



A Stress Reduction Supplement Improves Acute PROMIS® Depression and Stress Scores in a Clinical Study

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Objective

- To evaluate the effects of a proprietary branded L-theanine ingredient on perceived stress and overall mental health outcomes in a healthy adult population

Background

- Stress reduction, sleep quality, and mental health are closely interlinked
- Recently, there has been an increased demand for supplements which may help reduce stress to improve overall mental well-being
- L-theanine is a widely researched dietary ingredient that promotes alpha brain wave activity, with numerous studies underscoring its benefits for managing sleep, stress, and anxiety

Methods

- 600 healthy adults (61% females, aged 21-79, lived throughout the United States) were virtually enrolled based upon a perceived interest to improve stress levels
- Two Groups:** 100mg L-theanine, produced by enzymatic fermentation using a process that mimic biosynthesis in the tea plant, and placebo, each taken daily with breakfast
- Validated instruments were used to assess outcomes including:
 - PROMIS® Depression 4A:** 4-item measure assessing feelings of depression in the past 7 days
 - NIH Toolbox® Perceived Stress Survey:** 10-item measure assessing perceived stress in the past 7 days
- Analysis:** Performed on Intent to Treat (ITT) participants who completed baseline assessments and at least one study week.

Improvements in PROMIS® 4A Depression

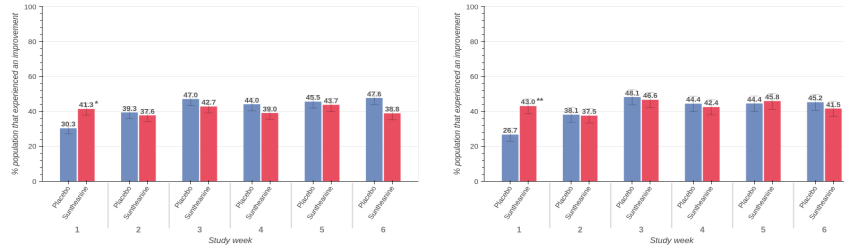


Figure 1: Minimal clinically important difference (MCID) analysis performed on ITT population (left) and age 40+ participants (right). Significant improvements in depression symptoms were observed within the first week, with results being more pronounced in individuals aged 40+ (11.0% vs 16.3% more participants in the active group experienced improvements in assessment scores) * Error bars S.E.M. p < 0.05, ** p < 0.01.

Table 1: PROMIS® Depression and NIH Stress results for participants

Questionnaire	PROMIS Depression 4A						NIH Perceived Stress
	General	Women	Age: 40+	Prolonged Stress*	Prolonged sleep disturbance*	Moderate to Severe Depression**	Age: 40+
Population Subset							
Total # of ITT participants	426	258	270	391	259	229	270
Active participants	208	126	135	193	125	106	135
Placebo participants	218	132	135	198	134	123	135
MCID improvement p value	0.0161	0.0362	0.0058	0.0437	0.0063	0.0230	0.02514
MCID risk ratio (+/- 95% C.I.)	1.372± 0.131	1.394± 0.159	1.621± 0.175	1.315± 0.136	1.627± 0.178	1.412± 0.152	1.321± 0.124
Difference in overall MCID (active - placebo)	11.07%	12.66%	16.30%	9.62%	16.28%	14.36%	13.33%

*based on baseline screener
**determined from baseline responses to PROMIS Depression 4A

Improvements in NIH Toolbox® Perceived Stress Assessment

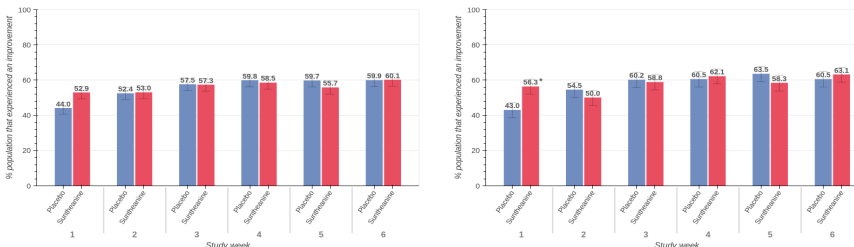


Figure 2: Minimal clinically important difference (MCID) analysis performed on ITT population (left) and age 40+ participants (right). Significant improvements in perceived stress levels observed within the first week, with results being more pronounced in individuals aged 40+ (8.9% vs 13.3% more participants in the active group experienced improvements in assessment scores) Error bars S.E.M. * p < 0.05.

Discussion

- Significant improvements in perceived stress scores were observed as early as week 1 in the L-theanine group compared to the placebo among participants aged 40 and above
- PROMIS® Depression 4A showed statistical improvements at week 1 in the overall populations (11.07% difference in overall MCID)
 - More pronounced effects in subgroups with varying differences in MCID:**
 - females (12.66%)
 - individuals aged 40+ (16.30%)
 - prolonged stress (9.62%)
 - people experiencing a prolonged sleep disturbance (16.28%)
 - people with moderate to severe depression (14.36%)
- Suggests acute benefits from L-theanine supplementation on mood and stress regulations

Conclusions

- L-theanine produced by enzymatic fermentation demonstrates a rapid, clinically meaningful reduction in perceived stress and depressive symptoms
- These findings highlight its potential as a fast-acting, natural solution for acute stress support
- L-theanine has more pronounced effects in more susceptible populations- offering targeted support for individuals who experience disruptions in sleep, stress, or mood
- L-theanine may be valuable in situations requiring short term stress relief

Acknowledgments

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