

Efficacy of Mandibular Advancement Appliances at Different Mandibular Protrusions for Obstructive Sleep Apnoea - A Randomised Controlled Trial

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Introduction

- Mandibular advancement appliance (MAA) is recommended for mild to moderate obstructive sleep apnoea (OSA) patients and for severe OSA patients who refused or intolerant to continuous positive airway pressure (CPAP)¹.
- Treatment efficacy of MAA between 50% and above 50% of mandibular protrusions showed no significant difference. However, evidence below 50% is lacking².

Aim

- To compare the two mandibular protrusion positions of MAA constructed at 25% and 50% of maximal mandibular protrusion in their efficacy in treating OSA patients by assessing the apnoea-hypopnoea index (AHI), minimum oxygen saturation (MinSaO₂), systolic blood pressure (SBP), and diastolic blood pressure (DBP).

Materials and Methods

- Single-blinded, two-armed parallel randomised controlled trial with allocation concealment.
- Sample size was calculated using G*power 3.1.9.2 with a two-sided 5% significance level, a power of 80%, and an effect size of 1.54 on AHI parameter³.
- 24 subjects were allocated randomly in a 1:1 ratio, stratified by gender, into 25% group (MAA at 25% of maximal mandibular protrusion) or 50% group (MAA at 50% of maximal mandibular protrusion).

Inclusion Criteria

- Mild or moderate OSA
- Severe OSA who had refused or was intolerant to CPAP
- At least 18 years old
- Absence of any structural obstruction
- Sufficient set of healthy teeth to hold the MAA

Exclusion Criteria

- Presence of periodontitis
- Exaggerated gag reflex
- Presence of symptomatic temporomandibular disorder (TMD)
- Diseases that could impair the compliance of MAA
- Medication intake that can influence sleep
- Other co-existing sleep disorder
- Pregnant or plan to conceive

Randomisation

Baseline assessments

- AHI (Polysomnography)
- MinSaO₂ (Polysomnography)
- SBP and DBP (Digital sphygmomanometer)

Issue MAA & review at 1 week for acclimatisation

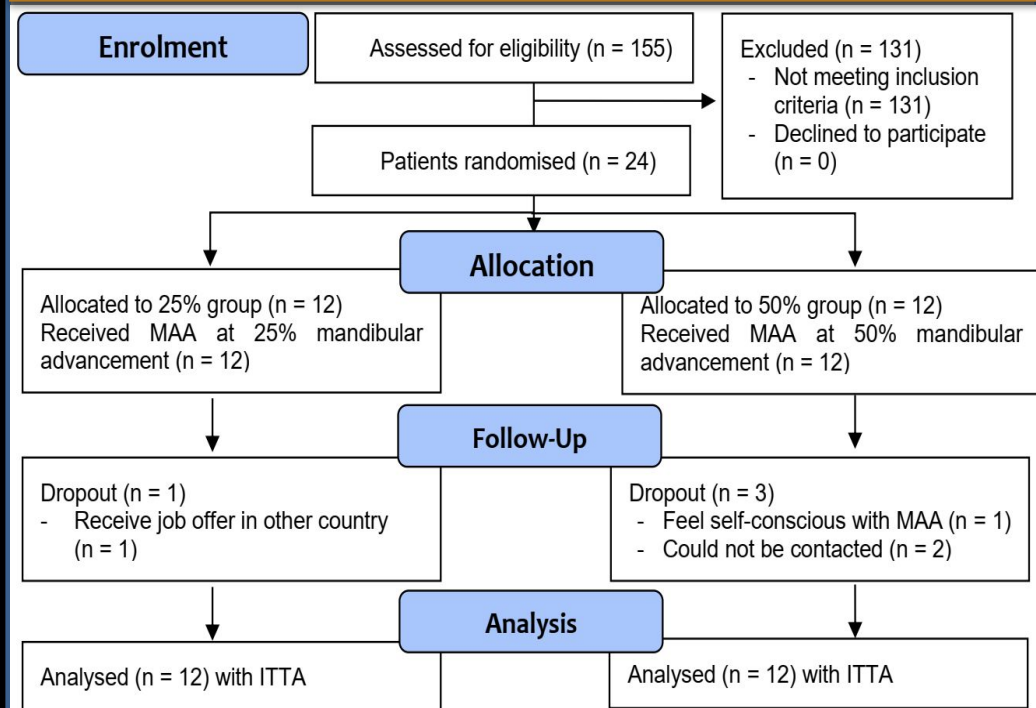
Review every 6-8 weeks

Outcome assessments after 6 months

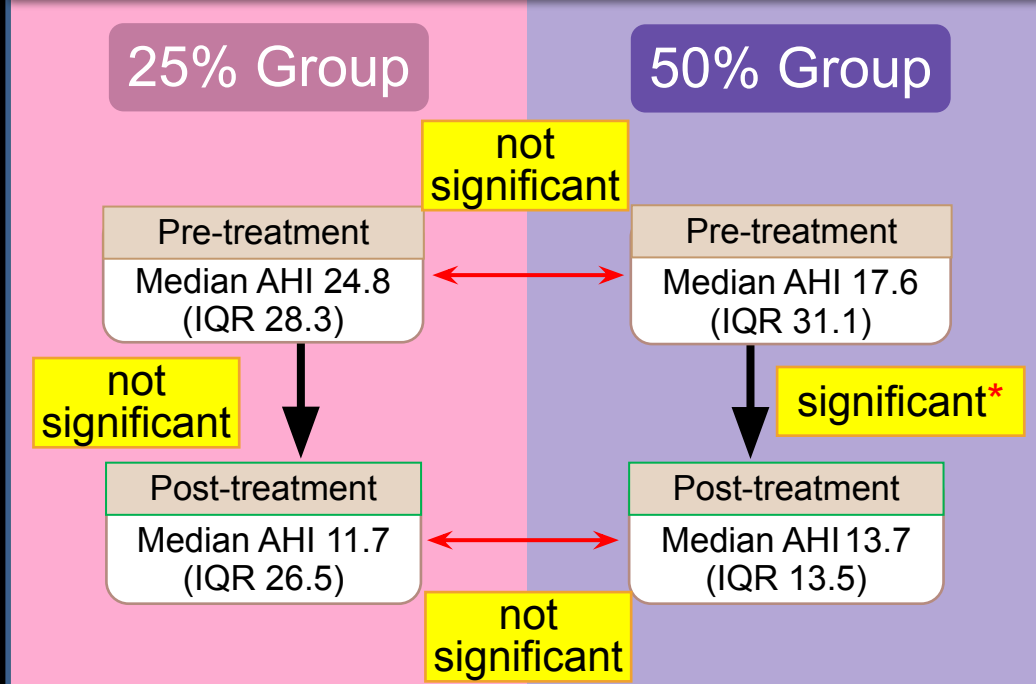
Trial completion

Results

1) CONSORT Flow Diagram



2) AHI (events/hour)



3) MinSaO₂

No significant changes in MinSaO₂ in both groups

4) SBP and DBP

No significant difference in SBP and DBP in both groups.

Conclusions

- MAA at 50% of maximal mandibular protrusion improved AHI for OSA patients better than MAA at 25% of maximal mandibular protrusion.
- MAA at 25% and 50% advancements do not cause significant changes in MinSaO₂ and blood pressure.
- Hence, MAA treatment with a therapeutic position of 50% mandibular advancement is recommended.

References

- Ramar, K., Dort, L. C., Katz, S. G., Lettieri, C. J., Harrod, C. G., Thomas, S. M., & Chervin, R. D. (2015). Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with Oral Appliance Therapy: An Update for 2015. *J Clin Sleep Med*, 11(7), 773-827. doi:10.5664/jcsm.4858
- Bartolucci, M. L., Bortolotti, F., Raffaelli, E., D'Antò, V., Michelotti, A., & Alessandri Bonetti, G. (2016). The effectiveness of different mandibular advancement amounts in OSA patients: a systematic review and meta-regression analysis. *Sleep Breath*, 20(3), 911-919. doi:10.1007/s11325-015-1307-7
- Aarab, G., Lobbezoo, F., Hamburger, H. L., & Naeije, M. (2010). Effects of an oral appliance with different mandibular protrusion positions at a constant vertical dimension on obstructive sleep apnea. *Clin Oral Investig*, 14(3), 339-345. doi:10.1007/s00784-009-0298-9

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