TITLE

Influence of Clinical, Physical, Psychological, and Psychophysical Variables on Treatment Outcomes in Somatic Tinnitus Associated With Temporomandibular Pain: Evidence From a Randomized Clinical Trial

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Abstract

Objective: To assess the influence of clinical, psychological, and psychophysical variables on treatment outcomes after application of exercise combined with education with/without manual therapy in people with tinnitus associated with temporomandibular disorder (TMD).

Methods: A secondary analysis of a clinical trial was performed investigating the effectiveness of including cervicomandibular manual therapy into an exercise combined with education program in 61 subjects with TMD-related tinnitus. Clinical outcomes including tinnitus severity and tinnitusrelated handicap were assessed at 3 and 6 months postintervention. Patients were assessed at baseline for clinical (tinnitus severity, tinnitus-related handicap, quality of life), physical (range of motion), psychological (depression), and psychophysical (pressure pain thresholds [PPTs]) variables that were included as predictors.

Results: The regression models indicated that higher scores of tinnitus severity at baseline predicted better outcomes 3 and 6 months post-intervention (explaining 13% to 41% of the variance) in both groups. Higher scores of tinnitus-related handicap at baseline predicted better outcome of tinnitusrelated handicap (45% variance) in the manual therapy with exercise/education group. Lower PPTs over the temporalis muscle at baseline predicted poorer clinical outcomes (10.5% to 41% of the variance) in both groups. Other predictors were sex and quality of life (6.7% variance) in the manual therapy group and PPTs over the masseter muscle (5.8% variance) in the exercise/education group.

Conclusion: This study found that baseline tinnitus severity and localized PPT over the temporalis muscle were predictive of clinical outcomes in individuals with TMD-related tinnitus following physical therapy. Other predictors (eg, sex, quality of life) were less influential. &

Key Words: tinnitus, outcome, temporomandibul0061r pain, manual therapy

INTRODUCTION

The term temporomandibular disorders (TMDs) represent a myriad of symptoms, including masticatory muscle/joint pain and restricted mandibular range of motion,1 which can also be associated with a substantial burden and impact.2 The OPPERA study found an incidence rate of lifetime first-onset TMD of 3.9% per year in individuals 18 to 40 years old.3 An old metaanalysis found that the prevalence of treatment need for TMD in adults was 15.6%.4 Patients with TMD can also experience other associated symptoms, such as tinnitus. A recent review reported that the prevalence of tinnitus is higher in patients with TMDs (35.8% to 60.7%) when compared to patients without TMDs (9.7% to 26.0%), with an odds ratio of 4.45.5 The etiology of tinnitus is multifactorial; however, tinnitus related to the somatosensory system of the temporomandibular joint (TMJ), muscles of mastication, or musculature of the cervical spine is referred to as somatic tinnitus, which is present in 36% to 43% of the subjects with subjective tinnitus.6

Physical therapy is a common conservative treatment used for the management of TMD-associated symptoms. It seems that manual therapy and exercises can be effective for reducing TMD-associated symptoms; however, no consensus exists on which therapeutic approach is the most effective.7,8 Similarly, there is also some evidence supporting the use of physiotherapy targeting the TMJ in the management of subjective tinnitus, although the quality of the trials in this area is relatively low.9 A recent randomized clinical trial reported that the inclusion of cervico-mandibular manual therapy interventions into an exercise and education program resulted in better clinical outcomes than the application of an exercise and education program alone in people Prognostic Outcomes in Somatic Tinnitus with somatic tinnitus attributed to TMD, providing promising results for the management of somatic TMDrelated tinnitus.10

Nevertheless, it is clinically observed that, depending on the patient's presentation and underlying pain mechanisms driving each condition, different clinical results could be expected. Some studies have tried to identify prognostic factors for future significant pain in individuals presenting with TMD-related pain.11,12 For instance, higher pain intensity and pain-related disability have been found to be associated with significant pain at 1 year after initial consultation in patients with TMD.11 In contrast, Demirkol et al.12 did not observe an association between tinnitus intensity and TMD variables in people with tinnitus associated with TMD. There is also evidence supporting a possible role of mood disorders in tinnitus, since individuals with concomitant TMD and tinnitus exhibit higher depressive levels than those with just tinnitus or TMD symptoms alone.13 However, no previous study has investigated potential prognostic factors associated with treatment responses after physical therapy in people with tinnitus attributed to TMD.

The objectiveof thecurrentstudywastodetermine the influence of clinical, physical, psychological, and psychophysical variables on treatment outcomes after the application of cervico-mandibular manual therapy, exercise, and education in patients with TMD-related tinnitus. We hypothesized that a combination of cervicomandibular manual therapy, exercise, and education will produce better outcomes in individuals with tinnitus associated with TMD showing higher tinnitus severity and related disability but lower levels of depression.

METHODS

Design

A secondary analysis was conducted alongside a randomized clinical trial10 to assess the predictive influence of clinical, physical, psychological, and psychophysical variables on treatment outcomes after the application of cervico-mandibular manual therapy, exercise, and education in patients with TMD-related tinnitus. Full details of the trial, participants, interventions, and the results of the clinical outcomes are reported elsewhere.10 The trial was approved by the Institutional Review Board of Universidad Complutense de Madrid, Spain (code 16/477-E) and it was registered (ClinicalTrials.gov: NCT02850055).

Participants

Consecutive patients with tinnitus symptoms referred to 1 of 3 private physical therapy clinics after thorough ear, nose, and throat screening and imaging screening were assessed for eligibility criteria: (1) were 18 to 65 years of age; and (2) had a diagnosis of tinnitus attributed to TMD (ie, an association between both disorders had to be self-reported by the patient).14 According to a recent Delphi study, different items, if present, strongly suggest a potential somatosensory influence of tinnitus.15 Patients included in our study self-reported the following items recommended in the Delphi study15: (1) tinnitus and TMD symptoms appear and aggravate simultaneously; (2) tinnitus is associated with myofascial trigger points of the neck or masticatory muscles; and (3) an increase of TMJ use (eg, clenching or biting) can increase tinnitus. In fact, all patients exhibited a diagnosis of TMD according to the diagnostic criteria for TMD.16

Participants were excluded if they presented with: (1) diagnosis of ear, nose, or throat medical pathology underlying the tinnitus; (2) any potential neurological problem potentially causing tinnitus; (3) inability to read, understand, and complete the procedures; (4) fibromyalgia syndrome; (5) having received physiotherapy or other treatment in the head/neck in the preceding year; or (6) any underlying medical condition not permitting physiotherapy treatment as noted in the patient's Medical Screening Questionnaire (eg, tumor or fracture). All subjects read and signed a written informed consent prior to their participation in the trial.

Randomization and Interventions

Participants were randomly assigned to receive either cervico-mandibular manual therapy, exercise, and education, or exercise and education alone. Details on randomization procedure have been previously published.10 Both groups participated in a total of 6 treatment sessions: 2 sessions the first week and a subsequent 4 sessions (once per week) of 30 minutes' duration. Each session included cervico-mandibular and TMJ exercises, self-massage of the masticatory muscles, and an educational program.17 Briefly, the exercise program included mobility, postural education, and motor control exercises of the TMJ, the tongue, and the cervical spine. Participants were asked to perform the exercises twice per day during the intervention period. The educational sessions included pain neurosciences, active coping strategies, distraction strategies, changing behaviors about pain, and identification of and correction of inappropriate behaviors pertaining to the TMJ. All participants received a self-care book for home.

Participants randomly allocated to the manual therapy group also underwent different cervico-mandibular manual therapy techniques during the treatment sessions. Interventions targeted the TMJ as well as masticatory musculature that are known to refer pain into the TMJ, auricular, and orofacial regions and can therefore contribute to tinnitus symptoms.18–20 A description of the interventions can be found elsewhere.10

Clinical Outcomes

Outcomes in the original clinical trial were assessed at baseline, at 1 week, and at 3 and 6 months after the intervention.10 The original trial included assessment of the intensity of TMD (via the numeric pain rating scale [NPRS]) and of the severity of the tinnitus (via the VAS) as primary outcomes. Tinnitus-related handicap (assessed via the Tinnitus Handicap Inventory [THI]), TMD-related disability (assessed via the Craniofacial Pain and Disability Inventory [CF-PDI]), health-related quality of life (assessed via the 12-item Short Form Health Survey [SF-12]), depressive symptoms (assessed via the Beck Depression Inventory [BDI-II]), pressure pain sensitivity (assessed via pressure pain thresholds [PPTs]), and mandibular range of motion were the secondary variables.10

In the current predictive analysis, we considered the severity of the tinnitus (mean value of tinnitus annoyance/ tinnitus loudness symptoms, as assessed via the VAS) and tinnitus-related handicap (assessed via the THI) as the main outcomes. The VAS consists of a 10-mm line with endpoints including two faces: a smiling one indicating lack of annoyance or no perception of tinnitus (left endpoint of the line) and a sad one indicating extreme annoyance or extremely loud tinnitus (right endpoint of the line).21 The use of the VAS for assessing these 2 subjective tinnitus symptoms exhibited both good reliability and validity.21 The THI is a self-reported questionnaire assessing the impact that tinnitus has on functional (11 items),catastrophic (5 items),and emotional (9 items) daily life activities.22 Although each scale can be scored independently, a total score ranging from 0 to 100 points is proposed.23 In the current predictive analysis, changes on each of these clinical outcomes, measured as the difference between scores at 3 and 6 months after intervention and scores at baseline, were analyzed.

Predictor Variables

Several clinical, physical, psychological, and psychophysical outcomes were included as predictor variables. Clinical variables included tinnitus severity and tinnitus-related handicap, TMD-related disability (assessed via the CF-PDI), and health-related quality of life (assessed via the SF-12) scores at baseline. The CFPDI evaluates pain symptoms, related disability, and functional status of the craniofacial region.24 It consists of 21 items with a total score ranging from 0 to 63 points, where higher values represent worse functional status. The SF-12 is a generic health rating short-version scale of the SF-36 questionnaire.25 After recoding raw scores for some items (ranging from 1 to 6), the raw scores are transformed to provide a total score, where 0 represents the worst health-related quality of life and 100 the best quality of life.25

Mandibular range of motion (maximal mouth opening and lateral excursion), evaluated with a plastic ruler device, was the physical predictor variable. This procedure has exhibited good intra- and inter-rater reliability.26

Depressive levels, assessed using the BDI-II, were included as a measure of psychological health. The BDIII assesses affective, cognitive, and somatic symptoms and is adapted in most pain conditions for detecting depressive symptoms.27

Finally, pressure pain sensitivity was used as the psychophysical outcome. PPTs were bilaterally assessed over the masseter and temporalis muscles and over the lateral aspect of the TMJ with a digital pressure algometer (kg/cm2). The mean of 3 trials, with a 30second rest period between, was calculated on each point and used for the main analysis. Since no side-to side differences were observed, the mean of both sides on each point was used in the main predictive analysis. Pressure algometry in the masticatory structures has exhibited high reliability.28

Sample Size Calculation

Sample size calculation for the main clinical trial was based on changes in tinnitus severity at 6 months' follow-up as previously described.10 A range of 10 to 15 subjects per potential predictor, with no more than 5 predictor variables, is usually recommended to develop an adequate sample size for prediction models and to avoid overestimation of the results.29 In this study, we presumed the possibility of 3 potential predictor variables at the final model, which generated a potential sample size of 30 subjects per treatment group.

Statistical Analysis

Descriptive statistics were used to describe participant features and can be found in the original report of the clinical trial.10 A multiple linear regression analysis was used to determine which predictor variable could be associated with clinical outcomes (changes in tinnitus severity and tinnitus-related handicap) at 3 and 6 months after the intervention. The following baseline variables were considered as potential predictors for inclusion within the model: age, sex, time with pain, baseline TMJ pain, baseline tinnitus severity and tinnitus-related handicap (assessed via the THI), TMD related disability (assessed via the CF-PDI), health related quality of life (assessed via the SF-12), mouth opening and lateral excursion range of motion, depressive symptoms (assessed via the BDI-II), PPT of the masseter muscle, PPT of the temporalis muscle, and PPT of the lateral aspect of the TMJ.

First, correlations between the predictor variables and the clinical outcomes (changes in tinnitus severity and tinnitus-related handicap) were assessed using Pearson correlation coefficients. Statistically significant variables ($P < 0.05$) associated with clinical outcomes were finally included in a stepwise multiple linear regression model to estimate whether those baseline variables predicted the outcomes at 3 and 6 months after the intervention in each group separately. The Pearson correlation coefficient was also applied to identify multicollinearity and shared variance between the variables (defined as $r > 0.80$). To examine the proportions of explained variance of each clinical outcome at each follow-up, a hierarchical regression analysis was conducted by group. The significance criterion of the critical F value for entry into the regression equation was set at $P < 0.05$. Changes in R2 were reported after each step of the regression model to assess the potential association of the additional variables.

RESULTS

From a total of 61 patients who were initially randomly allocated into the exercise and education group (n = 30) or the exercise and education plus manual therapy group (n = 31), 56 (92%) were included in the current predictive analysis. The flow diagram of patient recruitment and retention is illustrated in Figure 1. Baseline variables were not significantly different between groups as previously described10 (Table S1).

The exercise/education plus manual therapy group experienced more pronounced improvements in clinical outcomes at 3 and 6 months after the treatment as previously reported10 (Table S2).

Prediction of Outcomes Following Manual Therapy, Exercise, and Education

The predictor variables showed significant correlations between them, but none was considered to be multicollinear (defined as $r > 0.80$); therefore, each significant predictor variable was included in the regression analyses.

Significant correlations between the clinical outcomes and some predictor variables were found at 3 and 6 months in the manual therapy, exercise, and education group (Table S3). In fact, sex, tinnitus severity, tinnitus-related handicap, health-related quality of life, and PPTs over the temporalis muscle were significantly correlated with both clinical outcomes at 3 and 6 months after treatment (all $P < 0.05$).

Tables 1 through 4 summarize the hierarchical regression analysis in the manual therapy, exercise, and education group for each clinical outcome at 3 and 6 months. The regression coefficients indicated that higher scores for each clinical outcome (ie, tinnitus severity or tinnitus-related handicap) at baseline predicted better outcomes at 3 and 6 months after the treatment (ie, greater changes in tinnitus severity or tinnitus-related handicap, explaining 12.5% to 47% of the variance in the respective outcome). The regression model also revealed that lower PPTs over the temporalis muscle at baseline predicted poorer outcomes in tinnitus severity at 3 and 6 months post-intervention, contributing to 24.4% and 18.1% of the variance, respectively. In addition, men experienced poorer outcomes in tinnitusrelated handicap 3 months after the treatment (explaining 6.7%), whereas health-related quality of life was a predictor of tinnitus-related handicap 6 months after the intervention (explaining 6.7% of the variance).

Table 1. Summary of the Stepwise Regression Analyses to Determine Predictors of Changes in Tinnitus Severity (Mean Score of Tinnitus Annoyance and Tinnitus Loudness, VAS) at 3 Months

	Predictor Outcome	***B***	**SE B**	**95% CI**	**β**	**t**	**P**
Exercise/education plus manual therapy	Step 1						
	Temporal PPT	3.572	1.094	1.334, 5.810	.518	3.265	.003
	Step 2						
	Temporal PPT	2.905	1.034	.786, 5.024	.422	2.809	.009
	Baseline tinnitus severity	.642	.250	.131, 1.154	.386	2.575	.016
Exercise/education	Step 1	1.070	.229	.601, 1.539	.662	4.676	<.001
	Baseline tinnitus severity						
	Step 2						
	Baseline tinnitus severity	0.843	.186	.462, 1.224	.522	4.544	<.001
	Temporal PPT	1.951	.455	1.038, 2.865	0.503	4.382	<.001

Exercise/education plus manual therapy: R^2 adj. = .244 for step 1, R^2 adj. = .367 for step 2;

Exercise/education: R^2 adj. = .418 for step 1, R^2 adj. = .648 for step 2

Table 2. Summary of the Stepwise Regression Analyses to Determine Predictors of Changes in Tinnitus Severity (Mean Score of Tinnitus Annoyance and Tinnitus Loudness, VAS) at 6 Months

	Predictor Outcome	***B***	**SE B**	**95% CI**	**Β**	**t**	**P**
Exercise/education plus manual therapy	Step 1						
	Baseline tinnitus severity	.983	.255	.461, 1.505	.582	3.854	.001
	Step 2						
	Baseline tinnitus severity	.792	.226	.329, 1.255	.469	3.503	.002
	Temporal PPT						
		3.167	.937	1.248, 5.086	.452	3.380	.002
Exercise/education	Step 1						
	Temporal PPT	2.091	.453	1.164, 3.019	.658	4.618	<.001
	Step 2						
	Temporal PPT	1.712	.403	.885, 2.538	.538	4.249	<.001
	Baseline tinnitus severity	0.566	.168	.222, .991	.427	3.373	.002
	Step 3						
	Temporal PPT	1.369	.404	.538, 2.199	.430	3.388	.002
	Baseline tinnitus severity	.617	.158	.293, .941	.465	3.910	.001
	Masseter PPT	1.141	.501	.111, 2.171	.278	2.277	.031

Exercise/education plus manual therapy R^2 adj. = .316 for step 1, R^2 adj. = .497 for step 2;

Exercise/education: R^2 adj. = .412 for step 1, R^2 adj. = .571 for step 2, R^2 adj. = .629 for step 3

Table 3. Summary of the Stepwise Regression Analyses to Determine Predictors of Changes in Tinnitus Handicap Inventory (THI) at 3 Months

	Predictor Outcome	***B***	**SE B**	**95% CI**	**Β**	**t**	**P**
Exercise/education plus manual therapy	Step 1						
	Baseline THI	.720	.136	.442, .998	.701	5.297	<.001
	Step 2						
	Baseline THI	.669	.129	.404, .993	.651	5.183	<.001
	Sex (1: men; 2: women)	6.121	2.681	.630, 11.611	.287	2.283	.030
Exercise/education	Step 1						
	Baseline tinnitus severity	2.766	1.145	.420, 5.122	.415	2.415	.023
	Step 2						
	Baseline tinnitus severity	2.935	1.053	.774, 5.096	.441	2.787	.010
	Temporal PPT	8.663	3.465	1.554, 15.772	0.395	2.500	.019

Exercise/education plus manual therapy: R^2 adj. = .474 for step 1, R^2 adj. = .541 for step 2;

Exercise/education: R^2 adj. = .143 for step 1, R^2 adj. = .278 for step 2

Table 4. Summary of the Stepwise Regression Analyses to Determine Predictors of Changes in Tinnitus Handicap Inventory (THI) at 6 Months

	Predictor Outcome	***B***	**SE B**	**95% CI**	**B**	**t**	**P**
Exercise/education plus manual therapy	Step 1						
	Baseline THI	.631	.124	.377, .884	.686	5.083	<.001
	Step 2						
	Baseline THI	.507	.128	.244, .770	.552	3.946	<.001
	SF-12	-.778	.345	-1.484, -.071	-.315	-2.256	.032
Exercise/education	Step 1						
	Baseline tinnitus severity	2.992	1.012	.919, 5.065	.488	2.957	.006
	Step 2						
	Baseline tinnitus severity	3.132	0.944	1.196, 5.068	.511	3.320	.003
	Temporal PPT	7.174	3.104	0.804, 13.544	.355	2.311	.029

Exercise/education plus manual therapy: R^2 adj. = .453 for step 1, R^2 adj. = .520 for step 2;
Exercise/education: R^2 adj. = .211 for step 1, R^2 adj. = .317 for step 2

Prediction of Outcomes Following Exercise and Education

Significant correlations between the clinical outcomes and some predictor variables were found at 3 and 6 months in the exercise and education group (Table S4). In particular, tinnitus severity and PPTs at the temporalis muscle were significantly correlated with both clinical outcomes at both 3 and 6 months after treatment (all $P < 0.01$).

Tables 1 through 4 summarize the hierarchical regression analysis in the exercise/education group for each clinical outcome at 3 and 6 months. The regression coefficients indicated that higher scores of tinnitus severity at baseline predicted better outcomes 3 and 6 months after the treatment in both clinical outcomes, explaining 14.0% to 41% of the variance, depending on the outcome. Again, lower baseline PPTs over the temporalis muscle predicted poorer outcomes in both tinnitus severity and tinnitus-related handicap at 3 and 6 months post-treatment, contributing to 10.5% to 41.5% of the variance, depending on the outcome. The regression model also revealed that lower PPTs over the masseter muscle predicted poorer outcomes in tinnitus severity at 6 months after treatment (explaining 5.8%).

DISCUSSION

This study evaluated the predictor variables of treatment outcomes in individuals with tinnitus associated with TMD after the application of an exercise and education program with or without the application of cervicomandibular manual therapy. We found that tinnitus severity and pressure pain sensitivity over the temporalis muscle at baseline were those variables most associated with clinical outcomes at 3 and 6 months.

The multiple regression models revealed that higher baseline scores of tinnitus severity predicted better outcomes at 3 and 6 months post-intervention (from 12% to 42% of the variance) for changes in tinnitus severity in both groups and for changes in tinnitusrelated handicap in the exercise/education group. These results were expected since it seems easier to elicit greater changes in an outcome with higher baseline scores because subjects with less pain and disability had less room to exhibit improvements. Current results agree with those of studies investigating prognostic factors in other conditions (eg, in subjects with carpal tunnel syndrome30 or whiplash-associated disorder31), in which higher pain or disability scores at baseline are also associated with greater change in the same clinical outcome after receiving physical therapy. Our results are also consistent with the fact that greater tinnitus intensity is not associated with poorer prognosis in patients with TMD-related tinnitus12 suggesting that those experiencing more severe symptoms can respond better to treatment.

Interestingly, baseline pressure pain hypersensitivity over the temporalis muscle was consistently associated with poorer clinical outcomes at 3 and 6 months (explaining 10% to 41% of the variance) in both groups. Higher localized pressure pain hyperalgesia at the temporalis muscle suggests that peripheral sensitization is associated with a worse response to exercise/ education, independently of the inclusion or not of cervico-mandibular manual therapy. The temporalis muscle is innervated by the trigeminal nerve and is relevant for TMJ proprioception. It is possible that temporalis muscle impairments could contribute to worse features of tinnitus due to the anatomical relationship between the TMJ and the inner ear.

Additionally, irritation or sensitization of the trigeminal nerve could also contribute to tinnitus due to the convergence between somatosensory information and auditory input in the brainstem.32 In such a scenario, somatosensory inputs originated in the trigeminal nerve could increase the spontaneous firing rate in the dorsal cochlear nucleus.32 This would be a relevant finding from a clinical viewpoint, since early identification of peripheral sensitization (decreased PPTs) over the trigeminal area could lead to better outcomes by implementing early management in individuals with TMD-related tinnitus. The relevance of peripheral sensitization as a prognosis variable for treatment outcomes after the application of physical therapy can also be related to the fact that manual therapy exerts a hypoalgesic effect (increasing PPTs) in people with musculoskeletal pain33 by complex neuro-physiological mechanisms in the central nervous system.34 However, it is important to consider that we assessed localized (peripheral), but not central (widespread), sensitization in patients with TMD-related tinnitus. It was previously found that central sensitization in musculoskeletal pain conditions is associated with poorer outcomes to conservative treatment.35 No previous study has investigated the prognostic role of widespread pressure pain sensitivity in individuals with somatic tinnitus.

Other prognostic variables observed in our study, but with less influence, within the cervico-mandibular manual therapy group included sex and health-related quality of life for tinnitus severity and tinnitus-related handicap, respectively. The fact that patients with tinnitus who have better self-perception of healthrelated quality of life exhibit better treatment outcomes may be related to personal beliefs, better attitude, or expectations of the patients. Since this variable was only observed in those subjects receiving cervico-mandibular manual therapy, it might be intrinsically related to the personal interaction between the patient and the therapist during the treatments, which could be associated with the intrinsic placebo effect of manual therapy.34 We also observed that men exhibited poorer treatment responses than women who had tinnitus associated with TMD. In fact, previous studies have found that TMDrelated tinnitus is more prevalent in females than in males (ratio 3:1).36–38 It is possible that biological39 and psychosocial40 gender differences explain the sex influence in the treatment response in our sample.

Our results should be considered according to the strengths and limitations of the trial as previously described.10 Among the limitations of the current prognostic analysis, first we should consider that we had a relatively small sample size. In order to minimize the risk of overestimating the results, it is generally recommended to include at least 10 subjects for each predictor variable when developing a prediction model.41 In our study, we included a total of 15 potential baseline prognostic variables, but only 3 were finally significant in the prognostic model. Therefore, our results should be considered with caution at this stage. Second, all patients participated in the same exercise and education programs. Therefore, we do not know if different programs would lead to different prognostic variables. Third, we only assessed clinical outcomes at 3 and 6 months; therefore, we do not currently know if the identified prognostic variables will be different at longer follow-ups. Finally, psychological variables such as anxiety levels, sleep quality, or patient expectations were not included in this study; hence, we do not know their potential influence in the treatment responses.

CONCLUSIONS

This study found that tinnitus severity and pressure pain sensitivity over the temporalis muscle at baseline were the variables most associated with poorer clinical outcomes at 3 and 6 months in people who have tinnitus associated with TMD after the application of an exercise and education program with or without cervico-mandibular manual therapy.

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Figure 1. Flow diagram of patients throughout the course of the study. BDI-II, Beck Depression Inventory; CF-PDI, Craniofacial Pain and Disability Inventory; PPT, pressure pain threshold; THI, Tinnitus Handicap Inventory; TMD, temporomandibular disorder.