

Proof of Concept Study of an Oral Orthotic in Reducing Tic Severity in Youth with Chronic Tic Disorder and Tourette Syndrome

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INTRODUCTION AND OBJECTIVES

Use of an oral orthotic device, called an occlusal splint is an emerging and novel treatment modality for reducing tic severity in children, adolescents, and adults. Anecdotal and observational clinical evidence supports the use of this device,^{1, 2, 3}, however, this is the first double blind, placebo-controlled, clinical trial to evaluate data on the safety and efficacy of the oral orthotic. Thus the primary aim of this study is to evaluate feasibility of a 2-week RCT of an active vs sham oral orthotic to reduce tic severity, and assess durability of effect over an additional 4-6 weeks. Secondary aims of this study include assessing the safety, tolerability, and initial efficacy of this device in reducing tic symptoms severity.

METHODS

Study Design.

The study is a double-blind, placebo controlled, randomized trial.

Study Sample.

The study sample includes 24 youth ages 7-25 with Tourette Syndrome (TS) or Chronic Tic Disorder (CTD). Participants must have at least moderate tic symptom severity ((YGTSS >14 for CTD or YGTSS > 22 for TS). TS or CTD must be the primary diagnosis for study inclusion, however comorbidities are not excluded unless not-indicated for study participation. Medication must be stable prior to study entry. Participants must obtain clearance from their primary dentist prior to study inclusion, and must not have braces or other orthodontics.

Study Measures.

The primary outcome measures for the study include the Yale Global Tic Severity Scale (YGTSS), the Clinical Global Impressions, Severity and Improvement Scales (CGI-S/I), and indicators of study feasibility & acceptability indicators, including intervention safety, subject recruitment & retention, reported adverse events, treatment adherence, and treatment satisfaction. A Vertical Height Assessment (modified Goetz procedure) is used to determine the vertical height observed to be most associated with tic relief for selection of active and sham tx conditions

RESULTS AND DISCUSSION

Study Feasibility Data.

Roughly 30 have been screened to date for study participation. Seven participants have been consented and enrolled in the study, and two additional participants scheduled for study consent and assessment for enrollment. One participant did not meet criteria due to insufficient tics during jaw assessment, and one participant did not return after the initial screening visit. Three participants have fully completed open trial study visits. Two participants are currently enrolled in the placebo-controlled trial.

Open Trial Data.

The three participants who completed open trial study participation reported high treatment satisfaction scores (mean satisfaction score = 26/28), and an average treatment adherence of wearing the orthotic about 50% of the time. The reported adverse events when wearing the orthotic were mild to moderate and included sore mouth, excess salivation, speech impediment, difficulty sleeping, and minor social discomfort.

Symptom Change Data

These participants all reported a decrease in tic symptoms on the YGTSS during the study period (see figure 1), following a stable baseline period. Two of the participants reached Very Much Improved status on the CGI-I by the

end of the study period, however none of the participants reached very much improved status following the initial two week acute intervention (see figure 2).

CONCLUSIONS

Thus far the oral orthotic appears to be a feasible, acceptable, & not harmful intervention, however data from the randomized, controlled portion of the study is necessary to determine true clinical effect.

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DISCLOSURES

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