

# Comparison between the Prognosis of Temporomandibular Disorders with and without Accompanying Otologic Symptoms after Non-Invasive Non-Pharmacological Treatment: Controlled Clinical Trial

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## ABSTRACT

Background: Otologic symptoms are commonly reported by patients with temporomandibular disorders.

Objective: This study aims to investigate the likely outcome or progression of temporomandibular disorders with and without accompanying otologic symptoms when treated in the dental clinic.

Methods: The study is registered under the International Standard Randomised Controlled Trial Number: ISRCTN49976724, DOI: 10.1186/ISRCTN49976724. Forty patients with temporomandibular disorders were included and allocated into two groups: Control group (n=20): isolated temporomandibular disorders symptoms, and Experimental group (n=20): temporomandibular disorders symptoms with otologic symptoms (confirmed by otorhinolaryngological evaluation to exclude primary ear pathology). All participants underwent non-invasive, non-pharmacological treatment. The treatment contained physiotherapy and custom-made occlusal splints. Outcomes (full/partial/no recovery) were assessed at 3 months by a single maxillofacial surgeon, with follow-up every 3 weeks. Statistical analysis included Fisher's exact test and odds ratios.

Results: Fisher's exact test revealed a statistically significant association between group allocation and recovery outcomes ( $\chi^2=5.979$ ,  $p=0.041$ ). The odds ratio was 5.33.

Conclusion: The presence of otological symptoms accompanying temporomandibular disorders might predict a better prognosis after non-invasive, non-pharmacological treatment, perhaps not as a direct predictor per se but as a confounding factor.

## KEYWORDS

temporomandibular joint disorders; occlusal splints; treatment outcome; prognosis; otolaryngology; physical therapy modalities

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## INTRODUCTION

Temporomandibular disorders (TMD) are a group of multifactorial conditions affecting the temporomandibular joint (TMJ), muscles of mastication, and related structures. Epidemiological studies reported a high prevalence ranging between 40% and 60% (1).

Otologic symptoms are commonly reported by patients with TMD, with an 87% comorbidity rate (2). A 2017 systematic review and meta-analysis quantified the prevalence of otologic symptoms associated with TMD, revealing: ear fullness 74%, otalgia 55%, tinnitus 52%, vertigo 40%, and hearing loss 38% (3).

Different theories about the pathophysiology correlating the otologic symptoms to TMD originate from both anatomical and neurological mechanisms. Anatomically, the auditory tube (4) and the discomalleolar ligament (5) create direct structural continuity between the TMJ and the middle ear. The discomalleolar ligament was described by Pinto in 1962, but because it was historically grouped with the anterior malleolar ligament or labelled as retrodiscal tissue, older classical anatomy textbooks often lack a specific description of this important anatomical structure, which connects the malleus in the tympanic cavity and the articular disc and capsule of the temporomandibular joint (6, 7). Furthermore, the TMJ and ear share some embryonic and anatomic-topographic origins, which can lead to secondary otologic symptoms when the TMJ is affected (8). Neurologically, both central sensitization (9) and neurophysiological convergence through the trigeminal nerve innervation (10) may contribute to the involvement of the central and peripheral nervous systems, respectively (11).

Early diagnosis and management of TMD are likely to improve prognosis and reduce healthcare costs for patients (12). Conservative treatments like occlusal splints and physiotherapy are effective first-line interventions for many patients (13).

Existing studies have identified multiple predictors of TMD including: arthralgia (14), cervical musculoskeletal dysfunction (15), parafunctional habits like bruxism (16), greater baseline pain intensity (17), and psychological distress (particularly anxiety and depression) (18). However, otologic symptoms remain absent from prognostic models despite their high prevalence and clinical significance. This is mainly because they are not included in most standardized diagnostic tools like the DC/TMD Diagnostic Criteria for Temporomandibular Disorders (19).

This represents a critical knowledge gap, as otologic symptoms may represent either a secondary phenomenon resulting from anatomical proximity and shared innervation or markers of a distinct TMD subtype with different treatment responsiveness. Current prognostic models cannot account for this possible variability, potentially leading to suboptimal treatment stratification.

To our knowledge, no previous studies have investigated the correlation between TMD and accompanying otologic symptoms using a prognosis-oriented approach (20, 21) rather than a diagnosis-oriented one.

This study is addressing this gap by investigating whether the otological symptoms accompanying TMD can be considered as a predictor. The null hypothesis of this

research work stated that there was no relationship between the prognosis of TMD and the presence of accompanying otologic symptoms.

## MATERIAL AND METHODS

### STUDY DESIGN AND PARTICIPANT ALLOCATION

This study was a single-centre interventional controlled clinical trial. It was approved by the Research Ethical Committee at Al-Sham Private University on 09.09.2024 with ID number: REC002 in accordance with the Helsinki Declaration. The study was registered with ISRCTN Registry under reference ISRCTN49976724, DOI: <https://doi.org/10.1186/ISRCTN49976724>.

### PATIENT RECRUITMENT

Participants entered the study through three routes: 1-Self-referred patients: individuals presenting directly to the TMD clinic. 2-General dentist referrals: patients referred by general dental practitioners for suspected TMD. 3-Otorhinolaryngological referrals: patients redirected to the clinic by otolaryngologists after the exclusion of primary ear-related pathology. A total number of 40 patients with temporomandibular disorders (TMD) were enrolled. They were divided into two groups: the control group (n=20), comprising patients with only TMD symptoms, and the experimental group (n=20), comprising patients with TMD accompanied by otologic symptoms. Written informed consent was obtained from all patients.

The control group comprised first 20 consecutive self-referred or dentist-referred patients with only TMD symptoms (no otologic symptoms), requiring no otorhinolaryngological evaluation. On the other hand, the experimental group comprised patients from all three pathways who reported otologic symptoms. For self-referred and dentist-referred patients in this group, otorhinolaryngological confirmation was mandatory to exclude primary ear-related pathology. Only the first 20 patients who met this criterion were enrolled.

A single maxillofacial surgeon conducted all study parts: clinical examination, diagnosis, eligibility assessment, non-invasive, non-pharmacological treatment, and follow-up evaluations. This ensures consistency in data collection and intervention delivery.

The diagnostic process began with a comprehensive review of each patient's medical and dental history, emphasizing TMD and otological symptoms. A systematic manual examination of the TMJ was then conducted in accordance with the standardized methodology described by Bumann and Lotzmann (22). This involved palpation of masticatory muscles for tenderness, auscultation for joint sounds during mandibular movements, and functional assessment of maximal interincisal opening, lateral excursions, and protrusive range.

Radiographic evaluation was reserved for cases requiring diagnostic clarification. Initial screening utilized panoramic radiography (orthopantomogram) to identify gross bony abnormalities, such as fractures or degenerative changes. When clinically warranted, tomographic

imaging in open and closed mouth positions provided cross-sectional views to detect subtler pathologies, including erosions, osteophytes, or intra-articular adhesions. Magnetic resonance imaging (MRI) was selectively employed to evaluate soft tissue structures like articular disc position.

Definitive diagnoses were established by synthesizing clinical findings, imaging results (where applicable). All evaluations, including diagnosis and subsequent treatment planning, were conducted by a single maxillofacial surgeon to ensure methodological consistency. The treatment approach was identical for both groups and tailored to individual clinical presentations.

#### PHYSIOTHERAPY AND OCCLUSAL SPLINT THERAPY

**Physiotherapy:** Both groups underwent identical non-invasive, non-pharmacological therapy combining physiotherapy and occlusal splint therapy. Physiotherapy aimed to reduce musculoskeletal tension and improve joint function through these techniques: massage, moist heat pack application, and infrared thermotherapy. Moreover, patients identified with joint compression during diagnosis were instructed to perform stretching exercises. Massage, moist heat pack application, and infrared thermotherapy were applied during clinical appointments every three weeks, while the stretching exercises were self-administered every day.

The massage was performed bilaterally to all the patients and lasted approximately twenty minutes per session. It targeted the primary masticatory and temporal muscles, specifically the anterior bundle of the temporalis and the upper fibres of the masseter, with additional attention to the suprahyoid musculature. The massage session began with three minutes of gentle surface sliding over the anterior temporalis in a counter-clockwise circular motion, followed by three minutes of cranial-to-caudal kneading of the upper masseter fibres. During kneading, the hands returned to the initial position with continuous caudal-to-cranial sliding along the suprahyoid musculature. This sequence of alternating surface sliding over the temporalis and kneading of the masseter was repeated in shorter durations (1 minute each) two more times to maintain tissue engagement and prepare for deeper work. Subsequently, deeper sliding over the temporalis was performed for three minutes, followed by three minutes of deeper kneading of the masseter, maintaining the cranial-caudal direction and suprahyoid return. This sequence of alternating deep sliding over the temporalis and deep kneading of the masseter was repeated in shorter durations (1 minute each), two more times, culminating in a brief light-touch at the end of the session. Throughout, circular movements over the temporalis and cranial-caudal kneading of the masseter were performed in a controlled, systematic manner to ensure effective stimulation of the targeted musculature. This massage technique was adapted from the approach described by El Hage et al. (2013) (23).

Moist heat packs (40–42 °C) were applied bilaterally to the masseter and temporalis muscles to all the patients

in a supine position for 10 minutes per session. The temperature was maintained using hydrocollator packs ( Chattanooga Group, Tennessee, USA) wrapped in a terrycloth towel to prevent thermal injury. The duration and technique of applying moist heat packs were adapted from a pilot study by Azam et al. (2023) (24).

The infrared thermotherapy was administered bilaterally to all the patients to alleviate muscle stiffness and relieve pain. The total session duration was 20 minutes, with 10 minutes for each side. The session started with positioning the patient in a well-supported posture, and the nature and effects of the treatment were explained to the patient. An infrared radiator (Philips PAR38 Healthcare IR 150W 230V, Amsterdam, Netherlands) was positioned 40 centimetres from the skin surface and maintained to target both the masseter and temporalis muscles at or near right angles to achieve maximum penetration. Adjacent areas, including the eyes, were protected from heating by the placement of a layer of towelling. Throughout each session, the clinician monitored for cutaneous erythema as a safety measure, prepared to discontinue treatment immediately if any adverse reactions occurred. The thermotherapy was conducted in accordance with the guidelines described in *Electrotherapy: Principles and Practice* (25).

Stretching exercises were administered by the clinician to the affected joint, consisting of three 5-minute repetitions (totalling 15 minutes for unilateral involvement or 30 minutes for bilateral cases). The technique, described by Bumann and Lotzmann, required the patient to open the mouth to the first level of muscle tension and then exert a light isometric force against the clinician's thumb. This technique causes the contractile muscle cells to stretch the noncontractile elements (22).

All patients were instructed to adhere to a soft diet to minimize mechanical strain on the TMJ.

Custom occlusal splints were fabricated using conventional dental techniques (26). Initial diagnostic impressions of the maxillary and mandibular arches were obtained with alginate (Hydrogum, Zhermack SpA, Badia Polesine, Italy) material to replicate dental anatomy, followed by a wax bite registration with a hard baseplate wax (Beauty Pink Wax, Moyco, York, USA) to establish an optimized mandibular position. Three types of occlusal splints were utilized according to the specific TMD conditions: relaxation splints, decompressing splints, and anterior repositioning splints. These splints are used to stabilize occlusion, to compensate for loss of vertical dimension, and to guide the mandible into a protrusive position, respectively (27). All occlusal splints were designed and fabricated based on individual clinical findings and the severity of the case.

#### OUTCOME MEASURES

Patients attended follow-up evaluations at three-week intervals to monitor therapeutic progress and optimize treatment adherence. During these visits, the maxillofacial surgeon assessed symptom progression, adjusted occlusal splints to maintain proper fit and functional alignment individually with consideration of the splint type,

**Tab. 1** Baseline sample characteristics.

Characteristic	Control group (n=20)	Experimental group (n=20)	Total (N=40)
Mean age, years	25.5	31.5	28.5
Standard deviation, years	10.62	13.07	12.14
Median age, years	21.5	27.5	25
Gender, n (%)	Male: 2 (10%)	Male: 7 (35%)	Male: 9 (22.5%)
	Female: 18 (90%)	Female: 13 (65%)	Female: 31 (77.5%)

and reinforced physiotherapy techniques as needed. Clinical feedback from patients, including subjective reports of pain reduction or functional improvement, guided iterative refinements to the therapeutic regimen. The endpoint for outcome assessment was defined at three months post-intervention, regardless of whether the treatment was finished for each individual patient or not.

Outcomes of the TMD symptoms were categorized as full recovery (complete resolution of TMD and otologic symptoms, if present), partial recovery (defined as any reduction in symptom severity), or no recovery (no improvement or worsening symptoms). TMD symptoms severity was evaluated using standardized clinical criteria, including the visual analogue scale (VAS) for pain intensity, mandibular mobility measurements, and the frequency of joint crepitus. Mandibular mobility was measured for opening, lateral excursion, and protrusive movements.

### STATISTICAL ANALYSIS

The SAS Studio software, release: 3.82 enterprise edition (SAS Institute Inc., Cary, North Carolina, USA) was used to perform statistical analyses. Fisher's exact test was used to examine the association between group allocation and recovery outcomes. In order to examine if there was a relationship between age and recovery status, the non-parametric test, Kruskal-Wallis, was used.

## RESULTS

### BASELINE SAMPLE CHARACTERISTICS

Baseline characteristics of the participants are summarized in Table 1. The mean age of the Control group was 25.5 ±10.62 years, the median age was 21.5 years, and 10% were male. Whereas the mean age of the Experimental group was 31.5 ±13.07 years, the median age was 27.5 years, and 35% were male.

### RECOVERY OUTCOMES

At the 3-month endpoint, 32.5% (n=13) of participants achieved full recovery, 65% (n=26) showed partial recovery, and 2.5% (n=1) reported no improvement.

The experimental group demonstrated a significantly higher rate of full recovery (50%, n=10) compared to the control group (15%, n=3). Conversely, partial recovery predominated in the control group (80%, n=16), while the experimental group split evenly between full and partial recovery (50% each, n=10). No participants in the experimental group exhibited "no recovery," whereas one case (5%) persisted in the control group (Table 2).

Fisher's exact test revealed a statistically significant association between group allocation and recovery outcomes ( $\chi^2=5.979$ ,  $p=0.041$ ), indicating that recovery patterns differed meaningfully between the control and experimental groups. To quantify this effect, an odds ratio was calculated for full versus partial recovery (excluding the single "no recovery" case). Participants in the experimental group had 5.33 times higher odds of achieving full recovery compared to the control group (odds in control: 0.1875; odds in experimental: 1; OR=5.33).

The Kruskal-Wallis test showed no significant difference in the age of patients across the recovery pattern groups ( $p=0.968$ ).

## DISCUSSION

This study observed a significantly higher prevalence of TMD in females than in males, which aligns with other epidemiological studies (28–30). Females are more susceptible to developing TMD due to hormonal (31, 32), behavioural (33), and psychological (34) factors.

A recent study that established a clinical profile of patients with TMD in relation to age and gender found that TMD is most frequently reported in young to middle-aged adults, with a peak incidence between 20 and 40 years,

**Tab. 2** Cross-tabulation of recovery outcomes by group.

Outcome	Type	Group		
		Control group	Experimental group	Total
Recovery	Full Recovery	3 (7.5%)	10 (25%)	13 (32.5%)
	Partial Recovery	16 (40.2%)	10 (25%)	26 (65%)
	No Recovery	1 (2.5%)	0 (0%)	1 (2.5%)
	Total	20 (50%)	20 (50%)	40 (100%)

affecting females more than males (35). These findings are consistent with the results of the present study.

This present study demonstrated a statistically significant association between TMD symptom profiles (with or without otologic symptoms) and treatment outcomes following non-invasive therapy. Thus, rejecting the null hypothesis. The experimental group (TMD + otologic symptoms) exhibited 5.33 times higher odds of full recovery compared to the control group (TMD only), with no cases of “no recovery” in the former. This suggests that otologic symptoms in TMD patients may not necessarily indicate poorer prognosis, contrary to some clinical assumptions, but could instead reflect a subtype more responsive to non-invasive, non-pharmacological therapies like occlusal splints and physiotherapy.

The observed disparity in recovery rates (50% full recovery in the experimental group vs. 15% in controls) raises questions about potential mechanistic differences.

Studies indicate that otological symptoms like earache and tinnitus can appear early in the progression of TMD. For instance, otological symptoms in TMD may stem from referred muscular tension (36) or Eustachian tube dysfunction (37), both of which could be alleviated by splint-induced joint repositioning or muscle relaxation, as two systematic reviews show (38, 39).

Naderi et al. found that non-invasive, non-pharmacological TMD treatments relieved both TMD and associated otological symptoms. The splints are significantly efficient in improving otologic symptoms, with more than 50% of the patients reporting complete or partial recovery after a 2-month follow-up (40).

Conversely, isolated TMD symptoms might involve more entrenched articular or degenerative pathology, requiring more extended intervention periods. This is supported by findings that show a significant association between TMD severity and treatment duration (41). There is a significant association not only between otologic symptoms and jaw functions (such as speaking, opening, and closing the mouth) but also between the severity of otologic symptoms and the severity of other TMD symptoms (42). A potential confounding factor in this association is that patients experiencing difficulties with jaw functions are more likely to seek medical care earlier in the course of TMD (43), whereas those with painless TMJ clicking may ignore their symptoms (44). This difference in care-seeking behaviour could influence the observed relationship between the prognosis of TMD symptoms and the presence of the accompanying otologic symptoms after non-invasive, non-pharmacological treatment.

Since the group assignment is predetermined by an external factor, which is the presence or absence of otological symptoms, this study design exhibits robust external validity (45). Nevertheless, it is accompanied by an inherent limitation of internal validity (46).

Another limitation of this study is the 3-month endpoint, which only shows short-term improvements. While patients requiring extended care received additional follow-up for up to six months, data beyond the three-month endpoint were excluded from formal analysis to provide consistency within the group. This would guarantee that comparisons of outcomes between groups would be based

on an identical timeframe, preventing confounding due to different treatment durations.

Further investigation is needed to explain the mechanism of how the otological symptoms are affecting the prognosis and to assess long-term improvements.

## CONCLUSIONS

Within the limitations of this study, it can be concluded that otologic symptoms may paradoxically predict better TMD recovery. In other words, the presence of otological symptoms accompanying TMD might predict a better prognosis after non-invasive, non-pharmacological treatment, perhaps not as a direct predictor per se but as a confounding factor.

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