Proof of Concept Study of an Oral Orthotic
in Reducing Tic Severity in Tourette Syndrome

The purpose of the proposed study is to assess the utility of an oral orthotic device for reducing tic severity in children. The device, known in dentistry as an “occlusal splint,” is a removable mouth-piece typically used for the orthodontic treatment of Temporomandibular Joint Dysfunction.

This randomized, double-blind, placebo controlled trial will enroll participants ages 7-17 years with Tourette syndrome (TS) or Chronic Tic Disorder (CTD). Twenty-four participants will be enrolled; twelve participants will receive an oral orthotic adjusted to the appropriate therapeutic height, and twelve participants will receive an identical placebo device that is not adjusted to the appropriate therapeutic height.

When treating temporomandibular joint dysfunction (TMD) in dental patients, improvement in tic severity was observed in those patients with co-occurring TMD and tic disorders. This phenomenon has been reported in the medical literature, and the novel treatment is now being used to treat children and adults with tic disorders (with and without TMD). Though there is an abundance of anecdotal evidence to support the use of the device for TS, no clinical trial has collected any data on the safety and efficacy of this device in a controlled research setting.

The study will take place over the course of 2 weeks, with a 10 week follow-up period. After being screened for eligibility, participants will be measured for an oral orthotic. The purpose of the measurement assessment is to determine the orthotic height that is most effective at reducing tics in a given participant. As each child is different, different orthotic heights will be more or less effective in different children.

Subjects will then be randomly assigned to either an active orthotic or a placebo orthotic. The active orthotic will be constructed at the appropriate height for a given child, while the placebo orthotic will be constructed at a lesser height than is optimal for that child. Participants that have a positive response to treatment will be followed for 10 additional weeks (12 weeks total) to assess the

durability, safety and acceptability of the device. Non-responders to the placebo device will be provided the appropriate active treatment at the end of the 2 week trial period, and will similarly be followed for treatment efficacy, durability and acceptability.

This pilot trial will establish the feasibility of the multi-disciplinary collaborative procedures needed for a large-scale trial of the orthotic device, and will collect preliminary data on its safety, acceptability and usefulness in children and adolescents with tic disorders. Should this study demonstrate feasibility of study procedures, the study team will pursue extramural funding to conduct a definitive randomized controlled clinical trial.

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