

Summer Conference 2023, 3–6 July 2023, Nutrition at key stages of the lifecycle

## Improved sleep outcomes and next-day cognitive function in adults following clinical testing of a powder-based drink containing Mulberry leaf extract and a natural source of Tryptophan

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Sleep requirements change across the lifespan and quality of sleep declines as we age<sup>(1)</sup>. Poor sleep across adulthood has been associated with ramifications on subjective health, quality of life<sup>(2)</sup> and advancement of cognitive decline and dementia<sup>(3)</sup>. Among the modifiable factors that are posited to contribute to sleep quality, diet and nocturnal metabolism are thought to be strong predictors of sleep quality<sup>(4)</sup>.

The aim of the current study was to evaluate the effectiveness of nutritional formulation (delivered in a powdered-based drink) containing 0.75 g Mulberry Leaf Extract (0.75g) and a natural source of Tryptophan (120mg) consumed concurrently with an evening-meal (Glycemic load of  $55 \pm 10\%$ ) to promote better sleep and next-day mood and cognitive performance in healthy adult poor sleepers.

The clinical trial was a double-blind, controlled, randomized, 2-arm, sequential groups cross-over design (ClinicalTrials.gov Identifier: NCT05372900). Adult (aged 25–50), self-identified poor sleepers (confirmed by Pittsburg Sleep Quality Index  $>5$  and  $<85\%$  mean sleep efficiency over 14-days at screening) received standardized meals and concurrent daily intake of the nutritional formulation or placebo approximately 4 hours before bedtime. Intervention phases lasted 14-days with a 28- to 42-day washout period in-between. Primary outcomes were Sleep Efficiency (SE) and Sleep Onset Latency (SOL) measured by actigraphy. Secondary outcomes included inter alia: mood (Brief Mood Introspection Scale), sleep quality (Karolinska Sleepiness Scale) and objective cognitive performance measures (Psychomotor Vigilance Task, 2-back task, NASA Task Load Index) taken at breakfast, lunch and dinner time (1–1.5- hours, 6- and 12-hours post-wake respectively).

Linear mixed model analysis was conducted with intention-to-treat, adjusting for baseline and treatment order for sleep, mood, and cognitive outcomes. Consumption of the active treatment resulted a significant improvement in SOL (actigraphy = -3.48 mins,  $p = .026$ ; self-report = -16.7mins,  $p = .031$ ) compared to control. There was no significant effect on SE ( $p = .230$ ). Sleep and mood self-report measures showed that participants felt significantly less sleepy ( $p = .041$ ) and more aroused ( $p = .026$ ) the next morning. Interestingly, cognitive performance was improved on several tests throughout the next day at breakfast, lunch and dinner assessment points: For psychomotor vigilance, reaction time ( $p = .598$ ,  $p = .051$ ,  $p = .024$  respectively) and number of lapses, where lapses are characterized as those made within 698 ms (2x median reaction time for the cohort) showed significant improvement ( $p = .027$ ,  $p = .005$ ,  $p = .004$  respectively). Participants also reported actively feeling these performance improvements (performance dimension of NASA TLX) following treatment compared to control conditions ( $p = .014$ ,  $p = .063$ ,  $p = .010$ , respectively). Our findings demonstrate that sleep onset, quality and next day cognitive performance can be ameliorated by a daily dinner time supplemental nutritional intervention and may represent a convenient strategy to support the betterment of sleep and mood and cognitive benefits in adult populations.

### References

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