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

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Background

Autism Spectrum Disorder (ASD) is a developmental disorder that impairs communication and daily functions.1, 2, 4, 6 It has a higher prevalence in children with ASD.7, 8, 11 FGID has a complex symptom profile with overlapping components and multiple symptoms, making treatment a viable option for children with ASD and FGID.8, 10, 11

Key Points

- Research suggests the possibility of a 3 times higher prevalence of FGID symptoms in children with ASD.1, 2, 4
- FGID symptom severity appears to correlate with ASD severity.1, 2
- 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.

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 allergies 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.

Methods

STW-5 Ingredients

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

Treatment Allocation

- Allocated to intervention
- Received 10 drops of STW-5 daily for 4 weeks.

Control Allocation

- Allocated to control group
- Received 10 drops matching placebo daily for 4 weeks.

Assessed

- FGID diagnosis via Pediatric Functional GI Disorders Questionnaire

Randomized

Randomization via random number generator by computer program

Follow-Up

- PedsQL questionnaire administered at 1 month

Excluded

- Did not meet inclusion criteria
- Declined to participate
- Comorbid developmental disability

Controlled Variables

- Analysis
- Assessed for eligibility
- Data collected and analyzed
- All participants completed treatment or follow-up

Analysis

- Analyses completed treatment or discontinued due to side effects
- Number lost to follow-up
- Analyses between group analysis differences

Discussion

Studies have shown a higher prevalence of FGID symptoms in children with ASD than their typically developed peers.1, 4 Symptom severity appears 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 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.

Acknowledgements

I want to give a very special thank you to the MUIH mentors who helped me with the editing process of this research design.

References