significant difference between the jaw exercise and stabilization appliance groups in this aspect. The patients in the treatment groups reported greater improvement on the PGIC compared to the no treatment group ( $P < .001$ ). There was a significant decrease in headache frequency ( $P = .028$ ), consumption of analgesics ( $P = .007$ ), and JFLS scores ( $P = .008$ ) in the jaw exercise group compared to the no treatment group. In the jaw exercise group, patients had fewer appointments and a lower mean treatment time compared to the group that received stabilization appliance treatment. **Conclusion:** Jaw exercises are effective in reducing pain intensity, headache, and consumption of analgesics in patients with masticatory myofascial pain. Jaw exercises are also cost-effective when compared to treatment with a stabilization appliance. *J Oral Facial Pain Headache 2020;34:364–373. doi: 10.11607/ofph.2670*

**Keywords:** dentistry, exercise, facial pain, physical therapy modalities, temporomandibular joint dysfunction syndrome

**T**MMD, a group of conditions affecting the TMJs and masticatory muscles, is one of the most common reasons for nondental pain in the orofacial region.<sup>1</sup> The most common symptom of TMD is myalgia of the jaw muscles. Headache, restricted mouth-opening capacity, and pain in connection to chewing or other jaw functions are also often reported by TMD patients.<sup>2</sup> Conservative and reversible treatment regimens, such as interocclusal appliances, pharmacologic treatment, cognitive behavioral therapies, and therapeutic jaw exercises, are common in the management of TMD myalgia.<sup>3,4</sup>

Interocclusal appliances are widely used for treating TMD.<sup>5,6</sup> Many different appliances have been described in the literature,<sup>3</sup> but the stabilization appliance has the best scientific support for efficacy and effectiveness. In a number of short- and long-term RCTs,<sup>7–9</sup> Ekberg et al have shown that stabilization appliances have a favorable effect on tension-type headache and TMD of both myogenous and arthrogenous origin. Systematic reviews have also shown that treatment with stabilization appliances is better than no treatment in the management of TMD.<sup>10–12</sup> A wide range of different mechanisms of action, such as increased vertical dimension, reversible elimination of occlusal interferences, and nonspecific effects linked to the patient-doctor relationship, etc, have been discussed.<sup>3,13</sup> Most likely, it is a combination of different mechanisms that leads to a positive end result.<sup>3</sup>

Another commonly used treatment for TMD consists of therapeutic jaw exercises that aim to attain relaxation in tender/sore jaw muscles and to reduce pain. The mechanisms behind this treatment effect are considered to be a result of proprioceptive neuromuscular facilitation, increased awareness, stretching, and reciprocal muscle inhibition.<sup>14</sup> Reciprocal inhibition is a process by which the contraction of a muscle group results in a stretch of muscle spindles, which in turn produces a reflexive response and inhibition of the opposing muscle group. This is an important process because the opposing muscle group might otherwise work against the intended movement.<sup>15</sup> The absolute number of muscle spindles in the digastric and mylohyoid muscles, which are responsible for jaw opening, has been shown to be sparse.<sup>16</sup> Still, even with a limited number of muscle spindles, the digastric muscle does not seem to lack reflex activity,<sup>17,18</sup> as some authors have suggested.<sup>19</sup>

Exercise has also been proposed to produce hypoalgesia by activation of the endogenous opioid system and descending inhibitory pathways.<sup>20</sup> Lanefelt et al<sup>21</sup> have shown that static contraction of the masseter muscle produces local hypoalgesia, a finding that indicates that jaw exercise can activate the endogenous opioid system. Some earlier RCTs have shown that jaw exercises can be effective in the treatment of TMD myalgia.<sup>14,22</sup> It was shown in a more recent RCT that jaw exercises in combination with counseling were effective in reducing TMD pain and that treatment with a stabilization appliance did not offer any significant additional treatment effect.<sup>23,24</sup> Due to a limited number of RCTs and small sample sizes in published studies, the effectiveness of exercises for the management of TMD is still uncertain.<sup>25</sup>

The aims of the present study were to study the treatment effect and cost-effectiveness of therapeutic jaw exercises in patients with masticatory myofascial pain in comparison to treatment with a stabilization appliance and waiting-list control subjects.

## Materials and Methods

### Study Population

The selection of patients was carried out according to the following inclusion and exclusion criteria:

The inclusion criteria were: myofascial pain with or without limited mouth opening according to the Research Diagnostic Criteria for TMD (RDC/TMD) Axis I<sup>26</sup>; pain intensity during rest and/or during jaw movements > 40 mm on a 0- to 100-mm visual analog scale (VAS)<sup>27</sup>; pain for a minimum of 6 months; and age  $\geq$  18 years. The patient could also have tension-type headache according to the International Classification of Headache Disorders<sup>28</sup>; disc dis-

placement with reduction; and/or arthralgia of the TMJ according to the RDC/TMD Axis I.<sup>26</sup>

The exclusion criteria were: osteoarthritis, osteoarthritis, and disc displacement without reduction according to RDC/TMD Axis I criteria<sup>26</sup>; complete dentures; treatment with an interocclusal appliance within the last 5 years; dental or neuropathic pain; rheumatic disease or general inflammatory condition; widespread pain (eg, fibromyalgia); whiplash disorder; severe morphologic malocclusion (ie, anterior open bite, pre-normality, forced crossbite, post-normality where the horizontal overbite exceeds 5 mm); known psychiatric disease; language difficulties; and/or gross occlusal interferences hampering the possibility of making an optimal interocclusal appliance.

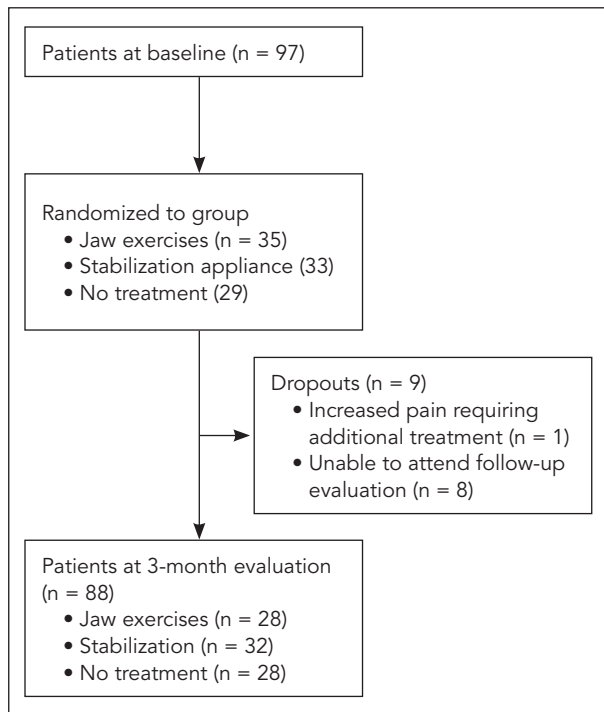
### Study Protocol

This was a prospective, randomized, controlled trial with three arms registered at researchweb.org (number 84441). The reporting of data followed the CONSORT (Consolidated Standards of Reporting Trials) guidelines.<sup>29</sup>

Patients referred to the Department of Stomatognathic Physiology, Public Dental Health Service, Uppsala, Sweden, who fulfilled the inclusion criteria and who wanted to participate were randomly divided into three groups: therapeutic jaw exercises (group 1), hard acrylic stabilization appliance (group 2), and no treatment (group 3). All patients received information about their diagnoses according to RDC/TMD Axis I criteria.<sup>26</sup> Randomization was carried out through the use of sealed envelopes containing information about the allocated treatment. Preparation of the randomization envelopes was done by a research assistant who did not participate in the other stages of the study. The randomization envelopes were constructed in one block. After including a patient in the study, the main author (E.L.) drew a randomization envelope that decided which group the patient was included in, and the patient was given a consecutive number and put on a list. This list was kept hidden from the research assistant, who evaluated the patients with follow-up questionnaires. The patients were not blinded to the treatment intervention, but none of them knew which treatment was being evaluated. The research assistant who evaluated the patients was totally blinded and did not know which treatment the patient had received.

Since there is no established placebo treatment for therapeutic jaw exercises, no treatment (ie, waiting-list patients) was chosen as a passive control. A hard acrylic stabilization appliance was chosen as an active control.

After statistical power calculation, a total of 174 patients evenly distributed among the three groups was considered to be enough to separate the groups with 80% power, a clinically significant difference of 30% (SD 52.5%), and a significance level of 5%. The



**Fig 1** Flowchart of study protocol.

aim was to include 210 patients to control for possible dropouts.

The present study began in September 2010 and ended in late December 2017 due to the project's settled time limit. During the course of this study, 882 patients were screened for eligibility, but only 98 fulfilled the inclusion criteria. One patient declined participation, and consequently 97 patients were included. After the described randomization procedure above, these patients were distributed according to the following: 35 patients in group 1; 33 patients in group 2; and 29 patients in group 3. Nine patients dropped out before the final evaluation at 3 months (Fig 1). The mean age was 35 years (SD 18), and a majority of patients were women (77 women and 20 men). The mean pain duration was 25 months (SD 36).

### Treatment Procedure

The patients in groups 1 and 2 were all treated by the main author (E.L.). The patients in group 1 received relaxation exercises, free movements of the mandible, movements of the mandible with light resistance, and finally stretching of the jaw muscles as described by Carlsson and Magnusson<sup>3</sup> (Fig 2). The patients were instructed to perform each exercise 10 times, except for the final stretching exercise, which they were instructed to do 2 to 3 times. The recommendation was to perform the exercises three times a day.

In group 2, alginate impressions of the maxilla and mandible were taken, as well as an interocclusal bite registration in centric relation with a wax wafer.



**Fig 2** Exercises included in the jaw exercise program involving free movements of the mandible: **(a)** maximum jaw opening, **(b and c)** laterotrusion, and **(d)** protrusion without resistance. Movement of the mandible with a small resistance (eg, with a couple of fingers): **(e)** jaw closing, **(f)** jaw opening, **(g and h)** laterotrusion, and **(i)** protrusion. **(j)** Stretching with fingers.

The impressions and wax wafer were sent to a dental technician, who made a hard acrylic resin stabilization appliance, which the patients received after 2 weeks. The stabilization appliances were carefully adjusted to optimal stability in centric relation, allowing for a freedom in centric relation of approximately 0.5 to 1.0 mm. The teeth in the opposite arch were given point contacts on the appliance both in centric relation and in the patient's own bite position. It was aimed to achieve canine guidance in lateral excursion and anterior guidance (with group function) in protrusion. The stabilization appliance was then polished, and the patients were instructed to use the appliance every night.

Carefully written patient information concerning treatment was distributed to the patients in both treatment groups. All patients in the treatment groups were offered four appointments, including the final

evaluation appointment. At the first appointment, the patients were examined and randomized to the different groups. The treatment groups then received their assigned treatment at the second appointment. Two weeks after the initiation of treatment, a control appointment was booked (third appointment). Finally, at the fourth appointment (after 3 months of treatment), the patients were evaluated. The patients were also informed that they could call the specialist clinic in case of questions or if they needed extra appointments.

The patients in the no treatment group returned to the waiting list after examination. The three groups were evaluated concerning change in subjective symptoms after 3 months. In the two groups that received active treatment, patient adherence was also documented. After 3 months, the no treatment group received indicated TMD therapy if still needed.

### Instruments for Evaluation of Treatment Effect

All domains for evaluation of treatment effect recommended by IMMPACT (Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials)<sup>30,31</sup> were used; ie, pain intensity, global improvement, symptoms and adverse events, and emotional and physical functioning.

Pain intensity (during rest and during jaw movements) was assessed by the patient on a 0- to 100-mm VAS with the endpoints marked no pain and worst imaginable pain, respectively.<sup>27</sup>

Global improvement was assessed with the Patient Global Impression of Change scale (PGIC)<sup>32</sup> with the response options: pain free; much improved; improved; unchanged; worse; much worse; and very much worse.

Depression and anxiety were assessed with the Hospital Anxiety and Depression Scale (HADS).<sup>33</sup> The HADS consists of two subscales, each with 7 questions. A score below 7 indicates a non-case, 8 to 10 a possible case, and 11 to 21 a definite case.<sup>33</sup>

Physical functioning was assessed with the Jaw Functional Limitation Scale (JFLS-20).<sup>34</sup> This scale consists of 20 questions that are each scored from 0 to 10 and is divided into three subscales: mastication, mobility, and communication. A global score for the JFLS-20 is obtained by calculating the mean of the three subscale scores.<sup>35</sup> Norms and cut-off values for this scale have not been established.<sup>35</sup>

Consumption of analgesics was assessed with type of analgesic and number of pills taken during the last month.

Frequency of tension type headache was assessed with the response options: almost never; 1 to 2 times/month; once/week; several times/week; and daily.

Side effects were reported by the patient in free text.

Pain intensity was chosen as the primary evaluation variable, and a pain reduction of 30% on the VAS was considered to be a clinically relevant improve-

ment.<sup>32</sup> Cost-effectiveness was measured by treatment time (minutes) and number of visits.

### Statistical Analyses

An intention-to-treat (ITT) analysis was carried out for the proportion of patients who experienced 30% and 50% pain reductions, and the number needed to treat (NNT) was calculated. For patients who dropped out during the course of the study, the last measurement of pain intensity was forwarded and used in the analysis. A per-protocol analysis was used for secondary outcome measures.

For analyses of categorical measures at one time point, chi-square test and Fisher exact test were used. Nonparametric variables were analyzed with Mann-Whitney *U* test (two groups) and Kruskal-Wallis test (three groups). Continuous measures at one time point were analyzed with Student independent *t* test (two groups) and analysis of variance (ANOVA; three groups). To account for repeated measures in the normally distributed outcomes (eg, VAS at baseline and 3 months), a generalized linear mixed-effects model (GLMM) was applied, including fixed effects. In the next step, a generalized estimation equation (GEE) model was fitted for the repeated categorical and non-normally distributed outcomes. The GLMM and GEE included the estimates for each visit, as well as the interaction between the visits and the treatments. All models used an unstructured covariance matrix.<sup>36,37</sup> For post hoc power calculation, independent ANOVA (three groups) was used. The analyses were carried out using SAS 9.3. A *P* value below 5% was considered statistically significant.

### Ethical Aspects

The normal waiting-list time at the Department of Stomatognathic Physiology, Public Dental Health Service, was, at the time of the investigation, approximately 6 to 8 months for nonacute patients. Patients who were referred to the clinic were assessed immediately, and those who were likely to fulfill the inclusion criteria were scheduled for an initial examination. This means that the patients in the no treatment control group did not wait longer for TMD treatment than other patients on the waiting list. Ethical approval was obtained from the regional ethical review board at Uppsala University (2010/067).

### Results

The baseline characteristics of the patients, including age, sex, pain duration, other pain locations in the body, education, occupation, and place of residence, are summarized in Table 1. The mean age was lower in the two treatment groups compared to the no treatment

**Table 1 Sociodemographic and Baseline Characteristics of Included Patients**

	No treatment (n = 29)	Stabilization appliance (n = 33)	Jaw exercise (n = 35)
<b>Age, y</b>			
Mean (SD)	40.5 (17.2)	32.7 (17.7) <sup>a</sup>	33.2 (18.7) <sup>b</sup>
<b>Gender, %</b>			
Women	72	79	86
<b>Pain duration, mo</b>			
Mean (SD)	31.1 (36.4)	16.1 (11.5)	29.1 (47.9)
<b>Other pain location</b>			
At least one extratrigeminal	21	22	20
<b>Education</b>			
Missing data	0	1	1
Elementary school	0	1	1
Junior high school	2	8	5
High school	12	19	22
College or university degree	15	4 <sup>c</sup>	6 <sup>d</sup>
<b>Occupation</b>			
Missing data	1	0	0
Employed	10	14	15
Student	8	14	15
Homemaker	0	1	0
Unemployed	2	1	1
Early retirement	2	0	0
Sick leave	3	1	0
Senior citizen	3	2	4
<b>Place of residence</b>			
Missing data	1	1	1
City	17	12	14
Main urban area	4	4	3
Town	4	9	11
Countryside	3	7	6
<b>Tension-type headache</b>			
Missing data	1	0	1
Almost never	1	3	3
1–2 times/mo	5	7	12
Once/wk	8	6	10
Several times/wk	8	6	5
Daily	6	11	4
<b>Consumption of analgesics</b>			
Missing data	0	0	1
Never	3	4	6
1–2 times/mo	7	5	11
Once/wk	4	8	7
Several times/wk	8	11	7
Daily	7	5	3

Data are reported as number of patients unless otherwise indicated.

<sup>a</sup>*P* = .032 and <sup>b</sup>*P* = .025 compared to no treatment.

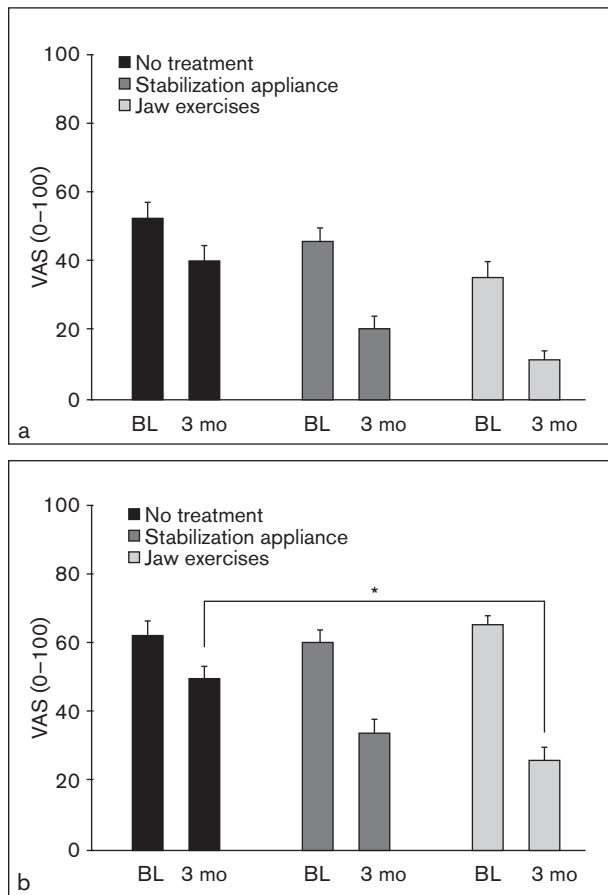
<sup>c</sup>*P* = .01 and <sup>d</sup>*P* = .002 compared to no treatment.

group. There were also more patients with a college degree in the no treatment group compared to the other groups. No other significant differences could be seen among the groups at baseline. Diagnoses according to RDC/TMD classification are shown in Table 2.

Nine patients, all women, dropped out before the 3-month evaluation. This group did not show any statistically significant differences compared to the other groups concerning sociodemographic or baseline

**Table 2 Proportion (%) of TMD Diagnoses According to RDC/TMD Criteria**

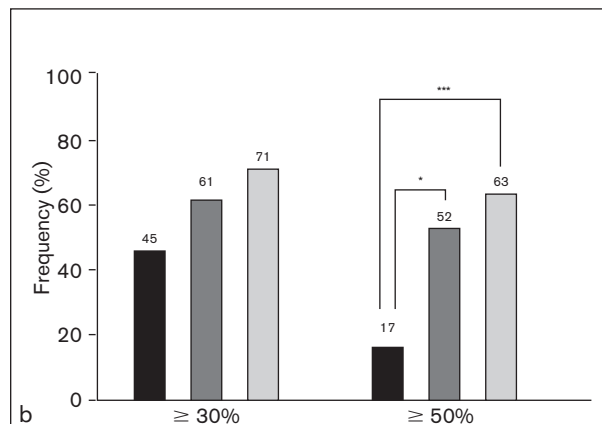
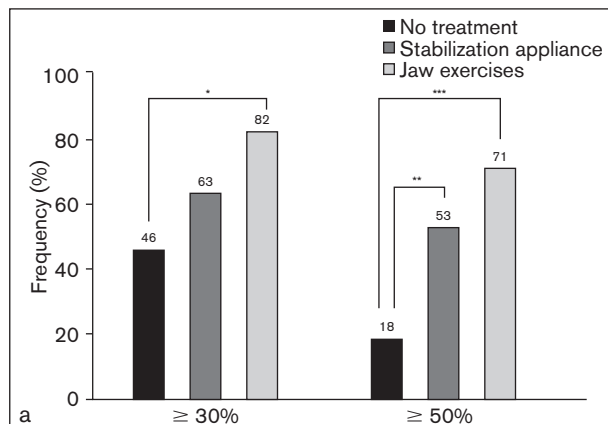
	No treatment (n = 29)	Stabilization appliance (n = 33)	Jaw exercise (n = 35)
Myofascial pain with or without limited mouth opening	100	100	100
Arthralgia	3	3	3
Disc displacement with reduction	34	30	49



**Fig 3** Changes in pain intensity (a) during rest and (b) during jaw movements according to 0- to 100-mm VAS score. Mean (SEM) values are presented. BL = baseline. \**P* < .001 (per-protocol analysis).

characteristics. The main reason for dropping out was that the patients were unable to attend follow-up visits, including the 3-month evaluation. Only one patient from the jaw exercise group stated that she dropped out due to an increase in jaw pain.

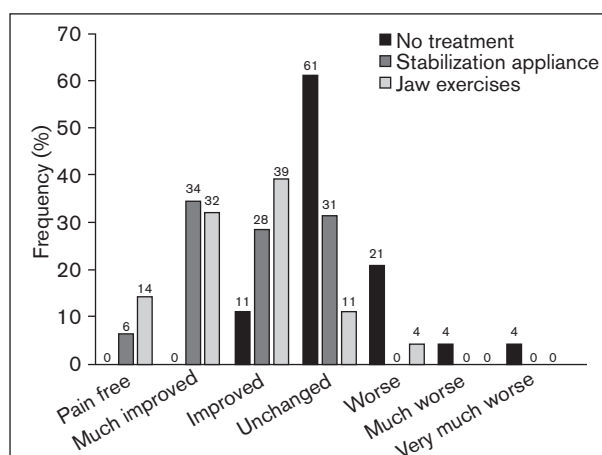
Pain intensity scores on the VAS (during rest and jaw movement) at baseline and at the 3-month evaluation are shown in Fig 3. Pain intensity at rest decreased in all three groups, and there were no



**Fig 4** Frequency (%) of patients with 30% and 50% pain reduction of their highest original pain scores (during rest or jaw movement) at the 3-month evaluation. **(a)** Per-protocol analysis. **(b)** Intention-to-treat analysis. \* $P < .05$ . \*\* $P < .01$ . \*\*\* $P < .001$ .

statistically significant differences among groups in this regard. Pain intensity during jaw movement decreased statistically significantly more in the jaw exercise group compared to the no treatment group. There was no statistically significant difference between the treatment groups in this aspect.

Figure 4 shows the number of patients who experienced 30% and 50% pain reductions (either during rest or jaw movement) in the per-protocol and ITT analyses. In the per-protocol analysis, there were significantly more patients in the jaw exercise group who experienced 30% and 50% reductions of maximum pain intensity compared to the no treatment group (Fig 4a). In the ITT analysis, there was a statistically significant difference between these groups only at the level of 50% reduction of maximum pain (Fig 4b). Furthermore, in both analyses, a significantly larger number of patients in the stabilization-appliance group experienced a 50% pain reduction compared to the no-treatment group. In the jaw exercise group, the overall mean reduction of pain intensity was 67% at rest and 62% during jaw movement. The corresponding figures in the stabilization-appliance group were 55% and 44%, respectively. Still, there were no statistically significant differences between the two treatment groups concerning number of patients who received a 30% or a 50% reduction of maximum pain intensity (Fig 4). Based on the values of the ITT analysis, the NNT values for 50% pain reduction in the jaw exercise group and the stabilization appliance group were 2.2 and 2.9, respectively. Since the goal for number of participants according to the a priori power analysis was not met, a post hoc power calculation was performed to see if the planned number would have been sufficient to show a difference between the treatment groups. This analysis showed that 153 patients, evenly distributed among the three groups, would have been enough to show a significant difference between the two treatment groups in favor of jaw exercises.



**Fig 5** Global improvement according to the PGIC. Percentages have been rounded to the nearest whole number.

According to the PGIC, the patients in both treatment groups reported a greater improvement compared to the no treatment group ( $P < .001$ ), in which most patients stated an unchanged or worsened situation (Fig 5). There was no statistically significant difference between the two treatment groups in this aspect.

There was a statistically significant decrease in the frequency of both headache and consumption of analgesics in the jaw exercise group compared to the no treatment group. Also, in the stabilization appliance group, there was a statistically significant decrease in consumption of analgesics, but not in headache frequency, compared to the no treatment group (Table 3).

There was a statistically significant reduction in JFLS score in the jaw exercise group compared to the no treatment group, but there were no differences over time concerning HADS scores. There were no statistically significant differences over time in the stabilization appliance group concerning JFLS or HADS scores (Table 3).

**Table 3 Per-Protocol Analysis of Secondary Outcome Variables at Baseline and 3-Month Evaluation**

	No treatment (n = 28)		Stabilization appliance (n = 32)		Jaw exercises (n = 28)	
	Baseline	3 mo	Baseline	3 mo	Baseline	3 mo
<b>Tension-type headache</b>	3.5 (1–5)	3.5 (1–5)	3.5 (1–5)	3 (1–5)	3 (1–5)	2 (1–5) <sup>b</sup>
<b>Consumption of analgesics</b>	3.5 (1–5)	3 (1–5)	3 (1–5)	2 (1–5) <sup>a</sup>	2.5 (1–5)	2 (1–5) <sup>c</sup>
<b>Hospital Anxiety and Depression Scale</b>						
Depression	3.5 (0–16)	2.0 (0–18)	2.5 (0–9)	3.0 (0–10)	1.0 (0–7)	1.0 (0–6)
Anxiety	6.5 (0–18)	6.5 (0–19)	8.0 (0–18)	7.5 (0–17)	5.0 (0–13)	4.0 (0–14)
<b>Jaw Functional Limitation Scale</b>						
Global score	1.5 (0–8.3)	1.6 (0–6.1)	1.1 (0–6.3)	0.5 (0–6.0)	2.0 (0–5.7)	0.4 (0–5.7) <sup>d</sup>

Data are presented as median (range). If there is an even number of numbers in the set, the median is the average of the two middle numbers.

<sup>a</sup> $P = .02$ , <sup>b</sup> $P = .028$ , <sup>c</sup> $P = .007$ , and <sup>d</sup> $P = .008$  compared to no treatment over time.

Both treatment groups were offered four appointments, including the final evaluation. Some patients called and requested more appointments, and some cancelled the control appointment because they felt it was not needed. In the jaw exercise group, patients had fewer appointments (mean three appointments, range three to four) and a shorter mean treatment time (24 minutes, range 14 to 52) compared to the group that received stabilization appliance treatment (mean four appointments, range three to five; 47 minutes, range 29 to 69). These differences were statistically significant ( $P < .001$ ) for both comparisons.

Patient adherence was greater in the group that received stabilization appliance treatment compared to the jaw exercise group. At the 3-month follow-up, only 4 patients in the jaw exercise group stated that they did the exercises according to the recommendations (three times a day). Ten patients did the exercises one to two times a day, and the rest ( $n = 14$ ) even more infrequently. In the stabilization appliance group, 15 patients used the appliance every night according to recommendations, and 6 stated that they used the appliance 4–6 nights a week. The remainder ( $n = 11$ ) used the stabilization appliance more infrequently.

Ten patients in the jaw exercise group and 12 in the stabilization appliance group reported that the treatment was associated with discomfort. In the jaw exercise group, the main discomfort was an increase in jaw pain in connection with the exercises, and in the stabilization appliance group, the main discomfort was a feeling that the appliance caused too much pressure on the teeth. There was no statistically significant difference between the treatment groups with respect to the number of patients who reported discomfort.

## Discussion

The main findings of this study were that jaw exercises were effective in decreasing pain intensity during

jaw movement, frequency of headache, consumption of analgesics, and JFLS scores in patients with masticatory myofascial pain compared to a control (no treatment) group. According to the PGIC, patients in both the jaw exercise group and the stabilization appliance group reported greater improvement compared to the no treatment group.

Only jaw exercises showed a difference compared to no treatment when it came to reduction of pain intensity during jaw movement. It is tempting to conclude that jaw exercises are therefore more efficient than stabilization appliances in reducing pain due to masticatory myofascial pain, but there was no difference between the treatment groups supporting such a claim. In accordance with the present results, other studies<sup>13,14</sup> comparing jaw exercises and occlusal appliance therapy in patients with TMD myalgia have not been able to show differences between the groups. However, the lack of difference between groups in the present study could be due to a type II error, since the post hoc test showed that a significant difference could have been identified if the goal for number of participants had been achieved.

In the per-protocol analysis, significantly more patients in the jaw exercise group received 30% and 50% reductions of pain intensity on the VAS compared to the no treatment group. The same difference was shown between the stabilization appliance and no treatment groups, but only at the 50% level. In the ITT analysis, this difference was only shown at the 50% level for both treatment groups. Earlier systematic reviews<sup>10,11</sup> have shown that stabilization appliances are more effective in reducing TMD pain than no treatment.

The present results show that the patients in the treatment groups perceived greater improvement according to the PGIC compared to the no treatment group. Pain is one of the most subjective feelings,<sup>38</sup> and in the absence of objective outcomes, the PGIC is considered to be a relevant clinical tool to assess the subjective perception of treatment impact in pain management.<sup>39</sup>

Treatment with jaw exercises showed a significant reduction in headache frequency compared to no treatment. Comorbidity of primary headaches (such as tension-type headache and migraine) with TMD is well established.<sup>40</sup> Several studies<sup>41,42</sup> have reported a correlation between TMD and tension-type headache and recommend TMD treatment in patients with TMD and recurrent headache. Considering these interactions, multidisciplinary teams of both physicians and orofacial pain specialists have been recommended for headache cases in order to attain the most precise diagnosis and most efficient treatment.<sup>43,44</sup>

Both treatment groups showed a reduction in analgesic consumption compared to the no-treatment group. It is reasonable to assume that a reduction in the need for analgesics is a sign of a reduction of pain intensity, which was, as mentioned above, shown for both treatments. Wright et al<sup>45</sup> concluded that a stabilization appliance and self-management therapies reduced the consumption of analgesics by 18% in patients with TMD and headache.

The JFLS-20<sup>34</sup> was used to describe possible changes in jaw function. There are no norms or cut-off values established for the JFLS-20, but a comparison between TMD cases and individuals who were negative for TMD over their lifetime showed a mean score similar to those found in the present study groups.<sup>46</sup> Doepel et al<sup>47</sup> have shown that occlusal appliances reduce JFLS-20 scores in patients with myofascial pain according to the RDC/TMD.<sup>26</sup> In the present study, a statistically significant reduction in JFLS-20 score could be seen in the jaw exercise group compared to the no treatment group.

Patient adherence is an important factor for treatment success for all kinds of treatment.<sup>48</sup> Patient adherence was lower in the jaw exercise group compared to the stabilization appliance group, which might have reduced the treatment effect in the jaw exercise group. Considering the achieved reduction of pain intensity in the jaw exercise group in spite of the fact that only four patients completely followed the recommendation to perform the exercises three times a day, it could be hypothesized that this recommendation may be excessive. Still, this study did not investigate any possible correlation between adherence and reduction of pain intensity. It could also be speculated that the higher dropout rate in the jaw exercise group could be due to a lower patient adherence.

Concerning treatment costs, jaw exercises are cheaper than stabilization appliances, which in Sweden are associated with a dental technician fee of approximately 150 to 200 USD. The patients in both treatment groups were offered four appointments, including the final evaluation appointment and any extra appointments they felt they needed. It can be concluded that jaw exercises are a more cost-effective treat-

ment compared to a stabilization appliance, with fewer visits to the clinic, lower overhead costs, and a lower mean treatment time. This finding is interesting, since Magnusson and Syrén<sup>14</sup> found the opposite concerning treatment time. This difference between studies can perhaps be explained by differences in the number of patients and in local clinical routines. The no treatment group was returned to the waiting list after examination, and because of this, they only received one appointment before the 3-month evaluation. Since the control group was offered fewer appointments than the treatment groups, it is not known if the treatment effect as shown in this study is due to the specific effect of the actual treatment or due to more general effects coupled with the number of appointments (eg, influence of empathic caregiver).<sup>49</sup> It has also been suggested that asking patients to wait for treatment puts them in a stalled stage of change where they become passive and do not move toward action on their own. This might result in less improvement than in a simply untreated group, where the patients might seek treatment elsewhere or attempt behavioral changes on their own.<sup>50</sup> Still, reduction of pain intensity was also seen in the no-treatment group. This can probably be explained by regression to the mean.<sup>51</sup>

### Strengths and Limitations

The initial power calculation concluded that a total of 174 patients, evenly distributed among the three groups, should be enough to separate the groups. The aim was to include 210 patients to control for possible dropouts. The post hoc power calculation, on the other hand, concluded that 153 patients randomly distributed among the three groups would have been enough to show a significant reduction in pain intensity in the jaw-exercise group compared to the stabilization-appliance group, as discussed above. Only 97 patients were able to be included during the course of the study. The main reason for the difficulty recruiting eligible patients was the exclusion criterion of treatment with an interocclusal appliance within the last 5 years. Interocclusal appliance therapy is a very common treatment in general dental practice,<sup>5</sup> and so most patients referred to the specialist clinic had received this treatment within the 5-year time frame. Additionally, the randomization process with sealed envelopes was constructed in one block based on the sample size calculation and possible dropouts ( $n = 210$ ), and that is why the number of patients was not equal between groups. A randomization in smaller blocks could have controlled the distribution between groups<sup>52</sup> even though the desired number of participants was not met. When the groups are small, as in the present study, the risk for unbalanced known and unknown factors increases.<sup>53</sup>



Even though a material is randomized, different proportions in certain patient factors can sometimes be seen.<sup>52</sup> There was a difference between groups concerning age. Older age has in some studies been suggested as a factor that can result in a poorer treatment prognosis for musculoskeletal pain.<sup>54</sup> However, a great number of studies have concluded the opposite, that age has no effect on the prognosis of musculoskeletal pain treatment.<sup>54</sup> A prerequisite for long-term treatment with a hard acrylic stabilization appliance is that the patient is skeletally fully grown and all teeth have erupted. For this reason, only patients 18 years and older were included in the present study.

A larger number of patients in the no treatment group had higher education (university degree) compared to the treatment groups. Low education level is one out of many socioeconomic factors that has been proposed to increase the prevalence of chronic pain.<sup>55</sup> To the present authors' knowledge, education level has not been correlated with treatment effect in TMD patients. A majority of the patients in the treatment groups had an education level equivalent to high school, which is fairly good from an international perspective.

Randomization minimizes differences between groups in the beginning of a study, but does not prevent differences in the treatment or assessment of outcomes between the groups. This may result in biased estimates of treatment effect. Blinding as many involved individuals as possible in a study minimizes the likelihood of such bias.<sup>56</sup> In the present study, the patients were not blinded to the treatment intervention, but none of the patients knew that jaw exercise was the treatment being evaluated. The research assistant who evaluated the patients through follow-up questionnaires was blinded and did not know which treatment the patient had received. The total dropout rate in the present study was below 10%, but there was a difference between groups; in the jaw exercise group ( $n = 35$ ), 7 patients (20%) dropped out, and this has to be considered when the reliability of the results is assessed.<sup>52</sup>

## Conclusions

This study showed that jaw exercises are effective in reducing pain intensity, headache, and consumption of analgesics in patients with masticatory myofascial pain. Jaw exercises are also cost-effective when compared to treatment with a stabilization appliance.

## Key Findings

- Jaw exercises are effective in the treatment of TMD patients with masticatory myofascial pain.
- Jaw exercises are a cost-effective treatment for masticatory myofascial pain.

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