Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2023/004**

Scientific title of trial: Acute effects of L-theanine and caffeine combination on selective attention in adolescents with attention deficit hyperactivity disorder

Date of commencement (enrolment of first participant): 14/10/2023

Progression: 6 months ☐ 1 year ☐ 2 years ■ 3 years ☐

At completion ☐

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: No

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status~~: pending~~/ recruiting/ ~~recruitment complete: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended / recruitment terminated~~

Number assessed for eligibility: 15

Number recruited and allocated/randomized: 14

Number allocated/randomized to each intervention/arm (please edit as relevant):

This is a placebo-controlled, counterbalanced, repeated measure crossover study. Therefore, the 14 participants were given each treatment three days apart. The treatment order is counterbalanced in a Latin Square design.

Losses/exclusions after allocation/randomization (please edit as relevant): None

3. Trial output

Date of trial completion ("last patient, last visit"):

Final sample size:

Trial is not completed

Summary of Interim (if available):

The results demonstrated no significant differences in hits and discrimination sensitivity (P>0.05). A trend toward reduced false alarms was observed with L-theanine caffeine combination (P=0.057) and methylphenidate (P=0.064) compared to placebo. Methylphenidate, but not L-theanine caffeine combination, significantly improved hit reaction time compared to placebo (△=39.17ms, P=0.035). The improvement of P3b event related potential amplitude by L-theanine caffeine combination was significantly greater than that of placebo in CP1 (△=2.75μV), P3 (△=3.01μV), and P4 (△=2.35μV) sites (P<0.05), with trend towards amplitude improvement at CP2 (△=2.42μV; P=0.06), and CZ (△=2.41μV; P=0.06). Compared to placebo, L-theanine caffeine combination exhibited a significant improvement of latency at CZ (△=30.78ms; P=0.047) with a trend towards improvement at CP2 (△=31.53ms; P=0.079).

Abstract presentations of results at scientific meetings
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	**Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).**
Effects of L theanine-caffeine combination on selective attention among adolescents with attention deficit hyperactive disorder: A proof of concept, double-blind, placebo-controlled, Crossover study	Nawarathna NGS, Ariyasinghe DI, Balasooriya NS, Dassanayake TL. Effects of L theanine-caffeine combination on selective attention among adolescents with attention deficit hyperactive disorder: A proof of concept, double-blind, placebo-controlled, Crossover study. Proceedings of the 15th SAARC International Psychiatry Conference and 21st Annual Academic Sessions of the Sri Lankan College of Psychiatrists. July 2024. (**Won the second place in the Oral presentation category**)

Publications
None
Note: please include a URL link or scanned copy of the publication

Title of paper	**Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)**

Dr. N.G.S Nawarathna
Name and signature of Responsible Registrant/
Principal Investigator

Date: 22/06/2025