

Study Protocol

Study Title: Modifying unconscious tongue movements to improve fluency in adults with a confirmed developmental stammer: a pilot randomized feasibility study

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NCT number [not yet assigned].

Identifiers: [NCT ID not yet assigned]

Intervention:

Participants will attend the Institute of Technology Sligo Health Science & Exercise Physiology Lab (B2004) or be assessed remotely three times for stammering severity: before intervention, after five-week trial period and three months post completion. Participants stammering severity will be assessed twice at each assessment period.

Participants will be required to practice quick eye movements at the start of words / syllables for 10 minutes twice a day for the trial period. Instruction in eye movement (saccade) modification will occur following the initial assessment in IT Sligo. Participants will be required to read outload from suitable texts while completing these exercises.

The new experimental treatment condition will be compared to a placebo control. Two arms will be instructed in the experimental treatment (control eye movement modification) and two arms in a placebo. In each condition, half will carry out an additional assessment in premonitory awareness of stammering before and after the trial period. Participants will video/voice message the principle investigator once per week during intervention period to confirm compliance.

Main outcome measures:

Primary Outcome Measurements: Stammering Severity (SSI-4)

Howell, P., Soukup-Ascencao, T., Davis, S., & Rusbridge, S. (2011). Comparison of alternative methods for obtaining severity scores of the speech of people who stutter. *Clinical linguistics & phonetics*, 25(5), 368–378. doi:10.3109/02699206.2010.538955

Secondary Outcomes:

Stammering Experience OASES-A; Yaruss, J. and Quesal, R. (2006). Overall Assessment of the Speaker's Experience of Stuttering (OASES): Documenting multiple outcomes in stuttering treatment. *Journal of Fluency Disorders*, 31(2), pp.90-115.

Premonitory awareness of stammering (PAiS) : Cholin, J., Heiler, S., Whillier, A. and Sommer, M. (2016). Premonitory Awareness in Stuttering Scale (PAiS). *Journal of Fluency Disorders*, 49, pp.40-50.

Objectives of Study:

1. Evaluate the effect modifying saccade origin (eye movements) has on stammering experience.
2. Explore how this new therapy compares to a placebo.
3. Examine effect premonitory awareness has on intervention and placebo.
4. Identify any adverse effects.

