

STW-5 as a Treatment for Functional Gastrointestinal Disorder Symptoms in Children with Autism Spectrum Disorder: A Pilot Study Research Design

Heather Walker, M.S. Candidate, Therapeutic Herbalism, Clinical Concentration
Maryland University of Integrative Health

Background

Autism Spectrum Disorder (ASD) is a developmental disorder that impairs communication and daily functions.⁵ An area of growing concern is the association between ASD and Functional Gastrointestinal Disorders (FGID) which might be correlated with gastrointestinal abnormalities seen in children with ASD.^{4, 8, 11} FGID symptoms have been known to effect quality of life and may also have an adverse effect on ASD behavior severity.^{1, 2, 4, 6} FGID has a complex symptom profile with overlapping components and multiple symptoms, making treatment options difficult, especially for children with communication disorders.

STW-5 is a 9-herb supplement demonstrating properties which work synergistically to target multiple FGID symptoms.^{3, 9} It has a good safety profile with no serious adverse side effects and a favorable tolerability making the herbal treatment a viable option for children with ASD and FGID.^{10, 12, 13}

Key Points

- Research suggests the possibility of a 3 times higher likelihood of FGID symptoms in children with ASD.^{1, 2, 4}
- FGID symptom severity appears to correlate with ASD severity.^{1, 4}
- ✿ STW-5 is a natural herb with a favorable tolerability and multi-target phytochemical characteristics.^{3, 9, 10}

Research Objectives

This pilot study's objective is to investigate the efficacy, tolerability, and safety of STW-5 as a treatment for FGID symptoms in children with ASD.

STW-5 Ingredients

Extracts⁸

- ✿ Greater Celandine
- ✿ Angelica Root
- ✿ Candytuft
- ✿ Lemon Balm Leaves
- ✿ Peppermint Leaves
- ✿ Caraway Fruit
- ✿ Licorice Root
- ✿ Chamomile Flower
- ✿ Milk Thistle Fruit



Figure 1.

Methods

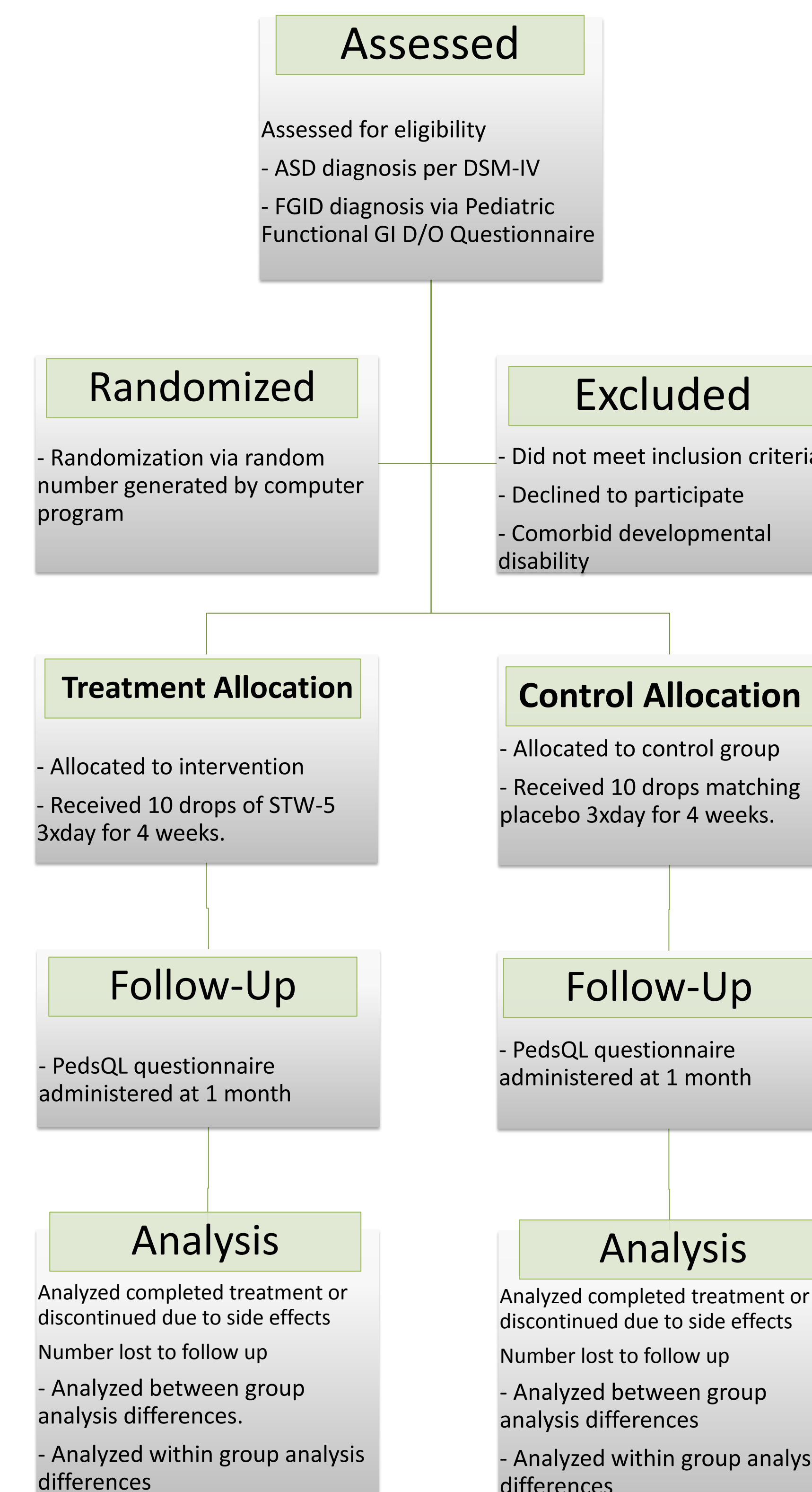
This randomized, double-blind, placebo-controlled 4-week pilot study will enroll approximately 40 participants age 6-12 with ASD and FGID.

Eligibility will be determined using the DSM- IV for ASD and the Rome III Diagnostic Questionnaire for the Pediatric Functional GI Disorders for FGID. Exclusion criteria includes: comorbid developmental disorders, absence of either disorder, and/or known allergens to ingredients.

Participants will be randomly assigned to receive 10 drops of STW-5 three times a day or a matching placebo.¹⁵

The PedsQL Gastrointestinal Symptoms Module parent-proxy report will be administered at baseline, week 2, week 4, and at a 1-month follow up.⁷

The primary outcome is between-group differences in PedsQL scores for FGID symptoms at week 4. Secondary outcome is within-group overall difference in scores.



Discussion

Studies have shown a higher prevalence of FGID symptoms in children with ASD than their typically developed peers.^{2, 4} Symptom severity appear to correlate with ASD severity.^{1, 4} This suggests FGID may have an influence on quality of life and behavior in children with ASD. Previous treatment options, such as gluten-free and/or casein-free diets, have not provided clinically significant relief in FGID symptoms in for children with ASD.¹⁴ STW-5 has the potential to alleviate multiple symptoms of FGID without serious adverse side effects, leading to a higher quality of life.

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Figure 1
STW-5 Ingredients. Iberogast. Retrieved from <http://www.iberogast.com.au/static/images/iberogast-bottle-n.png>.

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