



hey freya

A Single Group Clinical Study to Assess the Effects of a Women's Daily Stress Support Supplement

Clinical Trial

Author: Citruslabs Research Team

Sponsor: Hey Freya.

Citruslabs, 1639 11th Street, Santa Monica, USA

Created 17 May 2024

Abstract

This single-group clinical study assessed the effects of the Hey Freya Thrive: Women's Daily + Stress Support supplement on various parameters associated with mental health and cognition over eight weeks. The study enrolled 38 females aged 25-50 who self-reported experiencing problems sleeping, reduced energy levels, and fatigue in the 4 weeks prior to the start of the study. Participants took 2 capsules of the test product each morning, with food and completed questionnaires at Baseline, Week 4, and Week 8. The Oxford Happiness (short form), GAD7, and PSS questionnaires determined the product's effect on mental health parameters: happiness, anxiety, and perceived stress, respectively. Progressive and statistically significant improvements were observed in the three questionnaires at all time points, with the greatest improvement seen in the GAD7 (anxiety) questionnaire. Similar statistical improvements were also observed in cognitive parameters (via questionnaires), with the highest improvements observed in feeling troubled about fatigue and low energy. Participants reported high satisfaction and willingness to continue using the product and to recommend it to family and friends. Despite the short duration of the trial, the findings strongly indicate that the product can improve a wide range of mental health and cognitive parameters in people previously experiencing difficulties in these areas.

1. Introduction

Stress has become increasingly prevalent in modern society, leading to various physical and psychological effects. Chronic stress contributes to fatigue, hormonal imbalances, cognitive impairment, reduced libido, and other adverse health outcomes¹. In response to this challenge, natural and nutritional approaches have gained interest in mitigating stress-related symptoms and improving overall well-being. The Hey Freya Thrive: Women's Daily + Stress Support is a supplement product that contains a blend

of ingredients hypothesized to ease exhaustion from stress, support hormone balance, increase mental clarity, lift energy, regulate stress response, and spark libido.

Vitamins and minerals, such as Vitamin A, D, E, K2, Folate (5-MTHF), Vitamin B12 (methylcobalamin), Biotin, Magnesium bisglycinate, Iodine, Iron bisglycinate, Selenium, Zinc, and Copper, are fundamental to overall health, including immune function, hormone regulation, and neurological health^{2,3}. For instance, Vitamin D has been associated



with mood regulation, while Vitamin K2 plays a role in hormonal balance. B-vitamins, like Folate and Vitamin B12, are crucial for cognitive function and mood regulation^{2,4}. Magnesium is known to support stress management, hormonal balance, and cognitive function⁵. Minerals such as Iodine, Iron, Selenium, Zinc, and Copper play various roles in hormone synthesis and regulation, as well as the functioning of the immune system^{6,7}.

The product also includes herbal ingredients like Green Tea Leaf, Ashwagandha Root, Rhodiola Root, Eleuthero Root, Lavender Flower, and Phosphatidylserine (PS). Green tea is rich in antioxidants, which have been linked to mood improvement and increased energy levels⁸. Adaptogenic herbs like Ashwagandha, Rhodiola, and Eleuthero have a history of use for reducing stress, enhancing cognitive function, and regulating hormones^{9,10}. In addition, Lavender is associated with relaxation and may contribute to stress reduction and improved sleep quality¹¹.

The existing literature provides a foundation for the potential efficacy of the product in addressing the symptoms of stress, exhaustion, hormonal imbalances, cognitive function, energy levels, stress response regulation, and libido enhancement. This clinical trial aims to build upon this knowledge by evaluating the product's effectiveness and safety through scientific investigation.

2. Methods

2.1. Participants

A total of 38 female-at-birth participants, aged 25-50, were recruited for this study. Statistical analysis was performed on all available data on an intention-to-treat (ITT) basis. All participants satisfied the following inclusion and exclusion criteria.

Inclusion Criteria:

- Assigned female at birth
- 25-50 years of age.
- Self-reporting as experiencing reduced energy levels and fatigue in the past 4 weeks.
- In the past 4 weeks, has experienced self-reported issues with three or more of the following:
 - Stress
 - Memory
 - Concentration
 - Focus
 - Anxiety
 - Food cravings
 - Low libido
 - Alertness
 - Fatigue
 - Brain fog
- Willing to maintain the current regimen of vitamins, minerals, and herbal supplements during the duration of the study.
- Willing to refrain from taking any new vitamins, minerals, or herbal supplements relating to stress or cognitive function during the study period.
- Willing to comply with the protocol and complete all questionnaires for the 8-week study period.

Exclusion Criteria:

- Anyone taking a daily multivitamin or other supplement with one or more of the ingredients in the product.
- Anyone taking blood thinners (anticoagulant) medications.
- Anyone pregnant, breastfeeding, or trying to conceive over the next 3 months.

hey freya



Anyone currently enrolled or will be enrolled in another clinical study over the next 8 weeks.

- Anyone with chronic health conditions, including oncological or psychiatric disorders.
- Anyone with a history of substance abuse.
- Anyone with any known serious allergic reactions that require use of an Epi-Pen.
- Anyone with known sensitivities or allergies to any of the product or placebo ingredients.
- Anyone with known allergies to nightshades (e.g., eggplant, tomato, bell pepper, potato).
- Has had any invasive medical procedures within the last 3 months, or has any planned during the study period.

2.2. Study Design and Intervention Procedure

This single-group study required participants to complete questionnaires at home. Before study onboarding, consent forms describing the study process, instructions, evaluation methods, and bill of rights were provided to participants. Following the consent and pre-screening process, participants were enrolled in the trial and completed the baseline questionnaire.

All participants used the test product, Hey Freya Thrive: Women's Daily + Stress Support supplement. Participants were required to take 2 capsules of the test product each morning, with food.

Questionnaires were completed at the end of weeks 4 and 8, with two additional participant perception questions on Week 8.

2.3. Data Analysis and Statistics

Data from the Oxford Happiness Questionnaire¹² (short form) questionnaire is presented as the average score of 8 parameters scaled from 1-6. Data

from the GAD7 Anxiety Questionnaire was calculated by determining the sum of seven questions (each scaled 0-3), resulting in a final scale from 0-21. Data from the Perceived Stress Scale was calculated by producing the sum of ten questions (each scaled 0-4), resulting in a final scale of 0-40.

Data from the other questions were collected using a textual 5-point Likert scale for each question. The textual Likert data was transformed into numerical values from 1 (worst outcome) to 5 (best outcome).

Statistical analysis compared participant outcomes at each check-in to their Baseline response. First, numerical questionnaire data were checked for normality using the Pearson test. Normally distributed data were analyzed using a mixed-effects analysis with Dunnet's multiple comparisons test, while abnormally distributed data were analyzed using a Kruskal-Wallis test with Dunn's multiple comparisons test. Statistical analyses were performed in GraphPad Prism 10, and the significance level was set at 0.05.

For product-specific questions evaluated only on Week 4, and Week 8, results were presented as the percentage of subjects reporting combined agree % (agree % + strongly agree %).

3. Results

3.1. Impact of the Hey Freya Thrive: Women's Daily + Stress Support Supplement on Mental Health Questionnaires

The Oxford Happiness (short form), GAD7, and Perceived Stress Scale (PSS) questionnaires determined the product's effect on mental health parameters: happiness, anxiety, and perceived stress, respectively. Significant improvements were observed in all three questionnaires at weeks 4 and 8 compared to baseline (Table 1, Figure 1). Improvements progressed linearly, i.e., the mean improvement was



higher at week 8 than at week 4. The highest improvement (50% at week 8) was seen in the GAD7 scale (anxiety).

3.2. Impact of the Hey Freya Thrive: Women's Daily + Stress Support Supplement on Cognitive Parameters According to Questionnaire

Participants reported on the following parameters at baseline, Week 4, and Week 8:

- To what extent has fatigue and low energy troubled you in general?
- How often have you had trouble with mental clarity (brain fog, poor memory)?
- How often have you had trouble with focus and concentration?
- How much have you struggled with food cravings?
- Thinking about the past month, how satisfied are you with your libido?

Significant improvements were observed in all parameters at Week 4 and Week 8, with the largest improvement seen in “To what extent have fatigue and low energy troubled you in general?” (Table 2, Figure 2). Similar to the data in Figure 1, the improvements increased over time.

3.3. Participants' Perceptions of the Hey Freya Thrive: Women's Daily + Stress Support supplement

Participants were asked to respond to questions at the end of Week 4 and Week 8, which provided insight into their perceptions of the test product. Participants responded to product evaluation questions on a “strongly agree” to “strongly disagree” scale. The “strongly agree” and “agree” responses were combined into a single “combined agree” result



to evaluate the overall participant perception (Table 3).

By Week 8, 4 of 12 parameters had the agreement of >70% of participants. 77.78% of participants agreed that their mood had improved since using the product. 75% of participants agreed that they felt less overwhelmed by day-to-day stressors since using the product. 72.22% of participants agreed the product helped with the ability to cope with everyday life. 75% of participants agreed that the product boosted their energy levels.

Moreover, at Week 8, 83.33% of participants agreed they would like to continue using the product, and 86.11% agreed they would recommend it to their friends and family.

Discussion

This study aimed to evaluate the impact of the Hey Freya Thrive: Women's Daily + Stress Support supplement on various mental health and cognitive parameters over 8 weeks. The findings demonstrate significant improvements in questionnaire data for all parameters tested, indicating the product's efficacy in enhancing participants' perceptions of their mental health and cognitive parameters. Improvements in perceived anxiety (GAD7) were particularly striking, with a 50% improvement in scores achieved by week 8.

The improvements progressed linearly for all parameters tested, indicating that the product continued to improve patient perceptions over time. This is significant because, in many cases, an initial good response is followed by a decline or plateau at later time points. It also suggests that although there are improvements seen as early as 4 weeks, the maximum benefits are achieved with prolonged use of the product.



The positive perceptions of the Hey Freya Thrive: Women's Daily + Stress Support supplement among participants further support its effectiveness in improving mental health and cognitive parameters suggesting that the product is well-received by users and is perceived as beneficial for enhancing wellbeing in the parameters tested.

The results of this study are overwhelmingly positive and pave the way for a larger gold-standard randomized controlled trial that may further elucidate the effects of this product on mental health over a longer period of time.

Conclusion

The results of this study demonstrate the significant and rapid improvements in participants' perceptions of mental health and cognitive parameters after using the Hey Freya Thrive: Women's Daily + Stress Support supplement. The product's ability to swiftly improve mental health parameters highlights its effectiveness in addressing common concerns in female participants aged 25-50. Moreover, the sustained improvements observed over eight weeks show the capacity of the product to deliver lasting benefits, particularly in anxiety (GAD7). The positive perceptions reported by participants further validate the product's efficacy and support its value in mental well-being.

While the study is limited in duration, these findings lay the groundwork for future research endeavors, particularly more extensive randomized controlled trials, to further investigate the product's effects on mental health. Overall, the study suggests that the Hey Freya Thrive: Women's Daily + Stress Support supplement holds significant promise as an effective support for mental health, stress, and cognitive improvement.

References

1. Yaribeygi H, Panahi Y, Sahraei H, Johnston TP, Sahebkar A. The impact of stress on body function: A review. *EXCLI J*. 2017;16:1057-1072. doi:10.17179/excli2017-480
2. Tardy AL, Pouteau E, Marquez D, Yilmaz C, Scholey A. Vitamins and Minerals for Energy, Fatigue and Cognition: A Narrative Review of the Biochemical and Clinical Evidence. *Nutrients*. 2020;12(1):228. doi:10.3390/nu12010228
3. Godswill AG, Somtochukwu I IV, AO K, E.C. Health Benefits of Micronutrients (Vitamins and Minerals) and their Associated Deficiency Diseases: A Systematic Review. *Int J Food Sci*. 2020;3(1).
4. Guzek D, Kołota A, Lachowicz K, Skolmowska D, Stachoń M, Głowska D. Association between Vitamin D Supplementation and Mental Health in Healthy Adults: A Systematic Review. *J Clin Med*. 2021;2021;10(21):5156. doi:10.3390/jcm10215156
5. Schwalfenberg GK, Genuis SJ. The Importance of Magnesium in Clinical Healthcare. *Sci Cairo*. 2017;2017(4179326). doi:10.1155/2017/4179326
6. Weyh C, Krüger K, Peeling P, Castell L. The Role of Minerals in the Optimal Functioning of the Immune System. *Nutrients*. 2022;14(3). doi:10.3390/nu14030644
7. Kim K, Wactawski-Wende J, Michels KA. Dietary minerals, reproductive hormone levels and sporadic anovulation: associations in healthy women with regular menstrual cycles. *Br J Nutr*. 2018;120(1):81-89. doi:10.1017/S0007114518000818
8. Chacko SM, Thambi PT, Kuttan R, Nishigaki I. Beneficial effects of green tea: a literature review. *Chin Med*. 2010;5(13). doi:10.1186/1749-8546-5-13
9. Panossian A, Wikman G. Effects of Adaptogens on the Central Nervous System and the Molecular Mechanisms Associated with Their Stress-Protective Activity. *Pharm Basel*.



2010;2010;3(1):188-224. doi:10.3390/ph3010188

hey freya

10. Singh N, Bhalla M, Jager P, Gilca M. An overview on ashwagandha: a Rasayana (rejuvenator) of Ayurveda. *Afr J Tradit Complement Altern Med*. 2011;8(5 Suppl):208-213. doi:10.4314/ajtcam.v8i5S.9
11. Koulivand PH, Khaleghi Ghadiri M, Gorji A. Lavender and the nervous system. *Evid Based Complement Altern Med*. 2013;2013(681304). doi:10.1155/2013/681304
12. Hills P, Argyle M. The Oxford Happiness Questionnaire: a compact scale for the measurement of psychological well-being. *Personal Individ Differ*. 2002;33(7):1073-1082. doi:10.1016/S0191-8869(01)00213-6



Table 1. Statistical Outcomes of Mental Health Questionnaires. Oxford Happiness Questionnaire (Short Form) Score, GAD7 Score, and PSS Score are provided for each time point. % Change indicates a change in mean values from the Baseline. An increase in score indicates an improvement for the Oxford Happiness Questionnaire, and a decrease in score indicates an improvement in GAD7 and PSS scores. Green cells highlight statistically significant outcomes ($P \leq 0.05$). This table provides the numerical data presented in Figure 1.

	Baseline (N = 38)		Week 4 (N = 38)				Week 8 (N = 36)			
	Mean	SD	Mean	SD	% Change	P-value	Mean	SD	% Change	P-value
Oxford Happiness Questionnaire (Short Form) Score	3.44	0.92	3.81	0.75	10.81	0.01	4.06	0.71	17.98	0.0001
GAD7 Score	9.92	5.71	5.79	4.79	-41.64	<0.0001	4.92	4.29	-50.44	<0.0001
PSS Score	22.92	6.29	18.47	5.78	-19.40	0.0002	16.75	6.13	-26.92	<0.0001



hey freya

Table 2. Statistical Outcomes in Cognitive Parameters According to Questionnaire Data. Participant perception data are presented for each question at each time point. % Change indicates a change in mean values from the Baseline. Green cells highlight statistically significant outcomes ($P \leq 0.05$). This table provides the numerical data presented in Figure 2.

	Baseline (N = 38)		Week 4 (N = 38)				Week 8 (N = 36)			
	Mean	SD	Mean	SD	% Change	P-value	Mean	SD	% Change	P-value
To what extent has fatigue and low energy troubled you in general?	1.89	0.69	2.97	1.00	56.94	<0.0001	3.28	0.94	72.99	<0.0001
How often have you had trouble with mental clarity (brain fog, poor memory)?	2.13	0.74	2.95	0.96	38.27	<0.0001	3.47	0.97	62.89	<0.0001
How often have you had trouble with focus and concentration?	2.11	0.73	2.97	0.82	41.25	<0.0001	3.31	1.01	57.01	<0.0001
How much have you struggled with food cravings?	2.24	1.13	3.24	1.26	44.71	<0.0001	3.53	1.16	57.71	<0.0001
Thinking about the past month, how satisfied are you with your libido?	1.89	1.09	2.71	1.25	43.06	0.001	3.22	1.24	70.06	<0.0001



Table 3. Participant Perceptions of the Impact of the Product on Mental Health and Cognitive Parameters.

Green cells highlight a combined positive response of >70%.

	Week 4 (N=38)	Week 8 (N=36)
How much do you agree or disagree with this statement:	Combined Agree	
Since taking this product, I feel more like myself.	52.63	69.44
Since taking this product, my mood has improved.	52.63	77.78
Since taking this product, I feel more calm.	63.16	61.11
Since taking this product, I feel less overwhelmed by day-to-day stressors.	57.89	75.00
This product helps with the ability to cope with everyday life.	52.63	72.22
This product has boosted my energy levels.	52.63	75.00
This product has increased my focus.	47.37	61.11
This product has improved my mental clarity.	55.26	55.56
Since taking this product, I experienced less brain fog.	50.00	66.67
Since taking this product, my food cravings are less severe.	36.84	47.22
This product has improved my libido.	42.11	50.00
Since taking this product, I have had an easier time getting in the mood for sex.	42.11	52.78
I would recommend this product to my friends and family.	-	86.11
I would like to continue taking this product.	-	83.33

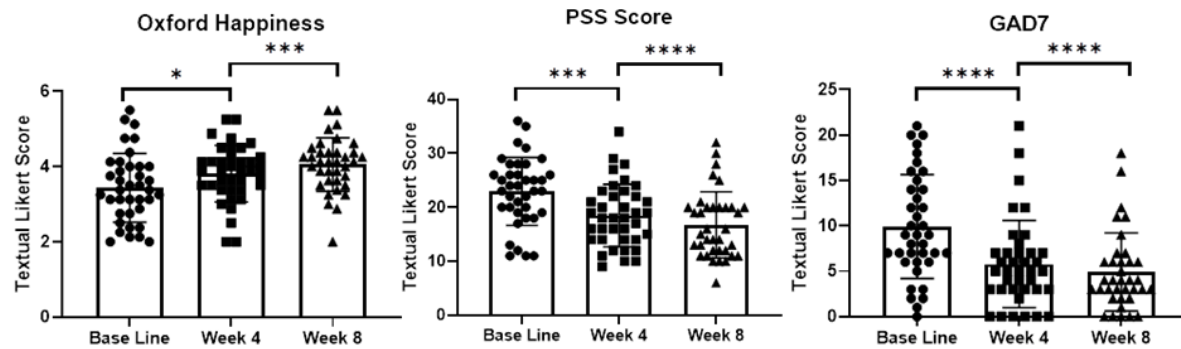


Figure 1. Statistical Outcomes of Mental Health Questionnaires. Data is graphed as group means with standard deviation and individual data points shown. An increase in score indicates an improvement in Oxford Happiness, and a decrease in score indicates an improvement in PSS and GAD7 parameters. * = $P \leq 0.05$, *** = $P \leq 0.001$, **** = $P \leq 0.0001$.

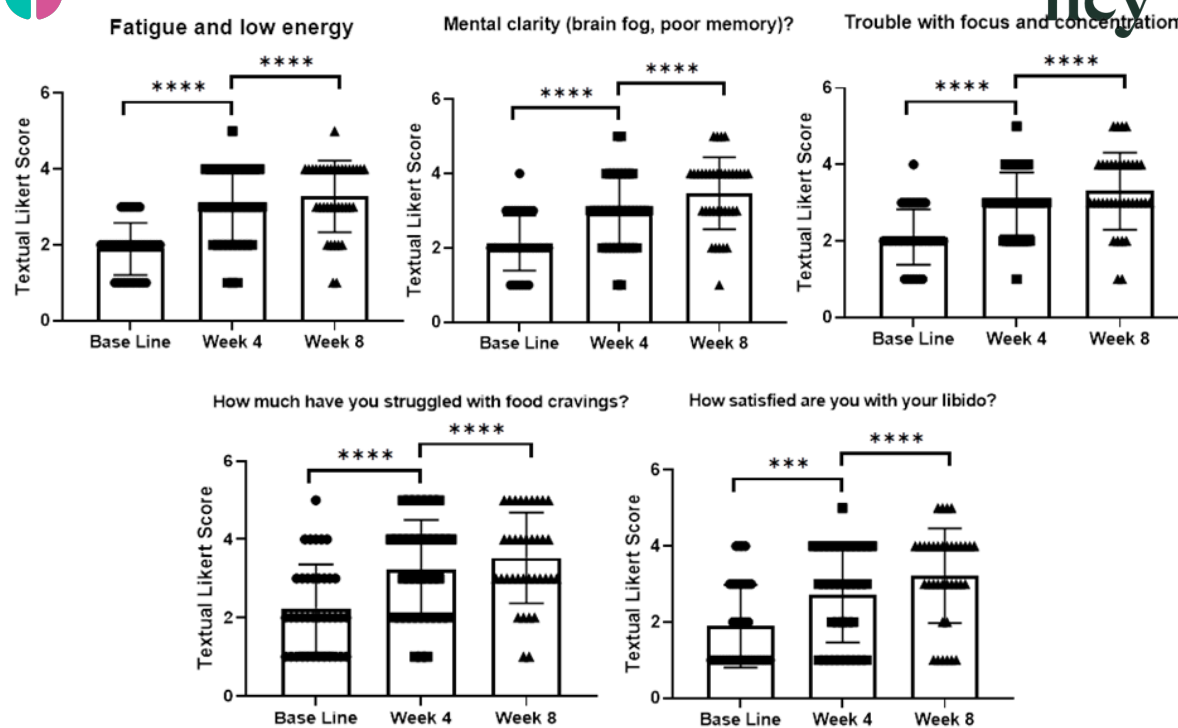


Figure 2. Visual Representation of Questionnaire Data. Data is graphed as group means with standard deviation and individual data points shown. An increase in score indicates an improvement. *** = $P \leq 0.001$, **** = $P \leq 0.0001$.



Appendix A: Data Interpretation

(Please consult an attorney before using any claims – these are just example claims from the data that could be used)

*The following information is provided for educational and informational purposes only. Claim examples by Citruslabs are not intended as legal advice or guidance. Citruslabs does not endorse any specific claims made by its clients and cannot guarantee the accuracy, reliability, or completeness of the information provided. The information contained herein is not a substitute for professional legal advice. Anyone seeking to make marketing claims based on the results of a clinical study should consult a qualified attorney to discuss the legal and regulatory requirements governing such claims. Citruslabs shall not be liable for any damages or losses arising from using this information or any reliance on the accuracy or completeness thereof.

By Week 4, the Hey Freya Thrive: Women's Daily + Stress Support supplement significantly improved:

- Happiness (as determined by the Oxford Happiness Questionnaire)
- Stress (as determined by the Perceived Stress Scale)
- Anxiety (as determined by the GAD7 Anxiety Severity Scale)
- Feelings of fatigue and low energy
- Mental clarity
- Focus and concentration
- Struggles with food cravings
- Satisfaction with libido

By Week 8, the Hey Freya Thrive: Women's Daily + Stress Support supplement significantly improved:

- Happiness (as determined by the Oxford Happiness Questionnaire)
- Stress (as determined by the Perceived Stress Scale)
- Anxiety (as determined by the GAD7 Anxiety Severity Scale)
- Feelings of fatigue and low energy
- Mental clarity
- Focus and concentration
- Struggles with food cravings
- Satisfaction with libido

In eight weeks:

- 77.78% of participants agreed that their mood has improved since using the product.
- 75% of participants agreed that they felt less overwhelmed by day-to-day stressors since using the product.
- 72.22% of participants agreed the product helped with the ability to cope with everyday life.
- 75% of participants agreed that the product boosted their energy levels.
- 86.11% of participants would recommend the product to friends and family.
- 83.33% of participants would like to continue taking the product.