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Title: Does conservative temporomandibular therapy affect tinnitus complaints? A systematic review.

Authors: Michiels S.^{1,2,4}, Nieste E.^{1,2}, Van de Heyning PH.^{2,3,4}, Braem M.^{5,6,7}, Visscher C.M.⁸, Topsakal V.^{2,4}, Gilles A.^{2,4,9}, Jacquemin L.^{2,4}, De Hertogh W¹.

Affiliations

 Department of Rehabilitation Sciences and Physiotherapy, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium
 Department of Otorhinolaryngology, Antwerp University Hospital, Edegem, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium
 Multidisciplinary Motor Centre Antwerp, University of Antwerp, Antwerp, Belgium
 Department of Translational Neurosciences, Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, Belgium
 Lab Dental Materials, University of Antwerp, Antwerp, 2610, Belgium
 Special Care Dentistry, University Hospital Antwerp, Edegem, 2650, Belgium

7 Faculty of Medicine and Health Sciences, University of Antwerp, Antwerp, 2610, Belgium
8 Department of Oral Health Sciences, Academic Centre for Dentistry Amsterdam, University of
Amsterdam and VU University Amsterdam, Research Institute MOVE Amsterdam, Netherlands
9 Department of Human and Social Welfare, University College Ghent, Ghent, Belgium

E-mail addresses:

Michiels Sarah: <u>sarah.michiels@uantwerpen.be</u> Nieste Evelien: <u>Evelien.nieste@hotmail.com</u> Van de Heyning Paul: <u>paul.vandeheyning@uza.be</u> Braem Marc: <u>marc.braem@uza.be</u> Visscher Corine: <u>c.visscher@acta.nl</u> Topsakal Vedat: <u>vedat.topsakal@uza.be</u> Gilles Annick: <u>annick.gilles@uza.be</u> Jacquemin Laure: <u>laure.jacquemin@uza.be</u> De Hertogh Willem: <u>willem.dehertogh@uza.be</u>

Contact details:

Sarah Michiels (Corresponding author) Address: Universiteitsplein 1 - 2610 Wilrijk, Belgium E-mail: <u>sarah.michiels@uantwerpen.be</u> Tel.: +32485840758

ABSTRACT

Aims: The aim of this review was to investigate if TMD treatment can positively influence tinnitus complaints.

Methods: Four online databases: Pubmed, Web of Science, Scopus and The Cochrane Library for trials, were searched till August 2018. The search strategy was based on the PICO-framework and the following search was entered in the different databases:

("tinnitus"[Mesh] AND "craniomandibular disorders"[Mesh]) AND (("physical therapy modalities"[Mesh] OR "dental care"[Mesh] OR "occlusal splints"[Mesh]) OR (physical therapy modalities OR splint therapy OR TMD therapy)). Two independent reviewers extracted the data and performed a risk of bias assessment.

Results: A total of eleven studies were included. These studies showed an overall positive effect of the combination of splint therapy and exercise treatment on tinnitus severity, tinnitus intensity on VAS and global perceived effect. One study specified that the treatment effect was only present in patients with severe to very severe tinnitus, where the others found an effect in the overall study group. The risk of bias in the included studies was high, mainly due to lack of statistical analyses between groups and before-after treatment, incomplete presentation of the data and selective reporting. Additionally, most included studies showed a lack of information concerning the blinding process of the subjects, therapists and investigators. The heterogeneity of the inclusion criteria, outcome measurements and treatments made data pooling or meta-analysis impossible.

Conclusions: There is low quality evidence for a positive effect of conservative TMD treatment on tinnitus complaints. The combination of splint therapy and exercise treatment is currently the best investigated treatment approach, showing a decrease in tinnitus severity and intensity. Despite the low level of evidence and the methodological issues in the included studies, it is noteworthy that all included studies show positive treatment effects.

KEYWORDS: Occlusal splints - Temporomandibular joint disorders – Physical therapy modalities – Somatic - Somatosensory

INTRODUCTION

Tinnitus is the perception of sound in the absence of a corresponding external auditory stimulus. ¹ It occurs in a large part of the adult population with prevalence ranging from 10% to 15%. ^{2, 3} Tinnitus may affect patients' quality of life, is associated with depression, can result in reduced productivity at work and may cause sleeping difficulties. ^{2, 4} Various types of tinnitus exist, with two main subtypes: objective and subjective tinnitus. In some cases, internal somatosounds can cause the tinnitus, for instance turbulences of the blood flow. In these cases, the underlying generator is often measurable or detectable by the physician and an objective tinnitus can be considered. In the absence of any acoustic stimulus (internal nor external) it is called subjective tinnitus, which is the most common form of tinnitus. ²

Subjective tinnitus can additionally be classified based on the etiology. Most tinnitus complaints derive from underlying otologic pathology, such as: age-related hearing loss and noise trauma. In other cases, tinnitus can be attributed to the somatosensory system of the cervical spine or temporomandibular area. ^{2, 5, 6} This type of tinnitus is called somatic or somatosensory tinnitus (ST) and has been described in 36-43% of a population with subjective tinnitus. ^{7, 8} Vice versa tinnitus was found to be eight times more prevalent in patients with TMD, compared to patients without TMD. ⁹

A physiological explanation for ST is found in the existence of connections between the cervical somatosensory system and cochlear nuclei (CN). ^{10, 11} Cervical somatosensory information is conveyed to the brain by afferent fibers, the cell bodies of which are located in the dorsal root ganglia or the trigeminal ganglion. Some of these fibers also project to the central auditory system. This enables the somatosensory system to influence the auditory system by altering spontaneous rates or synchrony of firing among neurons in the CN, inferior colliculus or auditory cortex. In this way, the somatosensory system is able to alter the intensity and character of tinnitus. ¹²

Up to 60% of patients with TMD also perceive tinnitus, which is more than in the general population.¹³ Additionally, the fact that tinnitus can be triggered by altered somatosensory input from the temporomandibular area, suggests that the treatment of TMD might decrease the tinnitus severity. To date however, we don't know if there is any evidence for this suggestion or how strong this possible evidence is. Therefore, the aim of this review was to investigate if TMD treatment can positively influence tinnitus complaints.

METHODS

Search strategy

A systematic search was conducted in the online databases Pubmed, Web of Science, Scopus and The Cochrane Library for trials, till August 2018. The search strategy was based on the PICOframework and the following search was entered in the different databases:

("tinnitus"[Mesh] AND "craniomandibular disorders"[Mesh]) AND (("physical therapy modalities"[Mesh] OR "dental care"[Mesh] OR "occlusal splints"[Mesh]) OR (physical therapy modalities OR splint therapy OR TMD therapy)).

Afterwards, the reference lists of the included articles were hand-searched for missed publications.

Study selection

For inclusion, studies needed to meet the following inclusion criteria: subjects had to be human, both tinnitus and TMD had to be present, the studied intervention was a physical therapy treatment modality, dental care, an oral appliance or a combination of the previous, a tinnitus intensity or

severity measure was one of the outcome measures, studies had to be written in English, French, Dutch or German and articles had to present original research. Articles not meeting all inclusion criteria were excluded.

After the initial search, all retrieved articles were screened for eligibility based on title and abstract. The included articles were then screened again on full text.

The inclusion procedure was conducted by the first and second author independently and supervised by the last author. In case of uncertainty about inclusion, a decision was made in a consensus meeting, starting from the three independent opinions.

Qualification of the investigators

The screening of the literature and risk of bias assessment was performed independently by the first author, PhD. with experience in tinnitus and neck related complaints and the second author, MSc. in rehabilitation sciences and physiotherapy. The last author, PhD with experience in neck related complaints, supervised the process. The second, fifth, sixth and seventh author, provided overall expertise on tinnitus complaints and the third, fourth and eight author provided overall expertise on TMD.

Data items and collection process

All relevant information extracted from the selected studies is presented in Tables 1 and 2. These tables contain the study characteristics (authors, year of publication, country, design), population characteristics (sample size, age, main complaint), applied intervention, used outcome measure for tinnitus, and the main findings. Table 1 describes the results of the cohort studies and table 2 describes the results of the RCT's and controlled trial.

Risk of bias in individual studies

To investigate the methodological quality of the included randomised controlled trials (RCT's) and controlled trial the PEDro scale was used, as recommended by the "Physiotherapy Evidence Database". The purpose of the PEDro scale is to rapidly identify which of the (R)CT's are likely to be externally valid (item 1), internally valid (item 2-9) and have sufficient statistical information to make the results interpretable (item 10-11). The scale comprises 11 items (yes, no), calculating a total score by summing the number of "Yes" answers on item 2-11. For the total score, item 1 is not considered. Points are only rewarded when a criterion is clearly satisfied.

The methodological quality of the cohort studies was assessed by the "Quality Assessment Tool for Before-After (Pre-Post) Studies with No Control Group", developed by the National Institutes of Health (NIH). This validity tool consists of 12 items, scored with a "Yes", a "No" or "Other" (comprising: cannot determine (CD), not applicable (NA) or not reported (NR)). The quality rating can be: "poor", "fair" or "good" quality, whereas a high risk of bias translates in a rating of poor quality and low risk of bias translates in a rating of good quality.

The methodological quality assessment was performed by the first and the second author independently. Afterwards, the results were compared and disagreements were discussed to reach a consensus. The level of evidence of our systematic review was scored based on the GRADE system.

RESULTS

Study Selection

After the initial search, 28 unique articles were retrieved from the 4 databases. After selection, based on title and abstract, 12 articles were screened on full text. Finally, 11 articles were included in the systematic review. In total, 17 articles were discarded, two were excluded due to the described population, three because of the described intervention, one because of outcome measures, 10 due to the design of the study and 1 study was excluded because of the language. Details about the selection process are shown in Figure 1.

Study characteristics

Of the 11 articles selected for this review, 2 were a randomised controlled trials, 1 was a controlled trial and 8 were cohort studies. The treatment of the patients consisted of occlusal dental splints, occlusal dental adjustments, physical therapy, biofeedback therapy, relaxation exercises, counselling, pharmacotherapy, acupuncture, laser therapy and psychological therapy. The duration of the interventions ranged from one session to 7 months, although duration and frequency of the interventions was often not specified.

The reported primary tinnitus outcome measurements were Visual Analogue Scale (VAS) for tinnitus severity (VAS-severity), VAS for change in tinnitus (VAS-change), VAS for tinnitus intensity (VAS-intensity), Tinnitus Questionnaire (TQ), Tinnitus Handicap Inventory (THI), Tinnitus Handicap Questionnaire (THQ), Numerical Rating Scale (NRS) for tinnitus severity (NRS-severity), Global Perceived Effect (GPE) and a custom made questionnaire.

Risk of Bias and Level of Evidence

The results of the risk of bias assessment are presented in figures 2 and 3.

Generally, a high risk of bias was present in the included studies. The main methodological limitations of the studies were related to the lack of statistical analyses between groups and beforeafter treatment, incomplete presentation of the data and selective reporting. Furthermore, the lack of information concerning the blinding process of the subjects, therapists and investigators caused a high risk of bias. Consequently, the level of evidence of this systematic review is low according to the GRADE system.

Synthesis of the Results

For each individual study, a summary of the characteristics of the study group, type of intervention and main results is presented in table 1 and 2. Table 1 presents the results of the cohort studies and table 2 presents the results of the RCT's and controlled trial.

Two RCT's ^{14, 15} and one controlled trial ¹⁶ investigated the effect of TMD treatment on tinnitus severity or intensity. These studies showed a positive effect of the combination of splint therapy and exercise treatment on tinnitus severity^{15, 16}, tinnitus intensity¹⁴ on VAS and global perceived effect¹⁵. One study ¹⁶ specified that the treatment effect was only present in patients with severe to very severe tinnitus (TQ-score: 47 – 84 points), where the others found an effect in the overall study group.

Additionally, the results of eight cohort studies were considered. Five of these ^{9, 17-21} investigated the effect of a combination of physical therapy modalities and dental care (oral appliances or occlusal adjustments). No unambiguous conclusions can be drawn from these studies. Improvement on

tinnitus severity using global perceived effect was shown in 14 to 86% of the treated patients ^{17, 21}. Improvement on VAS for tinnitus change was reported in 44% of the patients in one study⁹. No significant decrease in Tinnitus Handicap Questionnaire score was found ^{18, 21}.

The remaining three cohort studies²²⁻²⁴ used oral appliances without physical therapy modalities. One study combined the oral appliances with acupuncture ²³ and one with counselling ²⁴. The application of oral appliances alone resulted in a significant decrease in tinnitus severity on VAS (23 – 48%) and Tinnitus Handicap Inventory (25 – 65%).²² In combination with acupuncture, application of oral appliances showed at least 50% decrease in tinnitus severity on VAS in 33% of the patients.²³ Combination with counselling showed that patients who's TMD improved faster, indicated a larger improvement on global perceived effect.²⁴

Differences in outcome measurements, unmatched group characteristics and the absence of a consistent TMD therapy made it impossible to perform either descriptive analysis or quantitative meta-analysis in this systematic review.

DISCUSSION

With this systematic review we aimed to investigate if TMD treatment can positively influence tinnitus complaints.

Overall, positive effects of conservative TMD treatment on tinnitus complaints were found. Several TMD treatment modalities have been described, but the combination of splint therapy and exercise treatment is the most investigated treatment for TMD related tinnitus complaints. This treatment approach showed a positive effect on tinnitus intensity and global perceived effect in two RCT's and a positive effect on tinnitus severity in patients with severe to very severe tinnitus in one controlled trial. Additionally, five cohort studies investigated a similar treatment approach, showing positive effects on tinnitus in three studies but little effect in the other two. It must however be noted that in the latter, improvement in tinnitus complaints can also be caused by the natural course of the tinnitus.

The effect of oral appliances alone or in combination with acupuncture or counselling are currently not investigated thoroughly enough to be conclusive.

The multifactorial aetiology of TMD cannot be ignored, especially when analysing a patient population with tinnitus. Studies have demonstrated that TMD patients show increased somatisation, stress, anxiety and depression, relative to healthy individuals.^{25, 26} These symptoms are also often associated with tinnitus itself and psychologically based treatments, such as 'Tinnitus retraining therapy' or 'Cognitive behavioural therapy', are currently recommended as best evidence based treatment in the general tinnitus population.²⁷

Therefore, specific multimodal therapies, incorporating behavioural and educational approaches, which seem to offer more benefit than a single-treatment program, should be advised in patients with TMD related tinnitus. ²⁸

Patients should be educated regarding the possible causes of TMD and it is important that they understand their own central role in the management of TMD.²⁹⁻³² Although patient education is an essential part in the treatment of TMD, four studies did not implement counselling in their treatment program.

Occlusal adjustments were included in two studies, which is an irreversible treatment that should be looked upon with extreme caution ³³, since evidence for the role of such occlusal adjustments in the management or prevention of TMD is lacking. ³⁴⁻³⁶

Additionally, when studying TMD treatment, only those subjects that require the treatment should be included. In the study from Attanasio et al. ²² for instance, patients without TMD, with a predisposition to TMD and with TMD were included. All these patients were treated with neuromuscular occlusal dental splints, an older treatment modality to reduce masticatory muscle tension and to protect teeth from bruxism and clenching. ^{37, 38} In 10 patients however, no TMD complaints were present and thus they did not require this treatment. Since splint therapy is not likely to change the tinnitus severity in these patients, the effect of the treatment in patients with tinnitus and TMD will be underestimated in this study.

Another study ¹⁵ included tinnitus patients without TMD in the control group and concluded that the patient group improved significantly more in comparison with the control group. Comparability of the study and control groups regarding type of tinnitus is however essential, since no improvement on tinnitus complaints can be expected after TMD intervention when the tinnitus is not related to TMD.

The risk of bias in the included studies was high, due to several limitations. First, there is lack of homogeneity in the studied population. In four of the included studies, the presence or absence of tinnitus was evaluated by simply asking the patients to report tinnitus symptoms, without performing otological or audiometric assessment.^{9, 17, 19, 24} Therefore, limited information about the tinnitus characteristics was present. Moreover, without performing an ENT examination it is not possible to confirm the presence of somatic tinnitus because tinnitus and TMD can also occur without causal relation.⁸ Additionally, the multifactorial aspects of TMD signs and symptoms should be considered. Some studies only included patients with myofascial TMD pain, while others included patients with different TMD aetiologies. Moreover, in some studies the criteria to confirm the presence of TMD were not clearly stated and different TMD classification methods were used. The Helkimo Index was used in two studies, while six studies evaluated the TMJ complaints by using the Research Diagnostic Criteria for Temporomandibular Disorders (RDC/TMD). The RDC/TMD was the internationally accepted classification system for TMD at the moment of publication of the studies.³⁹ Nowadays, the, in 2014, updated version of the RDC/TMD is the most appropriate tool. ⁴⁰ Due to the lack of homogeneity, in both tinnitus and TMD evaluation, generalisation of the conclusions is not possible. Furthermore, many different tinnitus outcome measures are used in the included studies. This hampers the comparability of the results. An international standard of outcome measurements in clinical trials of tinnitus is required to enable meta-analysis, as was also ascertained by Hall et al.⁴¹ An international standard is being developed, but to date, no consensus has been reached yet.

Second, a high risk of bias was present due to a lack of statistical analyses between groups and before-after treatment, lack of randomisation and lack of blinding of subjects, therapists and/or assessors and additionally, due to incomplete presentation of the data and selective reporting.

Apart from the high risk of bias in the included studies a second limitation of the studies included in this review is the lack of evaluation of Axis II findings and the duration of the TMD symptoms. Since the duration of TMD symptoms and psychosocial influences will largely influence the outcome of the TMD therapy, these items should be taken into account in every study investigating the effect of TMD treatment. Moreover, when psychosocial influences are present or TMD symptoms persist, other treatment modalities should be considered, including more psychology-based treatments.

Future research should focus on investigating the effect of the current best evidence based TMD treatment, including the treatment of co-existing increased somatisation, stress, anxiety and depression. A combination of psychology-based tinnitus treatments such as: 'Tinnitus retraining therapy' or 'Cognitive behavioural therapy' and TMD treatment can be a good way to include the

treatment of psychosocial influences on both TMD and tinnitus. This type of treatment should be evaluated using high quality RCT's in large populations of patients with TMD related tinnitus and using outcome measures with good psychometric properties, such as the Tinnitus Functional Index⁴² or the Tinnitus Questionnaire⁴³.

In conclusion, there is low quality evidence for a positive effect of conservative TMD treatment on tinnitus complaints. The combination of splint therapy and exercise treatment is currently the best investigated treatment approach, showing a decrease in tinnitus severity and intensity. Despite the low level of evidence and the methodological issues in the included studies, it is noteworthy that all included studies show positive treatment effects.

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Figure Legends:

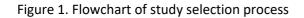
Figure 1. Flowchart of study selection process

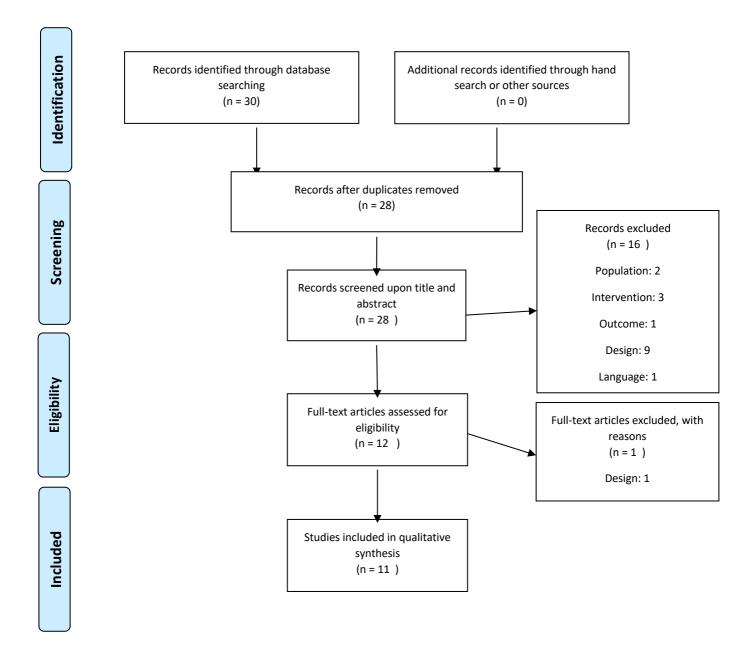
Figure 2: Risk of Bias assessment (Randomized) controlled trials – PEDro scale

Green: Yes, Red: No, Orange: Not mentioned

Figure 3: Risk of Bias assessment cohort studies – Quality assessment tool for before-after studies with no control group

Green: Yes, Red: No, Orange: Other (cannot determine, not applicable, not reported)





Study	Eligibility criteria were specified	Randomization subjects	Allocation was concealed	Similarity groups at baseline	Blinding of subjects	Blinding of therapists	Blinding of assessors	Measures of at least one outcome from more than 85% of subjects	Intention to treat analysis	Results of between group analysis for at least one outcome measure	Point measures and measures of variability provided
Bösel et al., 2008											
Erlandsson et al., 1991											
Tullberg et al., 2006											

Figure 2: Risk of Bias assessment (Randomized) controlled trials – PEDro scale

Study	Objective clearly stated	Eligibility criteria prespecified	Participants representative for clinical population	Were all eligible participants enrolled	Sample size sufficiently large	Intervention clearly described and delivered consistently across participants	Outcome measures prespecified and of good quality	Blinding of assessors	Loss to follow-up less than 20% and intention to treat analysis performed	Statistical analysis before and after treatment	Interupted time series design	Group level analysis
Attanasio et al., 2015												
Buergers et al., 2013												
Peroz et al., 2001												
Sobhy et al., 2004												
Ström et al., 2013												
Suvinen et al., 1997												
Wright et al., 1997												
Wright et al., 2000												

Figure 3: Risk of Bias assessment cohort studies – Quality assessment tool for before-after studies with no control group

STUDY CHARACTERISTICS	POPULATION CHARACTERISTICS	INTERVENTION AND CONTROL	FREQUENCY AND DURATION OF INTERVENTION	TINNITUS SEVERITY OUTCOME	FOLLOW-UP	RESULTS
ATTANASIO ET AL., 2015, ITALY DESIGN: COHORT	N = 55 Females: NR Males: NR Age: 18-60 Diagnosis: chronic subjective tinnitus (that had lasted at least for the last 12 months) Group I: without TMD; n=10; age: 43.9 (± 7.87) Group II: with a predisposition to TMD; n=30; age: 44.5 (± 12.4) Group III: with TMD; n= 15; age: 35 (± 6.72)	Neuromuscular occlusal splint	6 months for a minimum of 8h to a maximum of 15h per day	VAS-severity Tinnitus Handicap Inventory (THI)	Post-treatment	 VAS-severity: Significant decrease in all groups between pre- and post- treatment (group I: - 22.92%; p=0.002, group II: -25.54%; p<0.001, group III: -47.97%; p=0.001) THI: Significant decrease in all groups between pre- and post-treatment (group I: -25.33%; p=0.005, group II: - 38.58%; p<0.001, group III: -65.38%; p=0.001)
BUERGERS ET AL., 2013, GERMANY DESIGN: PROSPECTIVE COHORT	N = 25 Females: / Males: / Age: / Diagnosis: TMD and tinnitus	Intraocclusal stabilisation appliance (all patients) and individual physiotherapeutic treatments (applied in 16 patients), including: passive muscle stretching, massaging of the affected masticatory elevator muscles, thermotherapy (moist heat), traction of the TMJ's and coordination exercises.	Not specified	Tinnitus Handicap Inventory (THI) VAS-tinnitus change (no change to baseline, improvement, complete remission, impairment)	3-5 months after the initiation of dental functional therapy	 THI: NR VAS: 8% reported complete remission, 36% improvement, 56% no change In patients with acute tinnitus (n=8), 7 reported improvement, 1 complete remission. 14 of the 17 patients with chronic tinnitus reported no change Improvement of total remission was reported by 8 of 16 patients who received physiotherapy, but only by 3 of 9 participants without physiotherapy.

PEROZ ET AL., 2001, GERMANY DESIGN: COHORT	N = 221 Females: 163 Males: 58 Age: 35 (18-81) Diagnosis: TMD Group I: TMD without ear symptoms (n=134; age: 35,7±13,6) Group II: TMD with otalgia (n=80; age: 40,5±15) Group III: TMD with tinnitus (n=8; inclusive one patient with tinnitus and otalgia; age: 46±13)	Individual conservative treatment comprising: self- inspection to avoid parafunctions, heat therapy, splint therapy, relaxation exercises, mouth opening exercises and counselling	Mean therapy duration: 7 (±5) months Mean therapy frequency: 4 consultations (minimum 1, maximum 16)	Global perceived effect (GPE)	1-year follow-up	GPE : One year after therapy, 1 patient reported less tinnitus noises, no change in tinnitus in the other 7 patients
SOBHY ET AL., 2004, EGYPT DESIGN: COHORT	N = 30 Females: 25 Males: 5 Age: 24.3 (11-40) Diagnosis: TMD and otalgia or tinnitus Group A: myofascial pain dysfunction syndrome and otalgia or tinnitus Group B: disc displacement with reduction and otalgia or tinnitus	Group A: counselling, analgesics, non-steroidal anti- inflammatory agents, muscle relaxants, physiotherapy and soft occlusal splints (night guard) Group B: as above, but with hard acrylic occlusal splints	Not specified	Tinnitus Handicap Questionnaire (THQ)	After treatment	THQ: Significant decrease of the scores after therapy, which means improvement of tinnitus (20% incidence of tinnitus in this study)

STRÖM ET AL., 2013, SWEDEN DESIGN: COHORT	N = 45 Females: 21; age: 49±12 Males: 24; age: 47±12 Diagnosis: long-standing tinnitus with jaw muscle tenderness	Splint therapy and acupuncture	Splint therapy: 6 months Acupuncture was given five to six consecutive sessions	VAS-severity	1-year follow-up	VAS: Significant decrease in subjective tinnitus after one year. One third of the patients (15) reported a reduction of 50% or more on their tinnitus evaluation on the VAS scale. All but 6 of the 45 patients reported reduction of their tinnitus.
SUVINEN ET AL., 1997, AUSTRALIA DESIGN: COHORT	N = 42 Females: 39 Males: 3 Age: 44.8 (SD: 17.0) Diagnosis: TMD	Counselling and standard interocclusal appliance therapy	Not specified	Global perceived effect (GPE)	6-months follow-up	GPE: Improvement in terms of ringing in the ears was greater in the rapid responding group*. *Subjects were divided into rapid and slow responders according to whether their subjective degree of improvement on a VAS scale (TMD pain) at 6 months following standard simple conservative management was above or equal to/below 50%, respectively.

WRIGHT ET AL., 1997, USA DESIGN: COHORT	N = 93 Females: / Males: / Age: 31 (18-67) Diagnosis: TMD and ringing or buzzing in their ears of head	Individual conservative TMD therapy comprising: self-care instructions, splint therapy, jaw-stretching exercises, behavioural psychological therapy, stretching exercises, posture training and or physical therapy modalities, pharmaceutical therapy (n=18), individual psychological consultations	Not specified	Global perceived effect (GPE)	Post-treatment	GPE : 56%, 30% and 14% reported their tinnitus had been resolved, significantly improved and minimal or no change, respectively.
WRIGHT ET AL., 2000, USA DESIGN: COHORT	N = 15 Females: 7 Males: 8 Age: 57.6 (43-74) Diagnosis: Tinnitus or dizziness and TMD or otalgia	Mandibular dental orthotic, standard TMD self-care instructions and additional TMD therapy (relaxation, biofeedback, physical therapy, counseling, cognitive therapy, medications, etc.)	3 months	Global perceived effect (GPE) Tinnitus Handicap Questionnaire (THQ)	Post-treatment 6 months follow-up	 GPE: Of the 14 patients who reported tinnitus, 6, 3 and 5 reported resolution, significant to moderate improvement and minimal to no change. THQ: No trends for the overall THQ score or any of its three factors being associated with patients' tinnitus improvement. In patients with at least moderate improvement in their tinnitus, THQ- score decreased from 46.3 to 20.4.

Table 1. Summary of the Cohort studies

TMD: Temporomandibular Disorders; NR: Not Reported; VAS: Visual Analogue Scale; THI: Tinnitus Handicap Inventory; CT: Controlled Trial; TMJ: Temporomandibular Joint; NRS: Numerical Rating Scale; GPE: Global Perceived Effect; THQ: Tinnitus Handicap Questionnaire

STUDY CHARACTERISTICS	POPULATION CHARACTERISTICS	INTERVENTION AND CONTROL	FREQUENCY AND DURATION OF INTERVENTION	TINNITUS SEVERITY OUTCOME	FOLLOW-UP	RESULTS
BÖSEL ET AL., 2008, GERMANY DESIGN: CT WITH CROSS- OVER DESIGN	N = 59 Females: 28 Males: 31 Age: 49 (12-69) Diagnosis: chronic tinnitus and at least 1 TMD symptom present	Cross-over of Splint therapy and self- therapy (heat treatment, massage of the jaw muscles and self-monitoring to reduce unconscious muscular tension) vs. Control	6 weeks splint therapy 6 weeks self-therapy	Tinnitus Questionnaire (TQ)	After first 6 weeks of treatment (splint therapy or self-therapy) Post-treatment (12 weeks)	TQ: No significant difference in pre-post treatment scores of patients with light to moderate tinnitus (TQ: 0-46). Significant decrease in pre- post-treatment scores in patients with severe to very severe tinnitus (TQ: 47-84). This difference was statistically significant in comparison with the control group.
ERLANDSSON ET AL., 1991, SWEDEN DESIGN: RCT WITH CROSS- OVER DESIGN	N = 32 Females: 14 Males: 18 Age: 50 (24-65) Diagnosis: severe tinnitus and self-reported TMD or headaches	Somatognatic treatment (SGT) comprising: occlusal splints, occlusal adjustments and exercise therapy vs. Biofeedback therapy (BFT) comprising: biofeedback training, progressive relaxation and counselling	Not specified	VAS-intensity (0-100) NRS-severity (1-9)	Post-treatment, 6 months follow-up	VAS-intensity: Significant decrease after SGT or BFT (n = 31) No significant changes after SGT or BFT alone (n = 13 or 18) NRS-severity: No significant changes
TULLBERG AND ERNBERG, 2006, SWEDEN DESIGN: RCT	Patients (P): N = 73 Controls (C): N = 50 Females: 39 (P) / 27 (C) Males: 34 (P) / 23 (C) Age: 48 (SD: 12) (P) 47 (SD: 14) (C) Diagnosis: Patients suffering from combination of tinnitus and TMD Controls suffering from tinnitus	Splints, occlusal adjustments, jaw exercises and laser therapy vs. Waiting list	1 to 6 sessions	Global perceived effect (GPE) Custom made questionnaire	Post-treatment (GPE) and 2-3 years follow-up (questionnaire)	 GPE: 73% reported improvement, 27% reported no change Questionnaire: Significant decreased tinnitus severity Significantly more improvement in the patients than in the control group

Table 2. Summary of the (Randomized) controlled trials and quasi-experimental trials

TMD: Temporomandibular Disorders; NR: Not Reported; VAS: Visual Analogue Scale; THI: Tinnitus Handicap Inventory; CT: Controlled Trial; TMJ: Temporomandibular Joint; NRS: Numerical Rating Scale; GPE: Global Perceived Effect; THQ: Tinnitus Handicap Questionnaire

OUTCOME	NUMBER OF PARTICIPANTS	QUALITY OF THE EVIDENCE
TINNITUS IMPROVEMENT	214 (3 studies)	Low
MEASURED USING A		(Due to serious risk of
VARIETY OF SCALES		bias*)

Table 3: GRADE evidence

* details in figure 2

GRADE DOMAIN	JUGEMENT	CONCERNS
RISK OF BIAS	See risk of bias assessment figure 2.	Very serious limitations, downgrade 2 levels
INCONCISTENCY RESULTS	All studies show consistent decrease of tinnitus symptoms.	No serious limitations, no downgrade
INDIRECTNESS OF EVIDENCE	There is direct evidence for tinnitus improvement.	No serious limitations, no downgrade
IMPRECISION	The group of 214 included patients is sufficiently large to show a decrease in tinnitus symptoms with 80% power, as calculated in a sample size calculation.	No serious limitations, no downgrade
PUBLICATION BIAS	There are no signs of publication bias.	No serious limitations, no downgrade

Table 4: GRADE evidence rating