

Prima's The Daily Promotes Positive Psychological, Physiological, and Emotional Outcomes Over a Two-Month Trial

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ABSTRACT:

Stress is an omnipresent part of society. Stress has both short- and long-term health consequences when not addressed effectively. The endocannabinoid system is one bodily system that helps regulate various health functions such as stress response, immune system function, appetite, and memory. Recent research has highlighted that cannabidiol might be an effective compound for supporting the endocannabinoid system. However, many cannabidiol products do not focus on high-quality ingredients that are readily bioavailable. This trial tested Prima's The Daily, a high-quality, bioavailable CBD product. The primary outcomes of interest in this trial included psychological outcomes (stress, nervousness, feeling overwhelmed), physiological outcomes (sleep quality and quantity), and emotional outcomes (positive and negative affective states). Overall, The Daily led to significant improvements in each of the three areas of interest. Participants had improved mood states and the ability to deal with stressful situations. Participants also experienced a significant improvement in the quality and quantity of sleep. This trial's results provide evidence of The Daily's efficacy on most of the outcomes tested.



BACKGROUND:

Stress and anxiety are serious health issues under-addressed in society today. Stress is one of the leading causes of poor health in the United States, and stress often leads to adverse long-term health outcomes (American Psychological Association, 2020). Recent research has also outlined that individuals in the United States today are more anxious than in any previous time that data was available (Salari et al., 2020). On their own, stress and anxiety lead to many adverse physical, psychological, and emotional outcomes. However, most of the harm caused by stress and anxiety is long-term. Stress and anxiety that are unchecked can lead to poor immune functioning (Dhabhar, 2014), impacts on psychology and social well-being (DeLongis et al., 1994), sleep (Kim & Dimsdale, 2007), and mental health markers (Ramierez et al., 1996). Due to the severe adverse outcomes faced by individuals who experience excessive stress, it is essential to explore avenues to reduce the likelihood of long-term stress and anxiety.

Cannabidiol (CBD) has demonstrated efficacy in helping reduce stress and promote sleep. CBD is the second most prevalent bioactive compound in the Cannabis sativa plant (White, 2019). However, unlike tetrahydrocannabinol, CBD does not contain psychoactive properties, meaning that individuals who use CBD do not experience a "high" when using the product.

CBD has previously shown benefits in helping reduce anxiety and has helped with improving symptoms related to anxiety disorders (Skelley, Deas, Curren, & Ennis, 2020). CBD has also demonstrated efficacy in helping sleep-related issues and has helped individuals fall asleep faster and stay asleep longer (Babson, Sottile, & Morabito, 2017). Early research examining CBD has been promising at promoting sleep while reducing stress and anxiety, but more research is necessary to understand the relationship better.

Supplementing with CBD provides support to the endocannabinoid system (ECS). The ECS contains neurotransmitters called endocannabinoids that regulate various body systems, including stress response, appetite, memory, and immune function. While the body naturally produces endocannabinoids, there is evidence people do not make enough to help with the multiple regulatory pathways that lead to optimal health. Being endocannabinoid deficient creates a variety of health issues that have both short and long-term effects. A common way to overcome this deficiency is to supplement with a CBD product. CBD supplementation can support these regulatory functions and positively impact immunity, stress, sleep, and mood.

A critical factor in the effectiveness of a CBD supplement is the bioavailability of the supplement. While the dosage of a supplement is often viewed as the limiting factor when



examining a product's effectiveness, it is often the bioavailability that dictates the supplement's effectiveness. The test product in this study uses a high-quality CBD product and an encapsulation process that makes CBD more bioavailable. Without high levels of CBD bioavailability, the impact of CBD supplementation will be minimal at best (Millar, Stone, Yates, & O'Sullivan, 2018) This study will aim to understand the effectiveness of a CBD product that contains high-quality, broad-spectrum hemp with a precisely designed bioavailable delivery system to ensure that consumers can experience the full benefit of CBD.

While previous research has laid the groundwork for the effectiveness of CBD in helping promote psychological and physiological health, there is still variation in the quality of products on the market. Few products focus on the quality of broad-spectrum hemp and bioavailability delivery system in the same way as Prima's The Daily. Therefore, this exploratory observation trial aimed to understand the efficacy of The Daily when used each day over a two-month trial period. The main outcomes of interest for this trial are sleep quantity, sleep quality, stress, affective states, moods, and ability to focus.

PURPOSE:

The following study has three overarching objectives:

- To assess the efficacy of a dietary supplement in reducing stress and promoting feelings of calmness by supporting the endocannabinoid system.
- To determine the effectiveness of the dietary supplement on self-reported sleep as well as device-measured sleep.
- To assess the efficacy of the dietary supplement at improving overall well-being by supporting the regulatory functions of the endocannabinoid system.

SUBJECTS AND METHODS:

36 participants were recruited to enroll in the trial. Participants were between 18 and 60 and experienced moderate self-reported stress, mood, focus, or sleep issues. Participants were also required to be in good health with no long-term health issues impacting their participation. Participants who currently used selective serotonin reuptake inhibitors or prescription medication for the treatment of depression or anxiety and have not been on a stable dose for at least 60 days were excluded. Participants were also excluded if they received other psychotherapeutic treatments for anxiety or depression.

Participants received 60 capsules of the dietary supplement and were informed to use one capsule per day for the study duration. Participants were asked to take the supplement consistently each day, and if they took it in the evening, the research team told them to take it at least 30 minutes before going to sleep.



Before starting the test product, participants took a baseline well-being survey (repeated on Months 1 and 2). The well-being surveys measured stress levels, feelings of calmness, perceptions of being overwhelmed, ability to cope with stressors, consistency of mood, ability to manage mood, sleep quality, sleep quantity, and ability to focus and avoid distractions, among other variables of interest.

Participants tracked their sleep using a wearable device (i.e., Apple Watch, Whoop, FitBit, or any other device that indicates sleep quality and quantity). Both variables were reported weekly during the study via a separate survey. Participants were also asked other questions in the weekly survey to capture their perceptions of the efficacy of the test product.

Participants who completed the trial and followed trial instructions received a \$100 Amazon gift card after the trial.

RESULTS:

Quantitative Findings:

Participants responded to surveys at baseline, at the end of Month 1, and the end of Month 2 (the study's conclusion). These surveys specifically asked questions that aligned with the main purpose of this trial. Repeated measures (RM) ANOVAs were used to examine the difference over time in the key outcomes of interest. Table 1 below highlights the questions, the means and standard deviations at each time point, and the RM-ANOVA result. The baseline measurement was taken before participants used Prima's The Daily. The scaling for these items was from 1 to 7. For the questions examining the frequency of something occurring 1 represented "never" and 7 represented "every day". For the questions examining the severity of the symptoms, 1 represented not experiencing symptoms, and 7 represented very severe symptoms. For the Baseline, Month 1, and Month 2 columns, the values are the mean and standard deviation, in that order.

Table 1. Mean Changes in Health Outcomes Across the Trial.

Question	Baseline	Month 1	Month 2	p-value	Percent Change from Baseline to Month 2
How often do you	5.39	4.89	4.97	.04*	7.8%



experience stress?	(1.22)	(1.14)	(1.23)		
If you experience stress, how severe would you rate your stress?	4.81 (0.75)	4.39 (0.80)	4.25 (0.81)	.002*	11.6%
How often do you feel nervous?	4.64 (1.15)	3.94 (0.96)	4.22 (1.12)	.004*	9.1%
If you feel nervous sometimes, how severe would you rate your nervousness?	4.31 (1.06)	3.81 (0.95)	3.81 (1.04)	.02*	11.6%
How often do you worry about things?	5.47 (1.08)	5.06 (1.19)	4.69 (1.19)	.001*	14.3%
If you worry about things, how severe would you rate this symptom?	4.56 (0.77)	4.17 (0.97)	4.15 (0.93)	.07	9.0%
How often do you feel overwhelmed?	4.53 (1.21)	4.17 (1.21)	4.25 (1.36)	.19	6.2%
If you get overwhelmed, how severe would you rate this symptom?	4.58 (1.08)	4.11 (1.14)	3.92 (1.16)	.009*	14.4%
In the past month, how often were you in a bad mood?	3.69 (0.86)	2.97 (1.08)	3.00 (1.04)	<.001*	18.7%
During the past month, how often did you feel irritated?	3.92 (0.87)	3.17 (0.97)	3.11 (1.06)	<.001*	20.7%
How often were you able to cope with stressful situations?	4.39 (1.23)	4.69 (1.17)	5.05 (1.07)	.03*	15.0%
How often do you feel to be in a good mood?	4.78 (0.96)	5.11 (1.09)	5.58 (0.84)	<.001*	16.7%
During the past month, how much of a problem has it been for you to keep up enthusiasm and get things done?	4.06 (1.01)	2.98 (1.23)	2.58 (1.11)	<.001*	36.5%



During the past month, how much of a problem has it been for you to focus?	4.11 (0.98)	3.25 (1.31)	2.86 (1.15)	<.001*	30.4%
During the past month, how often did you have trouble sleeping because you felt stressed?	4.33 (0.89)	2.67 (1.17)	2.61 (1.27)	<.001*	39.7%
During the past month, how often did you feel refreshed and rested after you woke up?	2.64 (1.20)	3.97 (1.21)	4.03 (1.21)	<.001*	52.7%
During the past month, how would you rate your sleep quality overall?	2.31 (0.79)	3.61 (0.87)	3.78 (0.83)	<.001*	63.6%
During the past month, how often did you feel stressed during the day?	4.47 (0.70)	3.44 (1.11)	3.17 (1.16)	<.001*	29.1%
During the past month, how often did you feel stressed at night/before going to bed?	4.28 (0.85)	3.03 (1.28)	2.67 (1.17)	<.001*	37.6%
How often do you feel rested?	3.11 (1.24)	4.39 (1.32)	4.89 (1.37)	<.001*	57.2%
How often do you feel calm?	3.92 (1.25)	5.08 (0.91)	5.28 (1.14)	<.001*	34.7%
How often do you feel physically well?	4.56 (1.34)	5.19 (0.95)	5.50 (1.03)	<.001*	20.6%

Note: The values in the table for Baseline, Month 1, and Month 2 are the mean and standard deviation at the respective time point for the question in the left column. The standard deviation is in parentheses. The statistical tests in this table are RM ANOVAs. * indicates a statistically significant RM-ANOVA. Percent change from Baseline to Month 2 was calculated by subtracting the Month 2 value from the Baseline value, taking the absolute value, and then dividing by the baseline value.

Participants experienced a significant improvement in stress frequency, stress severity, nervousness, nervousness severity, worry frequency, the severity of feeling overwhelmed, negative mood states, feeling irritated, and feeling in a good mood across the two-month



trial. Also, participants coped more effectively with stressful situations, had higher enthusiasm, and improved focus. Participants also had fewer issues falling asleep due to stress, felt more rested when they woke up and improved self-reported sleep quality. Lastly, participants felt more rested, calmer, less stressed at night, and more physically well. Overall, there were significant improvements in the first aim's outcomes of interest.

To further explore the effects of the test product, the weekly check-in questionnaires asked participants directly about the effects they felt after using The Daily. Tables 2 and 3 below list the percentages of participants who either agreed or strongly agreed with the statements.

Table 2. Participant Perceptions of Improvements in Weeks 1-4.

	Week 1	Week 2	Week 3	Week 4
The Daily helped me feel less stressed	52%	61%	66%	69%
The Daily helped me improve my focus	39%	47%	63%	64%
The Daily helped me get more restful sleep	52%	50%	71%	72%
The Daily helped me wake up more refreshed.	44%	50%	57%	69%
My mood improved in the past week after taking The Daily	56%	67%	58%	69%
The Daily helped me feel calmer in the past week	56%	64%	66%	69%
The Daily helped me feel better physically in the past week	47%	39%	51%	50%
The Daily helped me feel overall better	47%	58%	60%	72%

Table 3. Participant Perceptions of Improvements in Weeks 5-8.

	Week 5	Week 6	Week 7	Week 8
The Daily helped me feel less stressed	67%	69%	69%	69%
The Daily helped me improve my focus	56%	61%	64%	61%



The Daily helped me get more restful sleep	78%	83%	72%	72%
The Daily helped me wake up more refreshed.	75%	67%	69%	67%
My mood improved in the past week after taking The Daily	72%	64%	66%	75%
The Daily helped me feel calmer in the past week	75%	67%	69%	69%
The Daily helped me feel better physically in the past week	58%	53%	61%	56%
The Daily helped me feel overall better	72%	69%	72%	72%

Note. The values in this table represent the percentage of participants at that time point that either agreed or strongly agreed.

Most participants agreed or strongly agreed with the statements asked each week. On average, the values increased over time, meaning that the longer participants took The Daily, the more likely they were to feel the product's positive effects on these outcomes.

The second purpose of this trial was to examine the effectiveness of The Daily on self-reported and devices measured sleep. Participants reported significant improvements in their sleep across the trial as seen in Table 1, Table 2, and Table 3. Specifically, participants significantly improved sleep quality and felt more refreshed after waking up. To fully answer the second question, participants were asked weekly about their average sleep across the week and their sleep score. The values in Table 4 below represent the average and standard deviation of time slept and sleep scores across the trial. The sleep score was calculated by the sleep tracker that the participant used. An important caveat of this analysis is that participants used different sleep trackers with different values. This inconsistency limits the generalizability of this analysis.

Table 4. Average Sleep Time and Sleep Score.

	Baseline	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	P-val ue
Sleep	5.63	6.67	6.91	7.29	6.92	7.25	7.16	7.18	7.35	.001*
Time	(1.10)	(1.01)	(1.09)	(1.60)	(0.98)	(1.39)	(1.12)	(1.14)	(1.09)	



 59.10 (21.36)					0.12
)		

Note. The sleep time analysis and sleep score analysis were RM-ANOVAs. The sleep time analysis was conducted with 34 participants as two participants did to give accurate sleep readings to the research team at each time point. The sleep score analysis was conducted with 24 participants because some participants did not give an accurate score at all time points, and some participants' fitness tracker only gave a categorical score that could not translate to this analysis.

Overall, participants taking The Daily experienced sleep improvements starting in Week 1 and continuing throughout the study. A post hoc analysis indicated that all sleep scores significantly improved from the baseline measurement. None of the other weeks were significantly different from each other. Within the scope of this trial, participants taking The Daily experienced a significant improvement in sleep time starting in Week 1 and maintaining that improvement across the trial. There was not a significant difference between the weeks in sleep score; however, there are confounding factors that contribute to that finding. All fitness trackers use proprietary algorithms that output the sleep score, likely quite different from each other. These trackers likely use different inputs that could affect the sleep score.

The third aim of this trial was to understand better global perceptions of wellness from participants across the trial. Participants were asked to rate how they felt mentally, physically, and emotionally on a scale from 1 (very poor) to 100 (very well) at baseline, Month 1, and Month 2. In addition, they were asked to rate their perceived ability to deal with stress on a scale from 1-100. The results are below in Table 5.

Table 5. Ratings of Health Perceptions.

Question	Baseline	Month 1	Month 2	p-value	Percent Change from Baseline to Month 2
How do you feel mentally?	59.64 (18.58)	64.25 (25.37)	74.03 (22.69)	.003*	24.1%



How do you feel physically?	58.86 (20.12)	70.36 (22.41)	73.83 (23.11)	<.001*	25.4%
How do you feel emotionally?	58.31 (18.87)	67.64 (22.67)	71.00 (23.61)	.004*	21.8%
How do you rate your ability to deal with stress?	53.08 (18.61)	65.58 (25.92)	69.53 (23.63)	<.001*	31.0%

Note. The mean and standard deviation of the ratings are in each box. Each statistical analysis was an RM-ANOVA. All statistical analyses were significant and demonstrated improvements in the areas examined. Percent change from Baseline to Month 2 was calculated by subtracting the Month 2 value from the Baseline value and then dividing by the baseline value.

Participants significantly improved their psychological, emotional, and physical health across the two-month trial using The Daily. Also, participants could deal more effectively with stress while taking The Daily than the baseline measurement.

DISCUSSION:

The first aim of this trial was to assess the efficacy of The Daily in reducing stress and promoting feelings of calmness by supporting the endocannabinoid system. Participants were asked about the frequency and severity of negative psychological states/situations. Overall, participants in this trial saw significant improvements in the majority of negative psychological outcomes of interest, including frequency of stress, the severity of stress, frequency of feeling nervous, the severity of feeling nervous, frequency of worrying, the severity of feeling overwhelmed, number of negative mood states, and the amount of time participants felt irritated. These significant improvements in negative psychological outcomes during the two-month trial were very robust, indicating that the test product was likely very helpful in aiding a reduction in negative psychological effects. Participants also reported a significant increase in being in a good mood and having more enthusiasm. The Daily helped participants experience fewer negative emotional and psychological outcomes while at the same time promoting positive emotional and psychological effects.

Participants also reported they could better focus and cope with stressful situations while taking The Daily. As mentioned in the Introduction, dealing with stressful situations and focusing are two areas in which individuals today often struggle. Focusing more effectively and dealing with stress will lead to positive health outcomes and likely more positive occupational and educational outcomes. Any improvement in occupational or



educational settings could lead to positive downstream effects like improved grades or more compensation for work.

Participants believed The Daily helped improve their emotional and psychological health. In the final week of the trial, 69% of participants thought that the daily helped them feel less stressed, and 75% of participants believed that their mood improved while taking The Daily. 69% of participants said they felt calmer while taking The Daily in Week 8, and 61% of participants reported The Daily helped improve their focus. These values are high considering these measured outcomes can be affected by various things happening in the participants' lives (i.e., a stressful day at work, family or friend stress).

The second aim of this proposal was to determine the effectiveness of the dietary supplement on self-reported sleep outcomes and device-measured sleep. Participants significantly reduced the times they had trouble going to sleep because they were stressed and increased the number of times they woke up and felt refreshed. Participants also noted a significant improvement in self-reported sleep quality across the trial. One of the reasons participants might have experienced an increase in sleep quality is that they reported a substantial reduction in the number of evenings they felt stressed before going to bed. Participants also noted a significant improvement in the number of hours slept from the fitness tracker used in the trial. Notably, participants significantly increased the number of hours slept between baseline and Week 1, indicating that the sleep improvements started quickly for participants using The Daily. Overall, participants got more sleep and reported higher quality, more restful sleep when using The Daily.

The final aim of this trial was to assess the efficacy of the dietary supplement in improving overall well-being by supporting the regulatory functions of the endocannabinoid system. Participants reported feeling significantly calmer, more rested, and more physically well while using The Daily. 72% of participants in this trial noted The Daily helped them feel better overall. Participants reported improvements in how they felt mentally, physically, and emotionally during the trial. Participants in this trial significantly improved their overall well-being, likely due to the better support of the regulatory functions governed by the endocannabinoid system.

Overall, participants using The Daily saw improvements in emotional, psychological, and physical health markers. Participants using The Daily significantly improved the amount of sleep they received during the trial and reported better sleep quality. Future studies should continue to examine the efficacy of The Daily to understand the underlying mechanisms of these changes better. Future research could continue to test the efficacy in a randomized controlled trial.



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Appendix A:

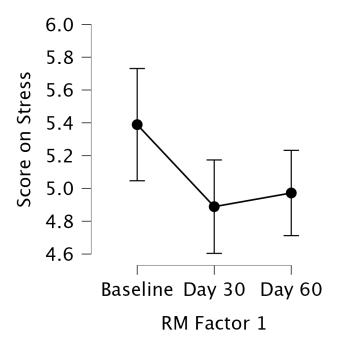
Supported Product Claims (please always speak to a qualified attorney before using any claims)

- Over two months while using The Daily, there was a statistically significant improvement in:
 - Frequency of stress
 - Severity of stress
 - Frequency of feeling nervous
 - Severity of nervous feelings
 - Worrying
 - Severity of feeling overwhelmed
 - o Being in a bad mood
 - Feeling irritated
 - Being able to cope with stress
 - Keeping up enthusiasm
 - Focus
- Participants reported the following sleep benefits:
 - Statistically significant improvement in the amount of sleep while taking The Daily (device measured sleep which is often more accurate than self-report).
 - Woke up feeling more refreshed.
 - Reported having better sleep quality.
 - Felt more rested.
 - Felt calmer
- After eight weeks of using The Daily:
 - 69% of participants felt less stressed.
 - 72% of participants were able to get more restful sleep.
 - 75% of participants experienced improvements in mood.
 - 67% of participants woke up more refreshed.
 - 69% of participants felt calmer.
 - 72% of participants felt better overall.
- Participants reported the following improvements across the duration of the trial.
 - Significant improvement in how participants felt mentally, emotionally, and physically.
 - Significant increase in the ability of participants to deal with stress.

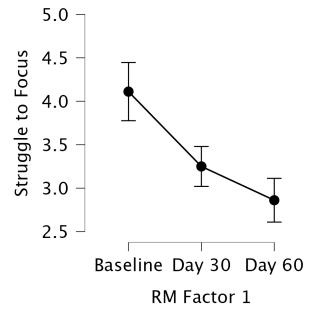


Appendix B: Selected Charts and Graphs from the Trial.

Perceptions of Stress Across the Trial (7.8% Improvement from Baseline to Day 60)

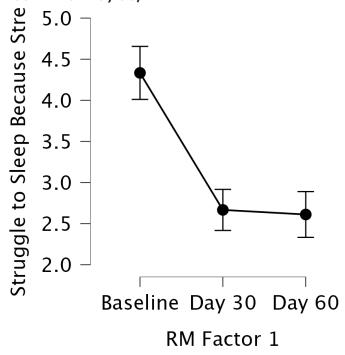


How much of a problem has it been for you to focus? (30.4% Improvement from Baseline to Day 60)

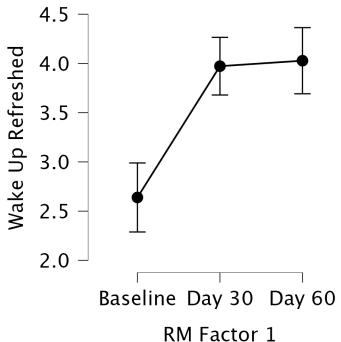




How often do you have trouble sleeping due to stress? (39.7% Improvement from Baseline to Day 60)

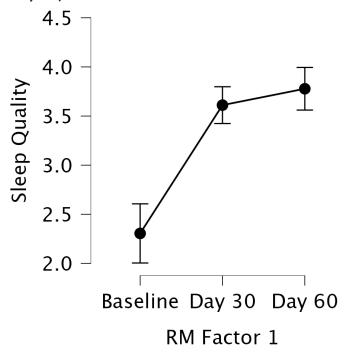


How often do you wake up feeling refreshed and rested? (52.7% Improvement from Baseline to Day 60)

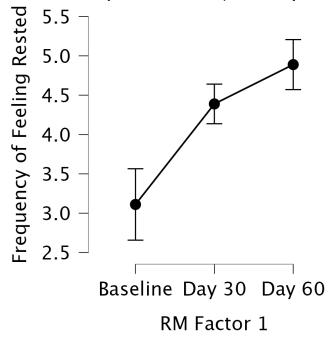




How would you rate your sleep quality overall? (63.6% Improvement from Baseline to Day 60)



How often do you feel rested? (57.2% Improvement from Baseline to Day 60)





Hours of Sleep Across the Trial (Measured Weekly)

