Effectiveness of orofacial myofunctional therapy in improving orofacial function and oral habits: a scoping review

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PRACTICAL IMPLICATIONS OF THIS RESEARCH

- An increasing number of dental hygienists are providing orofacial myofunctional therapy. Yet, its effectiveness is sometimes questioned. Therefore, a critical appraisal of the available evidence is needed to guide this practice.
- Although this scoping review found 12 intervention comparisons using orofacial myofunctional therapy for 7 different myofunctional disorders affecting orofacial soft tissue structures or oral habits, no confirmed level 1 evidence (highest) was found.
- More randomized controlled trials with larger samples and longer follow-ups are needed to confirm the effectiveness of orofacial myofunctional therapy.

ABSTRACT

Background: The effectiveness of orofacial myofunctional therapy (OMT) has yet to be confirmed in the literature. This scoping review aimed to answer the question, "What evidence exists to support the effectiveness of OMT in treating/managing orofacial myofunctional disorders (OMDs) affecting orofacial structures' function and oral habits?" **Methods:** A librarian at the University of Alberta, Canada, developed a comprehensive search strategy and applied it to 6 databases and grey literature. The reference lists of included studies were cross-checked. Two independent reviewers screened the retrieved records in 2 phases; 1 extracted data. The evidence level of each article was assessed using the Oxford CEBM Levels of Evidence. A third reviewer solved conflicts. **Results:** After screening 11,518 records, 58 were included (50 primary studies and 8 reviews). The addressed OMDs were ankyloglossia (8 studies), atypical swallowing (9 studies), lip incompetence (13 studies), mouth breathing (10 studies), non-nutritive sucking habit (10 studies), low tongue position at rest (2 studies), and simultaneous OMDs (9 studies). Only 11 studies (19%) were randomized controlled trials. Most presented no proper randomization process and no allocation concealment description; half were open-label studies. Although 86% of primary studies reported positive results using OMT, of 12 comparisons found, only 9 were considered plausible (6 at level of evidence 3, 2 at level 2, and 1 at level 1). None was deemed to have confirmed the effectiveness of OMT. **Discussion:** Conducting methodologically sound clinical trials with larger samples and longer follow-ups is crucial to answering the research question. **Conclusion:** In some scenarios, OMT produces clinical changes. However, insufficient high-level evidence exists to fully confirm OMT's effectiveness.

RÉSUMÉ

Contexte : L'efficacité de la thérapie myofonctionnelle orofaciale (TMO) n'a pas encore été démontrée dans la littérature scientifique. Cette étude exploratoire visait à répondre à la question suivante : « Quelles sont les preuves qui appuient l'efficacité de la TMO dans le traitement et la gestion des troubles myofonctionnels orofaciaux affectant la fonction des structures orofaciales et les habitudes buccodentaires? » **Méthodes :** Un bibliothécaire de l'Université de l'Alberta, au Canada, a créé une stratégie de recherche exhaustive et l'a appliquée à 6 bases de données et à la littérature grise. Les listes de référence des études comprises ont été contre-vérifiées. Deux évaluateurs indépendants ont examiné les dossiers récupérés en 2 phases; un évaluateur a extrait les données. Le niveau de preuve de chaque article a été évalué à l'aide de l'Oxford CEBM Levels of Evidence. Un troisième examinateur a résolu les conflits. **Résultats :** Après avoir examiné 11 518 dossiers, 58 ont été inclus (50 études primaires et 8 examens). Les troubles myofonctionnels orofaciaux traités étaient l'ankyloglossie (8 études), la déglutition atypique (9 études), l'incompétence labiale (13 études), la respiration buccale (10 études), l'habitude de succion non nutritive (10 études), la position basse de la langue au repos (2 études) et les troubles myofonctionnels orofaciaux simultanés (9 études). Seulement 11 études (19 %) étaient des essais contrôlés randomisés. La plupart de ces études ne présentaient pas de processus de randomisation approprié ni de description de la dissimulation de l'affectation; la moitié d'entre elles étaient des études ouvertes. Bien que 86 % des études primaires ont montré des résultats positifs grâce à l'utilisation de la TMO, seulement 9 des 12 comparaisons trouvées ont été jugées plausibles (6 avec un niveau de preuve de 3, 2 avec un niveau de 2 et 1 avec un niveau de 1). Aucune des études n'ont été trouvées à confirmer l'efficacité de la TMO. **Discussion :** Il est primordial de mener des essais cliniques de manière méthodologique appropriée avec un échantillonage plus vaste et une prolongation des suivis pour répondre à la question posée. **Conclusion :** Dans certains scénarios, la TMO produit des changements cliniques. Cependant, il n'existe pas assez de preuves de niveau élevées pour confirmer l'efficacité de la TMO.

Keywords: ankyloglossia; deglutition; mouth breathing; myofunctional therapy; scoping review; tongue habits
CDHA Research Agenda category: risk assessment and management

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INTRODUCTION

The International Association of Orofacial Myology (IAOM) defines orofacial myofunctional disorders (OMDs) as "atypical, adaptive patterns that emerge in the absence of normalized patterns within the orofacial complex."[1] Examples of OMDs include non-nutritive sucking habits, labial incompetence (the habit of resting with the lips apart), an atypical tongue rest posture (between or against the teeth), and atypical swallowing patterns such as tongue thrust.[1] OMDs are believed to be associated with some dental conditions, such as specific malocclusion traits and orthodontic relapse, among others.[1,2]

Orofacial myofunctional therapy (OMT) involves individualized programs, usually based on oral and peri-oral exercises, to help patients retrain the adaptive patterns of muscle function, creating and maintaining a stabilized stomatognathic system. OMT usually focuses on normalizing tongue and lip postures at rest, establishing nasal breathing, correcting chewing and swallowing patterns, and ceasing harmful oral habits.[1,3,4]

The interest in muscle training to improve orthodontic outcomes dates to the beginning of the twentieth century,[5] and the term "myofunctional therapy" was first used around the same time.[6] However, a century after this first report, papers supporting[4] and questioning[3] OMT effectiveness continue to be published. Although the possible effectiveness of OMT in treating temporomandibular disorders (TMD)[7] and obstructive sleep apnea (OSA)[8] has recently been discussed, its effectiveness as a treatment option for other OMDs remains uncertain/controversial.

Therefore, this scoping review aims to answer the question, "What evidence exists to support the effectiveness of OMT in treating/managing orofacial myofunctional disorders (OMDs)?" This article focuses on OMT for OMDs affecting the function of orofacial soft tissue structures and oral habits; a second article will focus on dental malocclusions.

METHODS

This scoping review was planned and conducted according to the Joanna Briggs Institute's *JBI Manual for Evidence Synthesis*[9], chapter 11[10]. The PRISMA extension for Scoping Reviews (PRISMA-ScR)[11] was used to report it. This study protocol was registered on Open Science Framework under DOI 10.17605/OSF.IO/M6HNS (available at https://osf.io/m6hns/).

The mnemonic PCC (population, concept, and context)[10] was used to frame the research question, considering the following:

- Population: individuals with OMDs
- Concept: completed OMT
- Context: in any health care setting and delivered by any health care professional

The inclusion criteria were as follows:

- Clinical trials (randomized controlled trials and non-randomized studies of interventions in which individuals with OMDs were treated with OMT regardless of health care setting or professional delivering the treatment)
- Reviews and guidelines (used as additional literature sources and to define the level of evidence whenever appropriate, e.g., a systematic review with good methodological quality that considered the same PICO framework of any comparison of this scoping review)
- Studies in which the OMT was combined with removable oral appliances
- Studies in which the OMT was used before or after lingual frenotomy or otorhinolaryngological surgery (septum, adenoids, or tonsils surgery)

The exclusion criteria were as follows:

- Studies that included patients with known physical, neurological, and/or orofacial abnormalities associated with other diseases or conditions (e.g., craniofacial syndromes, congenital malformations, head and neck cancer, any-cause dementia, cerebral palsy, facial palsy)
- Studies in which OMT was used to manage obstructive sleep apnea, temporomandibular joint diseases or dysphagia
- Studies in which OMT was used for cosmetic reasons
- Studies using orthodontic myofunctional appliances without associated exercises
- Studies in which OMT was only tested in people without OMDs (healthy patients)
- Studies in which it was impossible to access the actual OMT delivered, either by description or cited literature
- Studies in which it was impossible to isolate the effects of OMT from co-interventions (e.g., when OMT was associated with frenotomy in a protocol for ankyloglossia treatment, with no control group and no evaluation immediately after the surgery)
- Case series with less than 10 participants, case reports, and preclinical studies (in vitro and animal studies)

An experienced health sciences librarian (JYK) developed a comprehensive literature search strategy to retrieve all relevant records published on OMT. The strategy used controlled vocabulary related to "myofunctional therapy" and relevant keywords and synonyms. Table 1 displays the search strategy used for the Ovid MEDLINE database.

Subsequently, the refined search strategy was adapted and then employed in five databases (Ovid Embase, Web of Science Core Collection, Cochrane Library, Scopus, and

Table 1. Ovid MEDLINE search strategy

Ovid MEDLINE(R) ALL <1946 to May 16, 2023>
1. exp Myofunctional Therapy/
2. myofunction* or myotherap*).tw,kf.
3. (myolog* and (orofacial* or facial or face or tongue* or soft palate* or palatal or oral or myofa?cial or lip or lips or cheek*)).tw,kf.
4. exp Palate, Soft/
5. exp Tongue/
6. (orofacial* or tongue* or soft palate* or palatal or myofa?cial or lip or lips or cheek*).tw,kf.
7. (suck* adj3 (habit* or behavio?r*)).mp.
8. ((thumb* or finger* or pacifier* or digit* or soother* or object*1) adj3 suck*).mp.
9. fingersucking.mp.
10. Sucking Behavior/
11. "atypical swallow*".tw,kf.
12. or/4-11
13. exp Exercise Therapy/
14. exercise*.tw,kf.
15. speech therap*.mp.
16. speech language patholog*.mp.
17. musculoskeletal manipulati*.mp.
18. manual therap*.mp.
19. or/13-18
20. 12 and 19
21. 1 or 2 or 3 or 20
22. animals/ not (animals/ and humans/)
23. (veterinary or rabbit or rabbits or animal or animals or mouse or mice or rodent or rodents or rat or rats or murine or hamster* or pig or pigs or piglets or swine or porcine or horse* or equine or cow or cows or cattle or bovine or goat or goats or sheep or lambs or ovine or monkey or monkeys or trout or marmoset$1 or canine or dog or dogs or feline or cat or cats or zebrafish).ti.
24. 22 or 23
25. 21 not 24

LILACS) and grey literature (ProQuest Dissertations & Theses Global and Google Scholar). No language or date limits were applied. The complete search strategies for each database and grey literature are available in Supplementary File 1.

JYK conducted all searches in May 2023. The records retrieved from each database or website were imported into Covidence (covidence.org), and the duplicate records were removed. Next, 2 independent reviewers (CMS and AAL) performed the screening process in 2 phases: titles and abstracts, and full-text reading, using the predefined eligibility criteria. Before each phase, a calibration round was performed, considering the first 10 titles/abstracts and 10 full texts. All discrepancies were resolved by a third reviewer (FMS) or by consensus within the review team. Additionally, the reference lists of included studies and the evidence maps on the American Speech-Language-Hearing Association (ASHA[12]) website were manually searched for potential studies fulfilling the eligibility criteria.

The included records were analyzed and critically appraised by the review team. CMS extracted data (population characteristics, target OMDs, intervention, comparison, and the effectiveness of OMT) from the studies using Covidence software. AAL cross-checked all information. Doubts were dispelled by consensus or discussion with the third reviewer (FMS).

The level of evidence was appraised using the Oxford CEBM Levels of Evidence for questions of intervention[13], as displayed in Table 2. The best evidence of the effectiveness of OMT in treating or managing each target OMD was used.

The evidence of the effectiveness of OMT for each comparison was rated as follows, according to the best level of evidence found:

- Confirmed: if level 1 evidence of the effectiveness existed
- Plausible: if level 2 or 3 evidence existed
- Inconclusive: if level 4 or 5 evidence existed
- Inexistent: if no evidence was found

Table 2. Oxford CEBM Levels of Evidence for questions of intervention

Question of interest: Does this intervention help? (Treatment benefits)
Level 1: Systematic review of randomized trials or n-of-1 trials
Level 2: Randomized trial or observational study with dramatic effect
Level 3: Non-randomized controlled cohort/follow-up study
Level 4: Case-series, case-control studies or historically controlled studies
Level 5: Mechanism-based reasoning
Note: the level may be downgraded based on study quality, imprecision, indirectness, inconsistency between studies, or when the absolute effect size is very small; the level may be upgraded if there is a large or very large effect size.

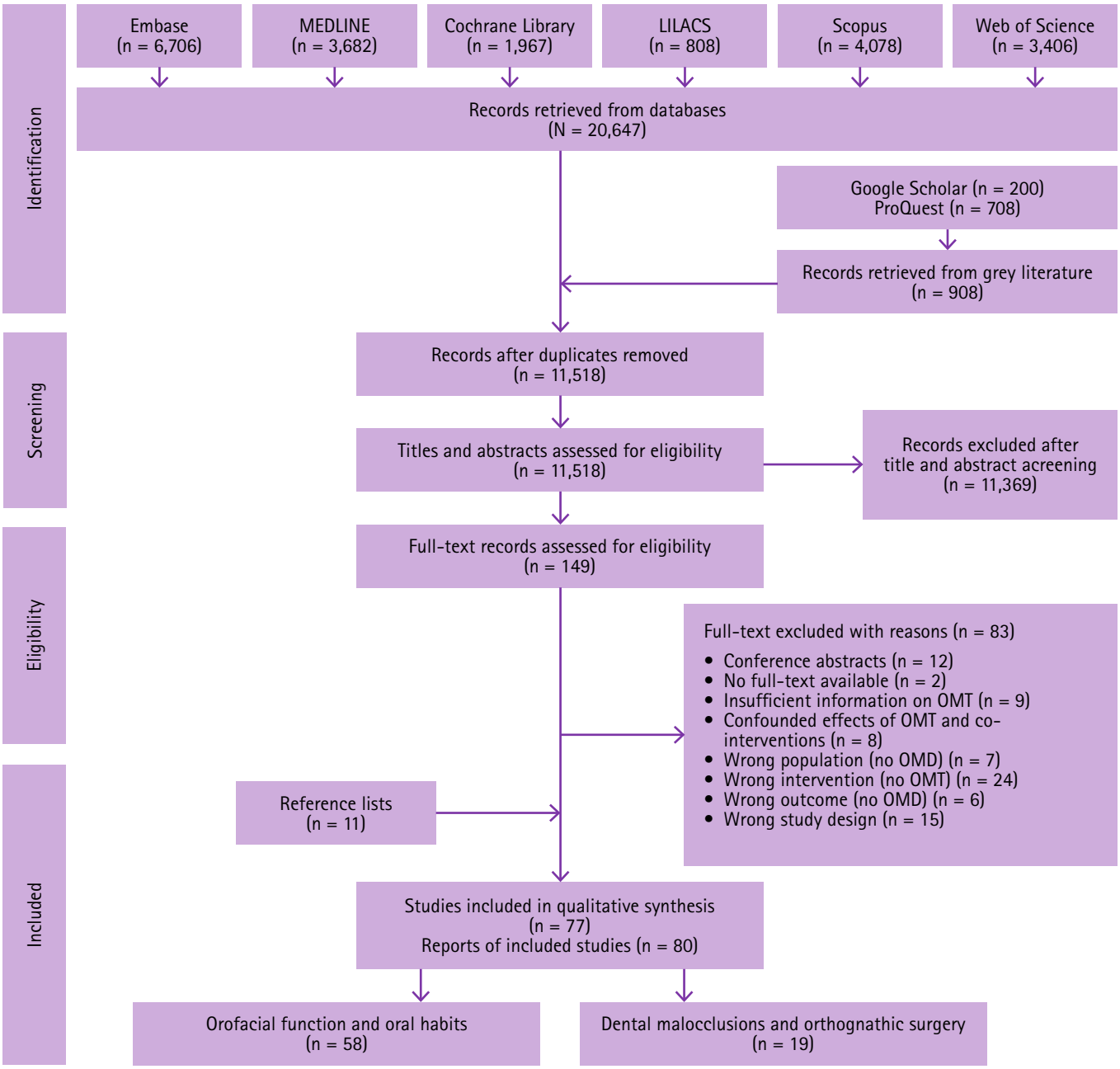
Adapted from: OCEBM Levels of Evidence Working Group. The Oxford Levels of Evidence 2. Oxford Centre for Evidence-Based Medicine. Available from: cebm.ox.ac.uk/resources/levels-of-evidence/ocebm-levels-of-evidence)

RESULTS

A total of 21,555 records were retrieved from databases and grey literature. The first 200 results from Google Scholar were considered.[14] After removing duplicates, 11,518 unique results remained. The title and abstract screening yielded 149 studies for full-text reading; 66 studies (69 reports) were considered for final inclusion. An examination of the reference lists retrieved 11 additional studies, resulting in 77 included studies (80 reports). Among the 77, 58 addressed OMDs associated with oral habits and soft structures and were included in this scoping review. The remaining 19 records addressed OMDs associated with malocclusions and will be considered in a second publication. The flowchart of the literature search and selection process is shown in Figure 1. Studies excluded after full-text reading and the reasons for exclusion are available in Supplementary File 2.

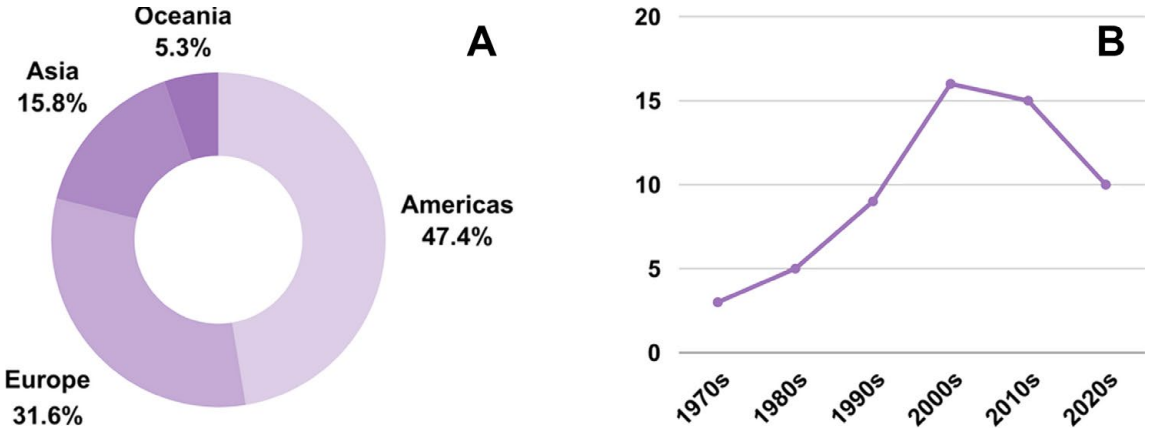
More than one report was found for 2 included studies. Degan and Puppin-Rontani published 3 papers[15-17] with different outcomes. From Yang et al., the published article[18] and the preprint[19] were retrieved and kept since they presented complementary information.

Figure 1. Flow diagram of literature search and selection criteria



Adapted from: PRISMA extension for scoping reviews (available from: prisma-statement.org/scoping)

Figure 2. Distribution of included studies (n = 58) according to the continent of corresponding author's address (A) and decade of publication (B)



Note: Figures created with Canva. Interactive version available from: canva.com/design/DAGE3VZNk30/ckR4t65UJYMbKa_E4LAEaA/view?utm_content=DAGE3VZNk30&utm_campaign=designshare&utm_medium=link&utm_source=editor

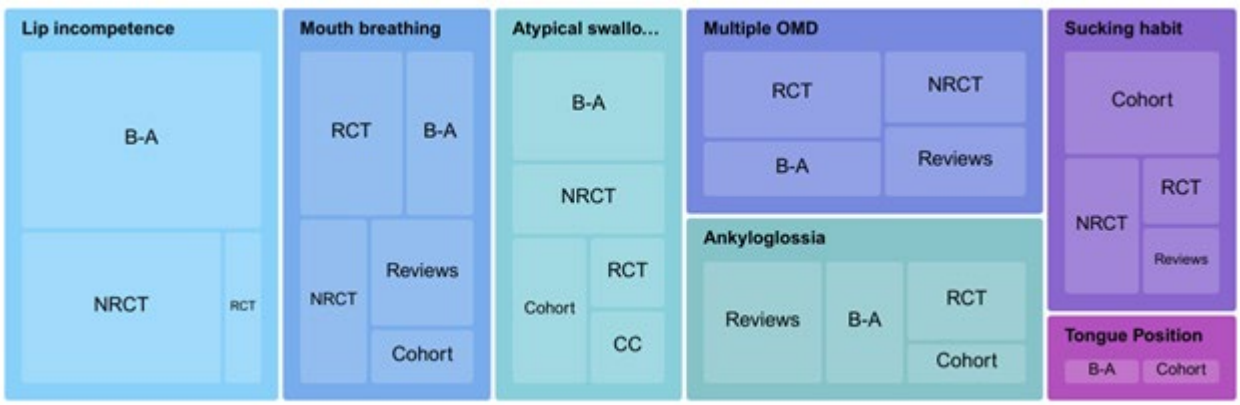
Considering the address of the corresponding author, most studies (n = 27, 47%) were conducted in the Americas, followed by Europe (n = 19, 32%) (Figure 2A). The country with the greatest number of studies was Brazil (n = 14, 24%), followed by the United States of America (n = 8, 14%) and Italy (n = 6, 10%).

The publication year ranged from 1975[20,21] to 2023[22]. Most studies (n = 41, 70%) were published from 2001 onwards (Figure 2B).

The most-used language to report the findings of the studies was English (n = 43, 74%), followed by Portuguese (n = 9, 16%). Regarding the study design (some reclassified by the scoping review authors according to the taxonomy proposed by Reeves et al.[23]), before-and-after (n = 18, 31%) was the most frequent design, followed by non-randomized controlled trials (non-RCTs) (n = 12, 21%), randomized controlled trials (RCTs) (n = 11, 19%), and reviews (systematic, integrative or narrative with systematized search) (n = 8, 14%). Studies were classified as RCT when the authors mentioned that randomization was performed (even in the absence of the randomization process description); studies were classified as non-RCT when randomization was not mentioned or when the patients were distributed into groups according to their availability or willingness in being treated.

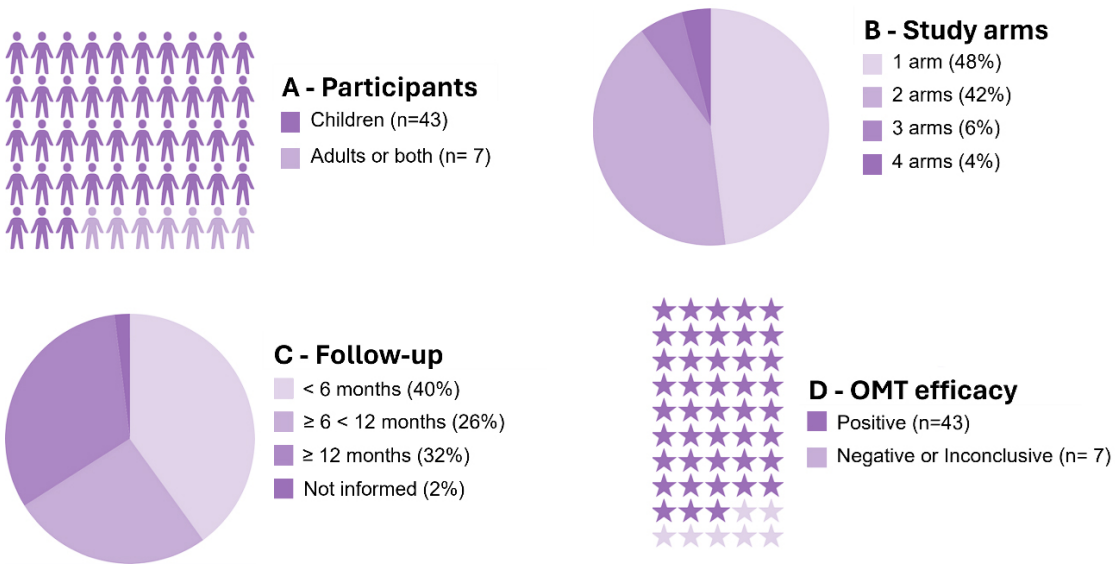
The OMDs considered in the included studies were associated with ankyloglossia (or altered lingual frenulum, also known as tongue tie) (n = 8), atypical swallowing (or tongue thrust) (n = 9), lip incompetence (n = 13), mouth breathing (n = 10), non-nutritive sucking habit (n = 7), low tongue position at rest (n = 2), and multiple (combined) OMDs (n = 9). The distribution of studies according to target OMDs and study design is shown in Figure 3.

Figure 3. Distribution of studies according to target OMDs and study design



Notes: B-A: before and after; CC: case-control; NRCT: non-randomized controlled trial; RCT: randomized controlled trial. (Figure created with Canva. Interactive version available from: canva.com/design/DAGE3VZNk30/ckR4t65UJYMbKa_E4LAEaA/view?utm_content=DAGE3VZNk30&utm_campaign=designshare&utm_medium=link&utm_source=editor)

Figure 4. Distribution of primary studies (n = 50) according to A) Target population (children x adults/both); B) Number of study arms; C) Follow-up period; and D) OMT efficacy (positive x negative/inconclusive)



Note: Figures created with Canva. Interactive version available from: canva.com/design/DAGE3VZNk30/ckR4t65UJYMbKa_E4LAEaA/view?utm_content=DAGE3VZNk30&utm_campaign=designshare&utm_medium=link&utm_source=editor

Considering only the primary studies (n = 50), the sample size varied from 6[24,25] to 723[26] participants. Two studies had a sample size of less than 10 participants.[24,25] Still, since both were prospective clinical trials (1 before-and-after[24] and 1 pilot RCT[25]), they were not excluded. In total, 3,264 patients were treated, of which 2,397 received the intervention of interest. The target population considered in most studies were children (2 to 18 years old) (n = 43, 86%) (Figure 4A). Most studies had 1 (n = 24, 48%) or 2 therapeutic arms (n = 21, 42%) (Figure 4B). The follow-up period was less than 12 months in most studies (n = 32, 64%) (Figure 4C). Concerning OMT efficacy, 43 (86%) studies reported positive results of OMT in the treatment of OMDs (Figure 4D).

Among primary studies, 17 (34%) used myofunctional devices associated with the OMT. Of these, 60% used devices designed to treat lip incompetence or improve lip function (e.g., lip buttons and traction plates) and 35% used orthodontic appliances, either custom-made or preformed.

Many primary studies did not describe the professional delivering OMT (n = 19, 38%). Among those that did (n = 31), speech-language therapists were the most frequent OMT provider (n = 21, 68%).

Analysis of the evidence found according to target OMD

Effectiveness of OMT in treating ankyloglossia-associated OMDs

Only 1 RCT[27], with no allocation concealment and short follow-up (1 month), compared tongue mobility after lingual frenectomy with or without OMT, achieving more positive results with the adjunctive OMT. Three single-arm studies[22,28,29] used OMT in the peri- and/or post-frenectomy period as part of an ankyloglossia management protocol. Even though these studies presented the results in a way that allowed for individualized analysis of the effects of the OMT, their conclusions focussed more on the effects of the surgery for ankyloglossia correction with adjunctive OMT as a protocol.

In fact, the absence of individualized results for the OMT in protocols for ankyloglossia management was the reason for the exclusion of several studies.[30-34] The 3 reviews on this topic[35-37] also included studies in which the results of OMT and surgery were not individualized. Therefore, any conclusion on the additional benefits of OMT, when associated with lingual frenectomy/frenuloplasty for the management of ankyloglossia-associated OMDs, is deemed questionable. Nevertheless, this finding suggests that OMT has been considered a well-established, indissociable part of protocols for ankyloglossia management.

Only 1 study compared the use of OMT alone versus no treatment for the management of ankyloglossia-associated OMDs.[25] However, this pilot study (no randomization process description, no allocation concealment, open label) had a small sample (6 patients), short follow-up (3 weeks), and subjective outcome evaluation. Therefore, although the authors reported improved tongue mobility after the treatment, the results are hardly generalizable.

The best evidence found for the comparison "OMT with lingual frenulum surgery vs surgery alone" was level 2 (1 small RCT[27] with some limitations). Hence, the effectiveness of OMT was considered plausible. For "OMT alone vs no treatment" for ankyloglossia-associated OMDs, the best evidence found was level 4 (1 pilot study[25] with serious limitations), and the effectiveness of OMT was considered inconclusive.

Table 3 summarizes the evidence found on the effectiveness of OMT in treating or managing ankyloglossia-associated OMDs. Supplementary Table S1 provides detailed information on the included studies.

Effectiveness of OMT in treating atypical swallowing (tongue thrust)

The included papers used the terms "atypical swallowing" and "tongue thrust" interchangeably. Since tongue thrust has been suggested to be the pathognomonic sign for reaching a definite diagnosis of atypical swallowing,[38,39] studies addressing atypical swallowing or tongue thrust were both considered.

Six of the studies found were single armed. Three before-and-after studies[39-41] treated 33 patients of different ages who had not received orthodontic treatment. All 3 showed improvements in clinical parameters[39-41], tongue strength[41], and electromyographic muscle activity[39] but small modifications in electropalatographic evaluation[40].

Table 3. Characteristics of the literature on the effectiveness of OMT according to target OMDs and respective levels of evidence

Target OMDs	Studies and designs	Comparisons and best evidence found[a]	Level of evidence and interpretation[b]
Ankyloglossia (short lingual frenulum) • 8 studies • 126 participants • 82 treated with OMT	Before-and-after[28,29] RCT[25,27] Retrospective cohort[22] Integrative review[36] Systematic review[35,37]	OMT alone vs no treatment (1 pilot study[25] with serious limitations) **OMT with lingual frenulum surgery** vs surgery alone (1 small RCT[27] with some limitations)	Level of evidence 4 (inconclusive) Level of evidence 2 (plausible)
Atypical swallowing (tongue thrust) • 9 studies • 279 participants • 218 treated with OMT	Before-and-after[39-41] Non-paired case-control[42] Non-RCT[46] Prospective cohort[43] Quasi-RCT[44] RCT[45] Retrospective cohort[21]	OMT alone vs no treatment (3 before-and-after studies[39-41]) **OMT combined with speech** therapy vs speech therapy alone (1 RCT[45] with important limitations) **OMT with re-education/impeditive removable orthodontic devices** vs orthodontic devices alone (short term) (1 non-RCT[46])	Level of evidence 4 (inconclusive) Level of evidence 3 (plausible) Level of evidence 3 (plausible)
Lip incompetence • 13 studies • 697 participants • 374 treated with OMT	Before-and-after[48,49,52,53,55-57] Non-RCT[18,20,50,51,58] RCT[54]	**OMT** vs no treatment (for lip strength and height) (1 small RCT[54] with important limitations and 4 non-RCTs[18,20,50,58])	Level of evidence 3 (plausible)
Mouth breathing (actual or habitual) • 10 studies • 481 participants • 226 treated with OMT	Before-and-after[24,60] Prospective cohort[59] Non-RCT[61-63] RCT[64,65] Integrative review[67] Systematic review[66]	**OMT with interventions for nasal breathing** vs interventions for nasal breathing alone (short term) (2 RCTs[64,65] with some limitations)	Level of evidence 2 (plausible)
Non-nutritive sucking habit • 7 studies • 1627 participants • 1379 treated with OMT	Retrospective cohort[26,70,72] Non-RCT[68,71] RCT[69] Cochrane review[73]	**Psychological interventions** vs no treatment (1 Cochrane review[73] with low evidence certainty) Psychological interventions vs palatal crib (1 non-RCT[68]) **Psychological interventions with OMT (tongue exercises)** vs no treatment (1 retrospective cohort[70])	Level of evidence 1 (plausible) Level of evidence 3 (plausible) Level of evidence 3 (plausible)
Low tongue position at rest • 2 studies • 78 participants • 53 treated with OMT	Before-and-after[75] Retrospective cohort[74]	OMT associated with re-educative removable orthodontic appliances vs no treatment (1 before-and-after study[75] and 1 small single-armed retrospective cohort[74])	Level of evidence 4 (inconclusive)
Multiple (combined) OMDs • 9 studies • 228 participants • 163 treated with OMT	Before-and-after[81,82] Non-RCT[79,80] RCT[15,77,78] (one[15] with two additional reports[16,17]) Narrative review with systematized search[83] Systematic review[84]	**OMT** vs no treatment (1 small RCT[15] with important limitations)	Level of evidence 3 (plausible)

Note: Descriptive characteristics of included studies for each target OMD are displayed in Supplementary Tables S1 to S7.

[a]The favoured intervention appears in bold type ($p < 0.05$). Comparisons not highlighted indicate no difference between interventions. Comparisons deemed inconclusive (level of evidence 4 or 5) were not highlighted, even in the event of statistically significant difference.

[b]The best evidence found for each comparison identified was considered. Only studies in which OMT effectiveness could be evaluated in an individualized way were considered to determine the level of evidence.

A non-paired case-control study[42], derived from a retrospective cohort, compared a group of successfully treated children (58%) to a group where atypical swallowing persisted or relapsed after therapy (42%). The success-associated factors were sex (girls over boys), type of therapy (in groups over individuals), and parental involvement.

A retrospective cohort[21] with 50 children and adolescents who received OMT for tongue thrusting, associated or not with fixed orthodontic appliances, showed that 5 years after the OMT ended, three-quarters of the participants had no tongue-thrust relapse or orthodontic relapse. Among those who suffered tongue-thrust relapse, some also showed malocclusion relapse, especially open bite.

A single-arm prospective cohort study[43] tested a protocol for atypical swallowing management in 57 children with malocclusion. After 8 weekly sessions of OMT, 47% of children achieved a normal swallowing pattern. Among children with Class II malocclusion who used a Bionator device, 62% achieved a normal pattern, suggesting a positive effect of combined orthodontic treatment and OMT.

Only 3 studies were 2-armed. One quasi-RCT[44] (no proper randomization, open label) compared the effectiveness of OMT combined with speech therapy with OMT alone, while a RCT[45] (no randomization description, no allocation concealment, small sample) compared the effectiveness of OMT combined with speech therapy with speech therapy alone. OMT alone was as effective for managing atypical swallowing as the combination of OMT with speech therapy[44], while speech therapy alone was not effective[45].

One non-RCT study[46] presented a 3-year follow-up of patients treated for atypical swallowing. It included 20 children with Class I malocclusion treated either by orthodontic removable appliances (a re-educating device during the day and an impediment crib device at night) or the same appliances and OMT. A first report from the same study[47] (full text not found, even after contacting the authors) showed an impressive improvement in atypical swallowing in children in the combined treatment group (100%) when compared to those using orthodontic appliances only (20%) at the end of the therapy (5 months). After 3 years, no relapse was observed in the combined therapy group, and 90% of the control group also achieved a normal swallowing pattern. In other words, the intensely treated children achieved a normal swallowing pattern earlier, but those in the appliance group also succeeded.

The best evidence for the comparison "OMT alone vs no treatment" was level 4 (3 before-and-after studies[39-41]). The effectiveness of OMT for this comparison was considered inconclusive. The best evidence for "OMT combined with speech therapy vs speech therapy alone" was level 3 (1 RCT[45] with important limitations). In addition, for "OMT with re-education/impeditive removable orthodontic devices vs orthodontic devices alone" (in the short term), level 3 evidence was found (1 non-RCT[46]). So, the effectiveness of OMT for the last 2 comparisons was considered plausible. Table 3 summarizes the evidence found on the effectiveness of OMT in treating atypical swallowing and the levels of evidence. Supplementary Table S2 provides detailed information on the included studies.

Effectiveness of OMT in treating lip incompetence

Lip incompetence was the target OMD with the highest number of studies, at 13. Of these, some included participants with other simultaneous OMDs, such as tongue thrust[20], malocclusion[18,48], anterior open bite[49], and habitual mouth breathing[50]. All studies aimed at circumoral musculature strengthening through exercises. Many used myofunctional devices combined with OMT, such as lip exerciser devices[20,50-56] or preformed myofunctional orthodontic devices[18,48]. The outcomes focussed mainly on lip strength[18,20,49,51-55,57] and endurance[52,53], lip function measured by electromyography (EMG)[48,54,55,58], and lip seal or position at rest[51-53,56]. All studies showed at least 1 positive effect of OMT on the considered outcomes.

Four non-RCTs compared OMT (lip exercises) with no treatment for lip incompetence[18,20,50,58] and suggested improvement in lip strength, function, height, and seal. One small RCT[54] (no randomization process description, no allocation concealment, open label) also compared OMT (lip exercises) with no treatment and found increased lip height and strength in the treated group. The OMT effects on lip strength were shown to last as long as 18 months after the end of the therapy.[20] However, the increased lip strength was not associated with a habitual closed lip posture.[51]

The best evidence for the comparison "OMT vs no treatment" (for lip strength and height) was level 3 (1 small RCT[54] with important limitations and 4 non-RCTs[18,20,50,58]). The effectiveness of OMT for this comparison was considered plausible. Table 3 summarizes the evidence found on the effectiveness of OMT in treating lip incompetence and the levels of evidence. Supplementary Table S3 provides detailed information on the included studies.

Effectiveness of OMT in treating mouth breathing

Eight primary studies[24,59-65] and 2 reviews[66,67] addressed mouth breathing as the target OMD. Two studies used myofunctional devices associated with OMT: a preformed myofunctional orthodontic device[61] and an oral screen[62].

One RCT[64] (small sample, no description of the randomization process, no mention of allocation concealment) included children with asthma and rhinitis and compared a group using a nasal corticoid spray with another using the same medicine associated with OMT for mouth breathing. Considering that both groups controlled the respiratory allergy, and, therefore, any mouth breathing present would be habitual, the effects of OMT could be evaluated in an isolated way. The OMT group showed a change in the breathing mode to nasal and improved closed lip position at rest 30 days after the OMT. Another RCT[65] (no randomization process description, no allocation concealment mentioned) included a larger sample (n = 159)

of children submitted to adenoidectomy (i.e., any mouth breathing present would be habitual), compared to OMT versus no treatment. OMT improved closed lip position at rest 30 days after the intervention. However, after 12 months, there was no difference between treated and untreated groups, indicating a tendency for improvement even if the mouth breathing was left untreated. Despite the absence of statistical significance, 38% of the children in the OMT group achieved a closed lip position at rest after 12 months, compared to 25% in the untreated group.

Among the other primary studies, 2 non-RCTs[62,63] and 3 before-and-after studies[24,59,60] described changes in the type of breathing and lip seal after OMT, while 1 before-and-after study[60] showed through EMG that the muscular activity required to hold lips together decreased after OMT. A third non-RCT[61] reported a positive impact of OMT in controlling the lower facial height increase and relieving the transverse restriction of the maxillary arch in children receiving OMT associated with a preformed orthodontic appliance.

Regarding the included reviews, the first was a systematic review,[66] aiming to evaluate the effects of OMT associated with drug treatment for asthma and rhinitis, which included only 1 study,[64] already included in this scoping review. The other, an integrative review,[67] focused on the use of EMG for diagnosis and assessment of therapy effectiveness in studies including children with mouth breathing. It found only 1 study[60] addressing the use of EMG to evaluate the effectiveness of OMT, which was also already included in this scoping review. Therefore, they were not considered for defining the level of evidence.

The best evidence for the comparison "OMT with interventions for nasal breathing vs interventions for nasal breathing alone" (in the short term) was level 2 (2 RCTs[64,65]). OMT effectiveness was considered plausible. Table 3 summarizes the evidence found on the effectiveness of OMT in treating mouth breathing and the levels of evidence. Supplementary Table S4 provides detailed information on the included studies.

Effectiveness of OMT in treating non-nutritive sucking habits

Non-nutritive sucking habits were targeted by 7 studies, of which 6 were primary studies[26,68-72], and 1 was a Cochrane systematic review[73]. This was the only systematic review evaluating the effectiveness of interventions in treating any OMDs found in the Cochrane database. Since Cochrane reviews are considered the gold standard for systematic reviews, those studies already included in the review conducted by Borrie et al.[73] were not individually considered in this scoping review.

The usual approach to controlling non-nutritive sucking habits is not traditional OMT (based on orofacial awareness and motricity exercises). Instead, it involves counselling and psychological approaches such as positive and negative reinforcements and rewards.[73] In fact, all 6 primary studies[26,68-72] used reinforcement and/or rewards as the intervention for non-nutritive sucking habits. Only 1 study[68] involved psychologists in the clinical team, while in 3 studies, the therapy was delivered by orofacial myologists[26,70,72], 1 by a dentist (general practitioner)[69], and the last one[71] did not identify who delivered the psychological intervention.

The Cochrane review[73] evaluated different interventions for non-nutritive habit cessation in children. It included 6 studies, all judged to have a high risk of bias. Two of them used behavioural (psychological) intervention, and the probability of habit cessation was 6 times higher compared to no treatment in the short (<12 months) and long term (≥12 months). The other studies compared impeditive orthodontic appliances (with or without psychological intervention) with no treatment or different orthodontic appliances (palatal arch versus palatal crib). No head-to-head studies comparing psychological intervention and orthodontic appliances were included. The authors concluded, with low certainty, that orthodontic appliances (palatal arch and palatal crib) and psychological interventions (positive and negative reinforcement) might be effective at improving non-nutritive sucking habit cessation in children.

Two large single-arm retrospective cohorts[26,72] (1,164 treated patients) showed high cessation rates (87%[26] and 100%[72]) with a low occurrence of emotional issues (17%[72]) when a motivational program (based on empathetic counselling and rewards) was used.

Two studies[68,71] compared psychological interventions (positive or negative reinforcements) versus orthodontic appliances (palatal crib) or no treatment. One non-RCT[68] found no differences in habit cessation when positive or negative reinforcement or palatal crib were used, and all were better than no treatment. The authors described no mental disturbances among the children who ceased the habit and no habit relapse after 1 year. One small RCT[71] (no randomization process description, no allocation concealment, open label) presented no results on habit cessation and focussed only on orthodontic outcomes, showing no statistical differences between the overjet and open bite after positive reinforcement or palatal crib.

Two studies used OMT exercises in habit control. One retrospective cohort[70] combined tongue exercises with counselling compared to no treatment and found improved habit cessation, reduced overbite, and overjet. One RCT[69] (no randomization process description, no allocation concealment, no blinding) compared OMT exercises for the lips and cheeks delivered in group and individual sessions for the digit-sucking habit, finding a higher cessation rate with group sessions.

It is important to highlight that, since the search strategy used in this scoping review focused mainly on OMT and its synonyms, not all available evidence on this sub-question may have been retrieved.

The best evidence for the comparison "Psychological interventions vs no treatment" was level 1 (1 Cochrane review).[73] However, since the authors judged the certainty of evidence to be "low," the effectiveness of OMT for this comparison was considered only plausible. The best evidence for "Psychological interventions vs palatal crib" was level 3 (1 non-RCT,[68] no difference between groups). Level 3 evidence was also found for the comparison "Psychological interventions with OMT (tongue exercises) vs no treatment" (1 retrospective cohort[70]). So, the effectiveness of OMT for these comparisons was considered plausible. Table 3 summarizes the evidence found on the effectiveness of OMT in treating non-nutritive sucking habits and the levels of evidence. Supplementary Table S5 provides detailed information on the included studies.

Effectiveness of OMT in treating low tongue posture at rest

Only 2 studies[74,75] evaluated the effectiveness of OMT in treating tongue posture at rest. Both used removable orthodontic appliances to support the exercises. One single-arm retrospective cohort[74] used a tongue elevator associated with lip and tongue exercises. One before-and-after study[75] used a removable device with a bead that could be rolled up and forward with the tongue, stimulating a more lifted position, and swallowing exercises with the tip of the tongue on the bead. Both evaluated the results through cephalometry, showing a tongue position closer to the palatal arch at rest at the end of the intervention.[74,75] One of the studies emphasized that the exercises associated with the appliance also changed the craniofacial morphology of children with Class III in the primary dentition.[75]

The best evidence for the comparison "OMT associated with re-educative removable orthodontic appliances vs no treatment" was level 4 (1 before-and-after study[75] and 1 small single-armed retrospective cohort[74]). The effectiveness of OMT for this comparison was considered inconclusive. Table 3 summarizes the evidence found on the effectiveness of OMT in treating low tongue position at rest and the levels of evidence. Supplementary Table S6 provides detailed information on the included studies.

Effectiveness of OMT in treating multiple (simultaneous) OMDs

In the 9 studies in this category, the authors did not define a single target OMD. Instead, these studies used OMT to treat or manage multiple (simultaneous) OMDs, which may reflect a common situation in the real world since the presence of a single OMD is unusual. As an example, in mouth-breathing syndrome, apart from mouth breathing, parted hypotonic lips, low tongue position, and atypical swallowing are common findings.[76]

Among the included studies, 3 were RCT,[15,77,78] with follow-up periods from 6 months[15,77] to 12 months[78]. However, only 1 RCT[15] (small sample, no randomization process description, no allocation concealment) compared OMT with no treatment for residual OMDs associated with non-nutritive sucking habit. Its 3 reports described improvement in lips, cheeks, and tongue resistance[15], tongue position at rest and swallowing pattern[16], and nasal aeration[17]. The second RCT[77] (no randomization description, no allocation concealment, open label) showed that a simplified, shortened OMT program could be as effective as regular OMT in improving nasal breathing, tongue posture, and atypical swallowing. The third RCT[78] (no randomization process description, no allocation concealment) compared traditional OMT with a myofunctional appliance (FaceFormer®) associated with exercises, finding no differences in lip strength and better results with FaceFormer® in swallowing and breathing patterns.

Regarding the non-RCT, 1[79] tested a brief OMT intervention versus no treatment and found improved breathing type, reduced biting habits, and reduced need for regular OMT among those receiving the brief intervention. The other[80] tested a specific OMT method (Padovan Method®) compared to no treatment, showing no differences in tongue pressure, lip strength, suction power, gross and fine motor skills, and differences in swallowing pattern, tongue position, and lip and tongue activities.

One before-and-after study[81] tested an oral myofunctional device (oral plate) as an adjunct to conventional in-office OMT and described improved lip and tongue position at rest and in function. The second study[82] confirmed the effectiveness of OMT in improving the swallowing pattern, lip appearance, tongue position, tonicity and mobility, and nasal breathing.

A narrative review[83] evaluated the effectiveness of OMT in correcting masticatory and perioral muscle disorders in pediatric patients with malocclusion and OMDs but focused on orthodontic myofunctional devices with no associated exercises. Only 1 study included in that review tested a device with exercises[85], and it addressed the efficacy of OMT in treating anterior open bite. A systematic review[84] focused on the speech-language therapist's work in OMD management. Five studies were already included in this scoping review[45,60,79,82,85], and the others were not eligible. Therefore, these reviews were not used to define the level of evidence.

The best evidence for the comparison "OMT vs no treatment" was level 3 (1 small RCT[15] with important limitations). Hence, the effectiveness of OMT for this comparison was considered plausible. Table 3 summarizes the evidence found on the effectiveness of OMT in treating multiple (simultaneous) OMDs and the levels of evidence. Supplementary Table S7 provides detailed information on the included studies.

DISCUSSION

This scoping review aimed to answer the question, "What evidence exists to support the effectiveness of OMT in treating/managing orofacial myofunctional disorders (OMDs) affecting orofacial soft tissue structures' function and oral habits?" Among the evidence found, only

comparisons in which OMT effectiveness could be assessed independently were considered to evaluate the level of evidence. Of the 12 comparisons on the effectiveness of OMT in treating/managing 7 different target OMDs, 9 were considered "plausible" (Table 3). Two of them came from RCTs (with some limitations) and were considered to offer level 2 evidence: OMT with lingual frenulum surgery versus surgery alone for ankyloglossia-associated OMDs[27], and OMT with interventions for nasal breathing versus interventions for nasal breathing alone for mouth breathing, in the short term[64,65]. Yet only 1 comparison presented more than 1 RCT to fulfill the principle of results reproducibility, defined as "obtaining the same results from the conduct of an independent study whose procedures are as closely matched to the original experiment as possible"[86]. Still, their methods were not identical.[64,65]. Reproducibility of results decreases the potential for bias in the results and conclusions. Considering that, it is not unusual that, when a clinical study method is reproduced, the results are not necessarily the same.[87]

Only 1 comparison was judged as presenting level 1 evidence (psychological interventions versus no treatment for non-nutritive sucking habit[73]), but even this comparison was not considered "confirmed." This evidence came from the only Cochrane review[73] included in the scoping review. Despite Cochrane reviews being considered the benchmark of evidence synthesis, this comparison could not be considered "confirmed" because its authors judged the evidence found as having "low certainty," according to the GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) approach.[88] Through the GRADE approach, the authors of a systematic review assess essential characteristics of the gathered evidence, such as the risk of bias, inconsistency, indirectness, imprecision, and publication bias, rating the certainty in the evidence found as "high," "moderate," "low" or "very low" for each outcome.[88] In the Cochrane review,[73] the authors downgraded the certainty of evidence mainly due to the low methodological quality of the primary studies included—a phenomenon consistently observed in this scoping review.

Although the methodological quality of the included studies has not been formally appraised, the overall quality of the studies was considered low. Almost 50% of the primary studies included in this scoping review were single-armed, i.e., uncontrolled. Some before-and-after studies had a non-diseased control group for comparison. However, without an untreated group, there is no certainty that the assessed OMD/habit would not improve anyway without treatment. The lack of an untreated control group in OMT studies has been justified by the ethical dilemma of leaving a diagnosed OMD untreated.[89] However, some RCTs dealt with this issue by providing both groups with the same best available treatment—e.g., frenectomy for ankyloglossia[27], nasal corticoids for allergies[64], adenoidectomy for nasal obstruction[65], speech therapy for atypical swallowing[45]—and OMT for one of the groups.

Despite RCTs being considered the reference standard for effectiveness trials, among the 11 included RCTs, only 1 trial[27] described the randomization process used, none mentioned allocation concealment, and half did not mention a blinded outcome assessor, even when subjective outcomes were evaluated—characteristics associated with an increased risk of bias.[90] As a result, among the 6 comparisons considered as level 3 evidence, 3 came from RCTs, downgraded due to important methodological limitations.

Many studies had small samples. Considering only RCTs, the mean sample size was 36 ±42.1 participants per study, of which 18 ±19.1 received the intervention of interest (OMT alone or combined with other interventions). None presented sample size or statistical power calculations. No RCT authors mentioned using the CONSORT checklist (Consolidated Standards of Reporting Trials)[91] for reporting the study.

Finally, the follow-up of two-thirds of the included studies was short (less than 12 months), which does not contribute to refuting the understanding that, after removing predisposing factors (such as enlarged adenoids, oral habits or malocclusions), some OMDs could resolve by themselves.[76] In fact, some studies found no differences between groups when a longer follow-up was considered.[46,65]

One important limitation of this scoping review is the multitude of terms used to refer to OMDs, such as perverted swallowing habit, visceral swallowing, deviant swallowing (for atypical swallowing), and to describe OMT, such as nonspeech oral motor treatment, circumoral muscle exercises, functional physiotherapy, and logopedic instruction. As a result, it is possible that not all evidence on the topic was retrieved during the literature search since not all of these terms were considered in the search strategy.

Another limitation may be the eligibility criteria, which may have narrowed this review's scope. For instance, the researchers opted to exclude studies that included patients with more severe conditions (e.g., craniofacial syndromes, congenital malformations, head and neck cancer, dementia, cerebral palsy, obstructive sleep apnea, temporomandibular joint diseases, and dysphagia). Treating these conditions usually requires a larger multidisciplinary team in addition to the professional delivering OMT and other interventions besides OMT, a reality that extrapolates the scope of this review.

Finally, this scoping review aimed to search the available literature for evidence of OMT effectiveness and not evaluate different interventions or protocols for OMD management. New well-conducted RCTs and systematic reviews are needed to answer more specific clinical questions.

CONCLUSION

Bearing in mind that the absence of evidence is not the same as evidence of absence of an intervention's effectiveness,[92] the conduct of methodologically sound

(controlled, truly randomized, blinded) clinical trials with larger samples (based on sample size calculations) and longer follow-ups (more than 12 months) is crucial to properly answer the question, "What evidence exists to support the effectiveness of OMT in treating orofacial myofunctional disorders (OMDs) affecting orofacial soft tissue structures' function and oral habits?" convincingly. To date, the answer is, "Apparently, in some scenarios, OMT produces clinical noticeable changes. However, insufficient high-level evidence exists to confirm OMT's effectiveness."

CONFLICTS OF INTERESTS

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DISCLOSURE OF AI-GENERATED CONTENT

While preparing this manuscript, the authors used AI (Google Translate App, v8.10.58.640328148.3) to translate 2 papers written in German to English in the data extraction phase.

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