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The Effect of Oral Appliance Therapy on Cardiometabolic Outcomes in Patients with Type 2 Diabetes and Obstructive Sleep Apnea: A Multi-Centered Randomized Controlled Trial

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Abstract:

This research project is a multicenter, parallel-group, randomized controlled study recruiting patients with Type 2 Diabetes Mellitus (T2DM) from the endocrinology clinics of McGill University Health Center and the University of British Columbia.

Obstructive sleep apnea is a disorder that is highly prevalent (60-80%) among patients with type 2 diabetes mellitus (T2DM) and literature supports a strong link between OSA and glucose dysregulation. However, current randomized trials assessing for metabolic outcomes in T2DM have been limited to continuous positive airway pressure (CPAP) treatment and these results have been inconsistent. A major drawback to CPAP therapy is the overall low objective adherence (~50%), leaving several patients only partially or completely untreated. Thus, the effect of alternative treatment options for OSA in patients with T2DM warrants further investigation. A mandibular advancement device (MAD) is an alternative treatment option for OSA that is generally better tolerated and accepted by patients than CPAP. However, to date, no randomized trials have assessed whether MAD can improve health outcomes in patients with T2DM.

In this study, the overall hypothesis is that 3 months of treatment with a MAD (Somnodent) will improve glycemic control and metabolic parameters in patients with OSA and T2DM as compared to a control device (mandibular Essix appliance). Moreover, identifying phenotypes of OSA that preferentially demonstrate improvements in metabolic parameters in response to OAT will be useful in the clinical selection of patients that would most benefit from therapy in the future. The study will also compare subjective and objective compliance rates of both devices.