

# Trial to Compare the Effects of Myo Munchee Therapy and Oral Motor Therapy (OMT) in Pediatric Patients to Treat Maxillary Deficiency and Orofacial Myofunctional Dysfunction (OMD).

NCT07088055

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Myo Munchee (Operations) Pty Ltd
<b>Enrollment</b>	48 participants

## Key Eligibility Criteria

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### Inclusion (3)

- Aged between 36 - 60 (3-5 yrs) months old and will not turn 6 years of age before the study completion
- Diagnosed with having at least two maxillary skeletal-dental malocclusion traits as determined by the dentist
- At least one of the identified Orofacial Myofunctional Dysfunction (OMD) traits determined by the Speech-Language Pathologist (CCC-SLP)

### Exclusion (13)

- A patient must be considered healthy to be included in this study. Definition of health: the patient does not have ongoing treatment, medication or specialized assessments (more than routine follow up exams) with health care providers regarding a condition. If they have had treatment for a condition (e.g. treated by respiratory physician for acute asthma hospitalization), it must have been 12 months or more since their last appointment with a health provider related to that condition.
  - Of particular consideration:
  - Ongoing care from a sleep physician or respiratory physician Current use of Continuous Positive Airway Pressure (CPAP), nasal sprays, sleeping or behavioral medication to treat diagnosed sleep disorder or behavioral disorder Adenectomy or tonsillectomy within last 12 months
  - Any previous or current tumors or traumas in the head, neck and jaw region Patients with any known genetic or congenital conditions that impair oral motor muscle function, oral motor coordination, or speech articulation, such as but not limited to muscular dystrophy, cerebral palsy, will be excluded from the study.
  - Patients with any known syndromic conditions to affect oral motor function, including but not limited to syndromes that involve craniofacial anomalies, neuromuscular disorders, or developmental delays affecting oral motor muscle control, speech articulation, or swallowing, such as Down Syndrome, Pierre Robin sequence, or Moebius syndrome.
- ... and 8 more (see full listing online)

## Locations (2 total)

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Center for Svedhyaya Therapy Services, Chicago, Illinois, United States  
Dentistry for Children, Chicago, Illinois, United States

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<https://clinicaltrials.gov/study/NCT07088055>

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