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# Effectiveness of Applied Relaxation Method vs. Splint in Treatment of Temporomandibular Disorders in Finnish Students

Applied relaxation in TMD treatment

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Abstract:

Background Temporomandibular disorders (TMD) include pain and dysfunction in masticatory muscles and temporomandibular joints (TMJs). Applied relaxation (AR) is a coping skill that may be applicable for treatment of TMD.

Objectives The aim of this randomized, controlled study was to evaluate the effectiveness of AR as compared to stabilization splint (SS), for treatment of TMD during 12-month follow-up.

Methods The data was derived from 96 university students seeking treatment due to TMD symptoms at Finnish Student Health Service in Finland. The subjects were randomly divided into two treatment groups: SS (n=41) and AR (n=51) group. Clinical TMD examinations (a modified version of DC/TMD, Axis I) were performed for both the groups at baseline, and 3-,

6- and 12- month follow-ups. Depressive and nonspecific physical symptoms (NSPS) were estimated with Axis II questionnaire (RDC/TMD), and number of other pain sites were screened at baseline and 12-month follow-up. Data was analyzed by means of Chi-square test for both groups on five variables, t-test for VAS pain intensity and repeated measures ANOVA for palpation pain at follow-up points. Statistical significance was set on $p < 0.05$.

Results Decrease in the number of painful masticatory muscles and TMJs and VAS on pain intensity did not differ between groups. During follow-up, NSPS and number of body pain sites decreased significantly more in the AR than the SS group. The drop-out was 56 patients.

Conclusion Neither of the treatments showed more benefit in decreasing local TMD pain. AR gave more benefit on psychological well-being and general pain symptoms.

Keywords: adult, pain, temporomandibular disorders, depression / mood disorder, stress, randomized controlled trial, pain management

Effectiveness of Applied Relaxation Method vs. Splint in Treatment of Temporomandibular Disorders in Finnish Students

INTRODUCTION

Temporomandibular disorders (TMD) comprise dysfunction or pain related to temporomandibular joints (TMJ) or masticatory muscles and associated structures. The most common TMD symptoms are TMJ noises, pain in TMJs and masticatory muscles, restricted opening of the mouth and disturbances of mandibular motion. Experienced pain is the main reason for seeking treatment also amongst TMD patients (1). TMD are relatively prevalent in the Finnish population: 25–50% of adults have TMD signs (2), and 21% of students have a minimum of one TMD symptom (3).

Treatment of TMD commonly includes patient information, instructions for self-care and fabrication of a stabilization splint (SS) (1). Although some studies show the efficacy of SS in treating TMD-related facial pain or headache (4, 5), other studies question its additional benefit compared to a placebo or other treatments (6, 7, 8). In some chronic pain cases the condition persists despite a possible response to SS treatment (9, 10).

Several studies have shown that psychosocial factors such as depression and somatization are associated with TMD (11, 12). Psychosocial factors also increase the risk of developing chronic pain and lesser response to treatment (10, 13, 14). An early identification of TMD risk patients and tailored treatment increases outcome of treatment (9, 15). Thus, other treatment models for TMD, especially those considering a holistic view of the patient, should be investigated.

Cognitive-behavioral treatment (CBT) in pain patients includes teaching various pain management skills, stress reduction methods and coping skills as well as education of the psychosocial effects of chronic pain (16). Several studies have shown a positive impact of CBT methods on well-being and reduced costs in treating different pain syndromes (17, 18, 19). Turner et al. have shown positive results of cognitive-behavioral methods in treating TMD (20).

Applied relaxation (AR) is a self-control method used successfully in panic and phobia disorders, depression, as well as in longstanding neck pain, chronic pain, and headache (21, 22, 23, 24, 25, 26). As pain in muscular TMD is similar to other chronic muscular pain conditions, and also related to psychosocial factors, AR may be applicable also for treatment of TMD. To our knowledge, no studies exist concerning the efficacy of AR in TMD treatment.

The aim of this randomized, controlled study was to evaluate the efficacy of AR in reducing facial pain and clinical signs of TMD, as compared to SS treatment, during a 12-month

follow-up. A second aim of the study was to compare the level of depressive and non-specific physical symptoms and number of body pain sites between patients treated with AR versus SS during the 12-month follow-up. Based on previous studies it can be hypothesized that both SS and AR treatment relieve local TMD signs and symptoms and that AR is more effective in relieving depressive and non-specific physical symptoms as well as body pain as compared to SS treatment.

METHODS

Ethics

A written consent of voluntary participation was obtained from the participants after providing thorough information. An ethical consent for this clinical study was obtained from the Ethical Committee of the Hospital District of Northern Ostrobothnia, diary number 186/2011. The trial was post-registered in the ISRCTN registry (study ID ISRCTN11790049).

Study subjects

A total of 123 university students were enrolled in an ongoing study after a visit to a nurse, doctor, dentist or physiotherapist at the Finnish Student Health Service due to pain in facial and/or head-neck area. The size of the sample was calculated with power analysis. It has been estimated that two points difference in VAS value is clinically relevant (27). Further, based on our previous study we also estimated that two points with SD 3.5 described statistically significance in pain decrease (7). Variable (total score of VAS) differences with a mean of 2 points (SD 3.5) between the groups can be achieved with 80% power (statistical significance $p<0.05$, using t-test) with the sample size of 39 per group, providing for a drop-out of 20 %.

The enrolled students were referred to the investigating dentist for clinical TMD examination and given an anamnestic questionnaire. The inclusion study criteria for the study were as follows: studying at the University of Oulu or the University of Lapland, aged

between 19 and 35 years, no previous diagnosis of mental disorder, fibromyalgia or rheumatic diseases, and having any diagnosis of TMD (according to the modified DC/TMD Axis I criteria, as described later). Finally, 96 students (80 women and 16 men) fulfilled the criteria and were recruited into the study between January 2012 and September 2013.

Study design and setting

Patients were randomly assigned by computer generated random number using IBM SPSS Statistics (version 18.0) (by author KS) into two treatment groups: SS (n=41, 34 women and 7 men, mean age

26 years, range 14) and AR treatment (n=55, 48 women and 7 men, mean age 25 years, range 13). The allocation was concealed from the examiner. The examining dentist (OH) was blinded for the treatment group and was trained by a senior dentist (KS).

Stabilization splints were made of heat-cured acrylic by the same dental technician with the instructions of a second dentist. The occlusion of the splint was defined in centric relation occlusion using wax (Astynax®, Associated Dental Products Ltd, UK). The patients were instructed to use the splint every night during the study. The fit and wearing of the splint were checked at the first dental office sitting and re-checked approximately two weeks after first fitting. Additional re-checks were performed when needed.

AR treatment was administered by a physiotherapist with prior education in the studied method and years of practice in several relaxation methods. AR was trained according to the protocol by Öst (28) and modified by Thorsell (25) in six sittings for eight weeks acknowledging the schedule of the studies. Steps of the intervention are shown in Table 1.

All the treatments were applied between February 2012 and December 2014 at the Finnish Student Health Service clinic in Oulu, Finland.

Data collection and instruments

Clinical TMD examinations were performed for both groups at baseline and 3-, 6- and 12-month follow-ups, based on a modified version of the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD-FIN) Axis I (29). The modified DC/TMD form included questions of TMD symptoms during the preceding 30 days. The clinical TMD examination was performed according to the modified protocol of DC/TMD Axis I presented in a symposium at the International Association of Dental Research (IADR) Conference in 2010 (30).

The prevalence of TMD signs was counted based on the subjects having one or more signs of TMD in the clinical examination. TMJ noises (clicking, crepitus) and joint or muscular pain was recorded during all movements of lower jaw. Limited mouth opening was recorded if less than 40mm. A bilateral palpation of the temporal and masseter muscles as well as TMJs were performed according to the DC/TMD Axis I protocol (29).

An anamnestic questionnaire filled in both at baseline and the 12-month follow-up included questions about general health, estimated grade of largest experienced pain during the last six months and current pain on a visual analog scale (VAS). Intensity of facial pain at baseline and at the 12-month follow-up was inquired using the following question: "How would you rate your facial pain right now, on a scale from 0 to 10, where 0 is "no pain" and 10 is "pain as bad as could be"?"

At baseline and 12-month follow-up, depressive and non-specific physical symptoms (NSPS) were estimated with the Axis II questionnaire included in the Finnish version of the RDC/TMD (Research Diagnostic Criteria for TMD) criteria (31) as follows:

1. NSPS (total sum scores); pain items included, and pain items excluded

2. Depressive symptoms (total sum scores)

Body pain was inquired with the following question: "Have you had problems (pain, ache, discomfort) during the last year (12 months) in the following parts of the body:

neck/occiput, shoulders, elbows, wrists/hands, upper back, lower back, one or both hips, one or both knees, one or both ankles/insteps?" The answers were dichotomized as no/yes. A pain drawing of the body outline (back view) was used to identify the areas.

Drop-outs

The study design is presented in Fig. 1. The number of participants was 96 at baseline and 40 (20 in each treatment group) at the 12-month follow-up. The high number of drop-outs (58.3%) was explained to stem from lack of time, graduation and lack of commitment.

The number of those who filled in and returned the RDC/TMD Axis II questionnaire was as follows: depressive symptoms at baseline by 52 participants and at 12-month follow-up by 40 participants, NSPS by 53 and 40, respectively and pain sites by 72 and 40, respectively.

Statistical analysis

All data was compiled in Microsoft Office Excel, the analysis was transferred to and analyzed by SPSS version 23 (IBM). The normality of the data based on was tested with Kolmogorov-Smirnov test using SPSS 25.0, and showed non-significance (p=0.65).

The drop-out analysis was used to evaluate variable differences between those who dropped out vs. those who stayed by using Chi square test and Student t-test for independent samples. The percentages of clinical TMD signs at baseline and every follow-up point were compared between the groups using Chi-square tests. The differences within groups in clinical signs were studied with ANOVA for repeated measures. The differences between groups in means of VAS on facial pain, total score of NSPS (with and without pain items), and depressive symptoms as well as number of body pain sites at baseline and 12-month follow-up were analyzed with the Independent samples t-test. Variable change was

calculated by subtracting a variable at 12-month follow-up from the baseline variable. Significance was set as p-value .05.

RESULTS

A drop-out analysis between those who had dropped out versus those who had stayed during the follow-up showed no significant differences in gender, group status, VAS on pain intensity, depressive symptoms, NSPS and number of pain sites at baseline except on values of VAS in the SS group at the 3-month follow-up (Table 2).

Of the studied population myalgia was present in 100% while arthralgia was present in 41% of the study population. Of the subjects, 43.5 % had only one diagnosis (myalgia), 46.7 % had two diagnoses, and 9.8% had three or more diagnoses. Overlapping of diagnoses was as follows: both arthralgia and myalgia was present in 35%, myalgia and/or arthralgia and/or degenerative joint disease and/or disc displacement with reduction was present in 29% of the subjects. DC/TMD myalgia sub diagnoses, or headache attributed to TMD were not used in this study.

Almost all clinical TMD findings decreased in the 12-month follow-up in both groups, with no significant difference between or within the groups. TMD signs fluctuated during the follow-ups. The percentage of masticatory muscle pain on palpation decreased during the 12-month follow-up in both groups (Fig. 2A). Pain during jaw movement in masticatory muscles decreased in both groups, whereas TMJ pain in opening and/or closing jaw movement increased in the SS group and decreased in the AR group. Restriction in mouth opening slightly increased in both groups (Fig. 2B). There was some fluctuation in TMJ noises during the follow-up, and a slight decrease was noted in the SS group (Fig. 2C).

At baseline, the VAS on pain intensity was 4.1 in the SS group and 3.7 in the AR group (p= .794). At the 12-month follow-up the corresponding values were 3.2 and 2.7 (p=.901). At baseline, the mean of the total score of depressive symptoms was 12.1 (SD 12.9) in the SS group and 12.5 (SD 11.4) in the AR group (p= 0.897). At the 12-month follow-up, the mean of the total score of depressive symptoms was non-significantly lower in the AR (7.3, SD 7.2) group compared to the SS group (10.3, SD 11.4) (p=.341). At baseline, the mean of the total score of NSPS with pain items was 12.8 (SD 7.7) in the SS group and 10.9 (SD 6.4) in the AR group (p= 0.320), and the corresponding values for NSPS without pain items were 5.5 (SD 5.1) and 4.4 (SD 3.5) (p=.355). The mean of the total score for NSPS with and without pain items was significantly lower in the AR group than the SS group at the 12-month follow-up (p=.008 and .026 respectively). At baseline, the mean number of body pain sites was at the same level in both groups. The mean number of body pain sites was significantly lower at the 12-month follow-up in the AR group as compared to the SS-group (p= .004) (Table 3).

DISCUSSION

This study compared the effect of SS and AR treatments on TMD signs and symptoms, and their impact on depressive symptoms, body pain and NSPS including and excluding pain. The results revealed no significant difference between these treatment methods in relieving TMD-related pain and clinical signs, although their decrease was noted in both groups. The positive results may be related to actual effect, placebo effect, or normal fluctuation, as was noted in the present study during the 12-month follow-up. This is typical for TMD subjective symptoms and clinical findings (8, 32). It should be noted that in both groups the VAS decreased only at 20-27% level, which does not indicate any remarkable or clinically relevant pain relief. Instead, AR treatment showed better impact on depressive symptoms, NSPS with and without pain and body pain sites as compared to SS treatment, showing a remarkable decrease (appr. 50%) in depressive symptoms and NSPS.

To our knowledge, this is the only study concerning the efficacy of AR treatment in TMD patients. The present results are at least partly supported by previous studies concerning the effect of psychosocial interventions or other relaxation methods. An earlier systematic review and meta-analysis found no evidence to distinguish the clinical effectiveness between stabilization splint treatment and psychosocial interventions on myofascial TMD pain, thus supporting the results of the present study (33). The present study implicated a statistically significant decrease of NSPS and body pain in the AR group compared to the SS group, which supports previous studies of the effect of relaxation (34). The same tendency for alleviating these general symptoms was also found in the SS group, although to a lesser extent than in the AR group. Doepel et al. (2018) reported that regardless of whether the pain was localized, or widespread, oral appliance treatment had a positive effect on pain, depression and somatization during the 12-month follow-up in myofascial TMD pain patients (35). These results are in accordance with the results of the present study as the scores in depressive symptoms, NSPS and number of body pain sites decreased also in the SS group. A recent study by Huttunen et al. (2018) showed some negative effect of NSPS with pain items and depressive symptoms when using SS in treating TMD pain (14), thus indicating like the present study that TMD patients with psychosocial risk factors should be offered a more comprehensive treatment protocol instead of mere local treatments.

In contrast, the relatively long-term effect of AR found in the present study is contradicted by the results of Wahlund and Larsson, who investigated the impact of relaxation therapy compared to occlusal appliance therapy on 116 adolescent subjects with frequent TMD pain. They reported that those who received occlusal appliance treatment showed more sustainable improvement than those treated with relaxation therapy combined with information about TMD during an extended follow-up time (5 to 21 years) (36). It should be noted that the relaxation method they used differed from the AR used in the present study, which may explain the differences.

The present study supports the results of previous studies which suggest that relaxation therapies can significantly decrease musculoskeletal pain in general (19, 24) as well as headache and tension-type headache (23).

Numerous studies on the impact of CBT and AR on chronic pain have been conducted with supporting results. Whole-brain analyses, and functional imaging studies show the positive effect of CBT as an increase of gray matter or neural connections (37, 38). The impact of CBT also on TMD has shown promising results, whereas the present study was the first where the assessment of AR was reported. Like other psychological coping methods, AR has shown to decrease longstanding pain by interfering psychological inflexibility instead of muscular relaxation (39). This could explain the non-significant impact on local symptoms as compared to splint treatment in the present study. Instead the beneficial effect of AR on NSPS and number of body pain sites, as found in the present study, may be related to the impact on the autonomic nervous system in stress, emotions and mental associations. Bair (2003) suggested in a literature review that a model which incorporates assessment and treatment of depression and pain simultaneously is necessary for improved outcomes, as they share biological pathways and neurotransmitters (40).


Stress and distress have been shown to be etiological factors especially in muscular TMD (3, 41, 42), which was diagnosed for 100% of the present study sample. Although the present study did not report the degree of stress severity, according to previous studies stress is common among students, e.g., because of worries related to studies and finances (43). In the present study, AR was successfully employed for students who likely are in a stressful phase of life. The impact of experiencing stress is multifocal: it can be the reason for or the consequence of pain or it can influence the longevity of pain. Stress also evokes an extended load of sympathetic nervous system activity and muscular tension and thus is a significant factor in present pain and developing chronic pain (44). The AR treatment may impact symptoms by decreasing stress level and improving coping skills. It remains interesting to evaluate whether AR intervention would be effective especially for patients with high stress level.

Many psychological and psychosocial factors are associated with both onset of pain and acute pain turning chronic. Also, depression, distress, anxiety and related emotions are related to pain and disability (45). The present study supports results of other studies which show that AR contributes also to the decrease of depression and anxiety with increased coping ability (21, 25).

Many pain-treating programs include various methods of relaxation aiming to restrict pain, activity of the sympathetic nervous system or muscular tension.

The present study at least partly supports the concept of tailoring a treatment protocol for TMD patients. As TMD patients are a heterogeneous group regarding background factors, tailored treatment for TMD patients has been recommended (15, 46, 47). On the other hand, as TMD is multifactorial (48), a better result is achieved by combining treatments instead of a single treatment (49). AR can be used in TMD treatment as one option, especially in cases with increased psychosocial load and multiple body pain condition. This method activates the patient and provides tools for coping and overall well-being. In the present study, the impact of treatment was better in subjects motivated in treatment mode. This was not analyzed but was raised in the discussions between the therapist and the examiner. AR is a well-structured treatment protocol and requires strong commitment to protocol learning. The group meetings included in the protocol give peer support and the relaxation sessions at home are documented by the patient. AR has no side effects, thus offering a usable instrument for self-care rehabilitating treatment of TMD.

Study strengths and limitations

Frequent and long follow-ups are considered as strength of this study, as well as the randomized, controlled, and blinded study design. The clinical examination in the follow-ups was performed by the same blinded dentist, thus increasing reproducibility. Using standardized DC/TMD clinical protocol is also a strength, even though the questionnaire was slightly modified due to waiting for final publication of DC/TMD Axis I criteria (29).

The study had several limitations. The great number of drop-outs is a weakness of the present study,

and as some of the drop-outs occurred already at the allocation point it also questions the power of the study. Therefore, this study is underpowered starting from the baseline, which can be regarded a limitation.

Only less than half of the subjects attended the 12-month clinical follow-up and even less returned the RDC/TMD Axis II questionnaire both at baseline and at the 12-month follow-up, which weakens the power of the data. However, the drop-out analysis showed no significant differences between the responders and non-responders at any stage of follow-up. Drop-out is often related to studies with long follow-up periods and may also in the present study be explained by the students' phase of life, i.e. obligatory studies, altering, ceasing or finishing studies during the follow-up period. It should be noted that the study sample comprised heterogenic material regarding the background factors in TMD. More exact and well-designed research is needed, especially in tailored treatment of myogenic TMD.

CONCLUSION

The present study results indicate that AR alleviates local TMD symptoms comparably to splint treatment. However, AR more than splint treatment reduces general pain and non-specific pain symptoms and thus defends the idea of tailored treatment. Based on our study, AR is a useful method for TMD patients with multiple pain and psychosocial loading. Impact of AR method in different subgroups of TMD remains to be studied further.

ACKNOWLEDGMENTS

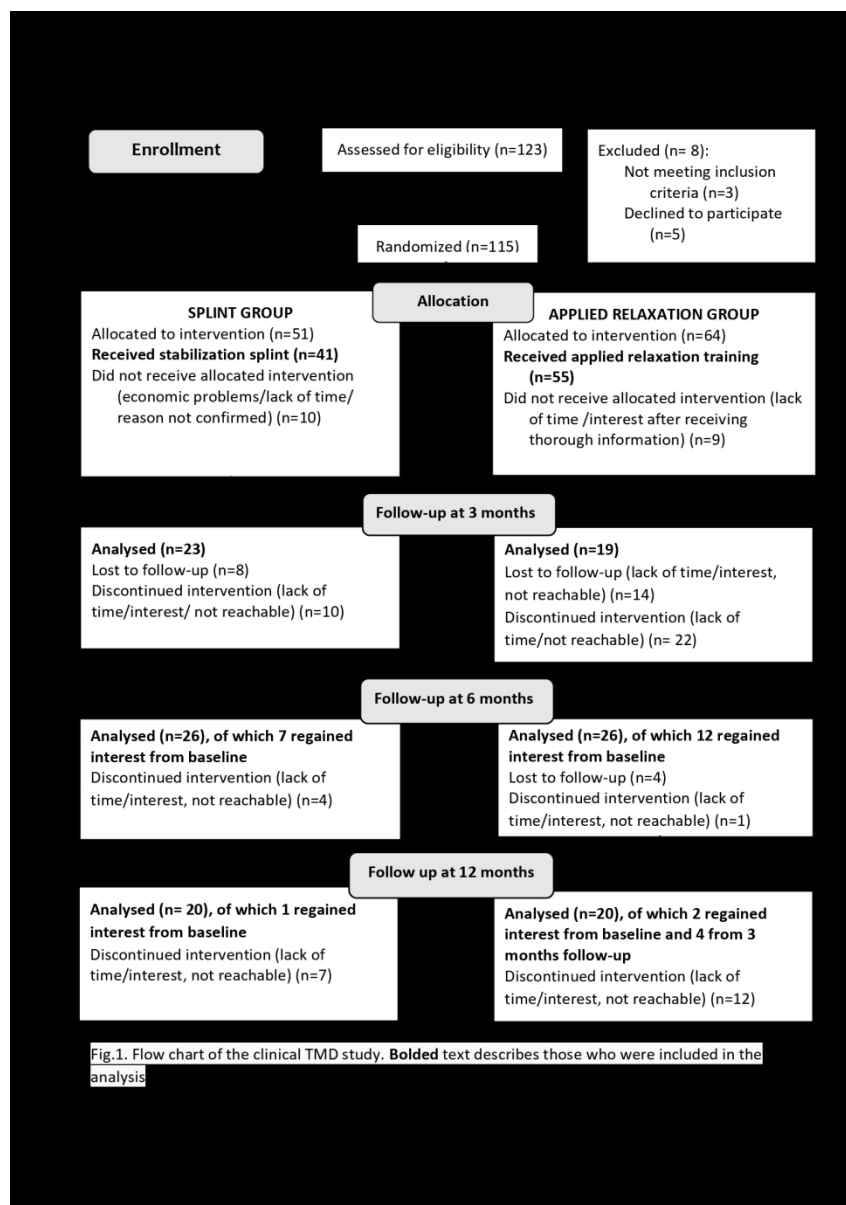| Sittings | Summary of content of applied relaxation (AR) |
|----------|-----------------------------------------------|
| S 1 | Intro. Progressive relaxation long version. Learning to differentiate between tension and relaxation by repeating a gradual process of tensing and relaxing different muscle groups at least once a day. Learning to relax sitting in an armchair with eyes closed. Special focus on relaxing the muscles of neck, shoulder and head. |
| S 2 | Progressive relaxation short version. Release-only relaxation is taught in order to be able to be repeated while sitting on lectures. |
| S 3 | Cue-controlled relaxation. The purpose is to create a conditioning between the self-instruction and the state of being relaxed with a self-selected cue for relaxation (e.g. "relax"). Finding situations when clenching occurs and applying the cue-word in those situations. |
| S 4 | Differential relaxation. Learning to relax in other situations with eyes open, i.e. sitting at a desk while doing things, etc. |
| S 5 | Differential relaxation. Learning to relax while standing, walking or biking. |
| S 6 | Rapid relaxation. Relaxing in natural stressful situations, and further reduce the time relaxing takes – the goal being 20-30 s. Application training in everyday situations. |

Table 1. Details of weekly exercises and summary of content of applied relaxation (AR), S1: first week, S2: second week, etc. The exercise program lasted for eight weeks considering the schedule of the studies.
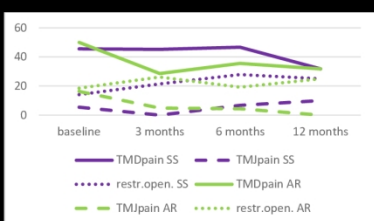
| | Drop-outs | Stayed | | Drop-outs | Stayed | | Drop-outs | Stayed | |
|---|---|---|---|---|---|---|---|---|---|
| | 3 mths | | | 6 mths | | | 12 mths | | |
| | n=51 | n=41 | p | n=47 | n=45 | p | n=52 | n=40 | p |
| gender / % of women at baseline | 45.7 | 44.3 | .783 | 46.8 | 53.2 | .170 | 59.5 | 40.5 | .166 |
| mass.pain on palp /mean(SD) | 4.0 (1.4) | 4.0 (1.4) | .934 | 4.1 (1.2) | 4.0 (1.5) | .710 | 3.9 (1.4) | 4.2 (1.4) | .322 |
| temp.pain on palp /mean(SD) | 2.6 (1.7) | 2.9 (2.0) | .518 | 2.6 (1.9) | 3.0 (1.8) | .279 | 2.8 (1.9) | 2.7 (1.9) | .961 |
| TMJ pain on palp /mean(SD) | 2.0 (1.5) | 1.8 (1.3) | .514 | 2.0 (1.5) | 1.8 (1.3) | .447 | 2.1 (1.5) | 1.7 (1.3) | .154 |
| pain on moving jaw /mean(SD) | 1.0 (0.2) | 1.0 (0.2) | .825 | 1.0 (0.1) | 0.9 (0.3) | .291 | 1.0 (0.2) | 0.9 (0.2) | .791 |
| TMJ noises /mean(SD) | 0.3 (0.5) | 0.5 (0.5) | .236 | 0.4 (0.5) | 0.4 (0.5) | .933 | 0.4 (0.5) | 0.4 (0.5) | .616 |
| | | | | | | | | | |
| VAS on facial pain/mean (SD) | 6.8 (2.0) | 5.5 (2.5) | **.036** | 6.6 (2.2) | 6.0 (2.3) | .363 | 6.8 (2.0) | 5.8 (2.4) | .124 |
| depressive symptoms/mean (SD) | 13.2 (11.4) | 11.2 (11.9) | .550 | 13.5 (12.1) | 11.3 (11.0) | .498 | 12.5 (11.6) | 12.2 (11.7) | .923 |
| NSPS with pain item/mean (SD) | 11.6 (6.7) | 12.0 (7.5) | .845 | 12.0 (7.3) | 11.5 (6.8) | .789 | 11.8 (7.3) | 11.8 (6.7) | .966 |
| NSPS without pain item/mean (SD) | 5.1 (4.1) | 4.7 (4.7) | .734 | 5.2 (4.0) | 4.6 (4.7) | .576 | 4.9 (4.0) | 5.0 (4.8) | .994 |
| body pain sites/mean (SD) | 6.9 (1.0) | 7.1 (1.1) | .346 | 6.8 (1.0) | 7.2 (1.0) | .132 | 7.0 (1.0) | 7.0 (1.3) | .990 |

Table 2. Drop-out analysis of patients with temporomandibular disorders treated with stabilization splint vs. applied relaxation, during the 12-month follow-up. The analysis for gender proportion was performed with Pearson's Chi-square, for the other variables with Independent Samples t-test

| | | N | mean | SD | 95% CI | N | mean | SD | 95% CI | p |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | **SS group** | | | | **AR group** | | | |
| VAS on facial pain | baseline | 31 | 3.6 | 2.32 | 2.39 – 4.81 | 37 | 3.1 | 2.23 | 1.83 – 4.25 | .441 |
| | 12-month follow-up | 18 | 3.5 | 1.61 | .95 – 2.07 | 15 | 2.8 | 2.18 | .67 – 3.30 | .468 |
| depressive symptoms | baseline | 23 | 12.1 | 12.87 | 6.57 - 17.69 | 29 | 12.5 | 11.42 | 8.54 - 16.56 | .897 |
| | 12-month follow-up | 22 | 10.3 | 11.42 | 5.25 - 15.38 | 18 | 7.3 | 7.15 | 3.78 - 10.89 | .341 |
| non-specific physical symptoms with pain item | baseline | 24 | 12.8 | 7.65 | 9.60 - 16.06 | 29 | 10.9 | 6.38 | 8.47 - 13.32 | .320 |
| | 12-month follow-up | 22 | 11.0 | 6.34 | 8.19 - 13.81 | 18 | 6.1 | 4.36 | 3.89 - 8.22 | **.008** |
| non-specific physical symptoms without pain items | baseline | 26 | 5.5 | 5.09 | 3.44 - 7.56 | 29 | 4.4 | 3.47 | 3.09 - 5.73 | .355 |
| | 12-month follow-up | 22 | 4.8 | 4.16 | 2.93 - 6.62 | 18 | 2.2 | 2.6 | .88 - 3.46 | **.026** |
| body pain sites | baseline | 32 | 7.1 | 0.94 | 6.76 - 7.43 | 40 | 6.9 | 0.11 | 6.60 - 7.30 | .556 |
| | 12-month follow-up | 22 | 7.2 | 0.77 | 6.86 - 7.54 | 18 | 6.4 | 0.92 | 5.93 – 6.84 | **.004** |

Table 3. Visual Analogue Scale (VAS) on current facial pain, depressive symptoms, non-specific physical symptoms (as evaluated using the Research Diagnostic Criteria for Temporomandibular Disorders) and other body pain sites in patients with temporomandibular disorders, treated with stabilization splint (SS) and applied relaxation (AR). CI= confidence interval, SD= Standard deviation. P values based on Independent Samples t-test for comparing means.

**Enrollment**

Assessed for eligibility (n=123)

Excluded (n= 8):
  Not meeting inclusion
    criteria (n=3)
  Declined to participate
    (n=5)

Randomized (n=115)

**Allocation**

**SPLINT GROUP**
Allocated to intervention (n=51)
**Received stabilization splint (n=41)**
Did not receive allocated intervention
  (economic problems/lack of time/
  reason not confirmed) (n=10)

**APPLIED RELAXATION GROUP**
Allocated to intervention (n=64)
**Received applied relaxation training
  (n=55)**
Did not receive allocated intervention (lack
  of time /interest after receiving
  thorough information) (n=9)

**Follow-up at 3 months**

Analysed (n=23)
Lost to follow-up (n=8)
Discontinued intervention (lack of
time/interest/ not reachable) (n=10)

Analysed (n=19)
Lost to follow-up (lack of time/interest,
not reachable) (n=14)
Discontinued intervention (lack of
time/not reachable) (n= 22)

**Follow-up at 6 months**

**Analysed (n=26), of which 7 regained
interest from baseline**
Discontinued intervention (lack of
time/interest, not reachable) (n=4)

**Analysed (n=26), of which 12 regained
interest from baseline**
Lost to follow-up (n=4)
Discontinued intervention (lack of
time/interest, not reachable) (n=1)

**Follow up at 12 months**

**Analysed (n= 20), of which 1 regained
interest from baseline**
Discontinued intervention (lack of
time/interest, not reachable) (n=7)

**Analysed (n=20), of which 2 regained
interest from baseline and 4 from 3
months follow-up**
Discontinued intervention (lack of
time/interest, not reachable) (n=12)

Fig.1. Flow chart of the clinical TMD study. **Bolded** text describes those who were included in the analysis

B.



C.