Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2023/006**

Scientific title of trial: Acute effects of a single dose of L-theanine and caffeine combination on selective attention in acutely sleep-deprived healthy adults

Date of commencement (enrolment of first participant): 05/04/2023

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: 43

Number recruited and allocated/randomized: 40

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

This is a placebo-controlled, counterbalanced, repeated measure crossover study. Therefore, all 40 participants were given one treatment, and after a washout period, the other. The treatment order is counterbalanced in a Latin Square design.

Losses/exclusions after allocation/randomization (please edit as relevant): 3 exclusions

One participant was excluded as the participant did not adhere to the test preparation protocol.

The second participant was excluded since the participant blinked too often during the test sessions and the electroencephalography (EEG) data were contaminated with too much eye-blink artefacts.

The third participant was excluded due to contamination of the averaged EEG with excessive drift artefacts

3. Trial output

Date of trial completion ("last patient, last visit"): 25/10/2023

Final sample size: 37

Summary of Interim/Final data (if available):

Compared to the placebo, the L-theanine-caffeine combination significantly improved the hit rate (P = 0.013) and A' (P = 0.031). Neither treatment significantly changed the false alarm rate (P > 0.05). Reaction time for accident scenes was significantly improved by both the L-theanine-caffeine combination (△ = 51.5ms, P = 0.001) and the placebo (△ =13.69ms, P = 0.023). The treatment x time interaction was also significant ($F_{1,37}$ = 10.28, p = 0.003), and the pre-post-dose reaction time improvement of the L-theanine-caffeine combination was significantly greater than that of placebo (△ = 37.9ms, P= 0.003). Compared to the placebo, the L-theanine-caffeine combination significantly improved the P3b ERP amplitudes in CZ (△ = 1.921μV, P = 0.006), CP1 (△ = 1.491μV, P = 0.01), CP2 (△ = 1.491μV, P = 0.033) and P3 (△ = 1.523μV, P = 0.007); and significantly reduced P3b latencies in CZ (△ = 29.16ms, P < 0.001), CP1 (△ = 28.74ms, P < 0.001), CP2 (△ = 27.58ms, P = 0.002), P3 (△ = 28.29ms, P = 0.003), P4 (△ = 34.78ms, P = 0.001), and PZ (△ = 30.22ms, P = 0.002).

Abstract presentations of results at scientific meetings: Yes
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).**
The effects of L-theanine-caffeine combination on selective attention in sleep-deprived young adults: a double-blind, placebo-controlled crossover study	Nawarathna, N.G.S., Ariyasinghe, D.I., & Dassanayake, T.L. (2024). "46th Annual Academic Sessions 2024," presented at the Kandy Society of Medicine, Hotel Grand Kandyan, February 9, p. 30. **(received Best Oral Research Presentation Award)**
High-dose L-theanine-caffeine combination improves behavioral and neurophysiological measures of selective attention in acutely sleep-deprived young adults: a double-blind, placebo-controlled crossover trial.	Nawarathna NGS, Ariyasinghe DI, Dassanayake TL. High-dose L-theanine-caffeine combination improves behavioral and neurophysiological measures of selective attention in acutely sleep-deprived young adults: a double-blind, placebo-controlled crossover trial. 33rd International Congress of Clinical Neurophysiology (ICCN), at Jakarta, Indonesia, September 2024.
The effects of L-theanine-caffeine combination on behavioral and neurophysiological measures of selective attention in acutely sleep-deprived young adults: A double-blind, placebo-controlled	N.G.S.Nawarathna, D. I. Ariyasinghe, and T. L. Dassanayake, "The effects of L-theanine-caffeine combination on behavioral and neurophysiological measures of selective attention in acutely sleep-deprived young adults: A double-blind, placebo-controlled crossover study," in 37th Annual Scientific Sessions of Physiological Society of Sri Lanka, Nov. 2024 **(received Best Oral**

crossover study	**Research Presentation Award)**

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)**

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Name and signature of Responsible Registrant/
Principal Investigator

Date: 05/06/2025