Asystems' Complete Calm Supplement is Effective at Promoting and Supporting Sleep

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ABSTRACT:

Sleep is intimately tied to overall health. Specifically, sleep has previously been tied to overall well-being and also psychological well-being. Two major components of psychological well-being that appear to be major issues in the modern world are stress and anxiety. This trial tested a novel supplement called Complete Calm that is intended to provide support for healthy sleep habits, lower anxiety, and lower stress. 28 participants completed this trial and took the Complete Calm Supplement for a month. The participants took questionnaires before the study began, at the study midpoint, and at the conclusion of the study. The questionnaires asked questions regarding sleep, anxiety, and stress to get a full understanding of how these concepts changed across the duration of the study. Participants experienced significant reductions in stress and anxiety in the trial. Also, participants experienced improved sleep and were able to experience deep sleep more frequently. Overall, it appears that Complete Calm is effective at enhancing sleep quality and sleep time. Complete Calm also appears effective at reducing stress and anxiety.

BACKGROUND:

Sleep is critical for physical and psychological rest and recovery. Sleep has been consistently tied to overall well-being, being able to fight off disease, mental health and physical recovery (Hamilton, Nelson, Stevens, & Kitzman, 2007). Not getting enough sleep has previously been linked to negative mood states, poor judgment, and lapses in memory (Hamilton, Nelson, Stevens, & Kitzman, 2007).

Even though it is well known that sleep is critical for overall health and well-being, issues related to sleep seem to be more prevalent today than at any other time in history. Some of the likely reasons why include busy, demanding lifestyles, constant access to technology, and the blurred lines between work and private life. These issues, and likely more, have led to more than 70% of adults reporting they do not get enough sleep at least once per month (Centers for Disease Control, 2008). Between 50-70 million Americans suffer from sleep-related issues (Centers for Disease Control, 2008). It is clear that getting enough sleep is becoming a critical issue in society.

Stress and anxiety have a recursive relationship with sleep. This means that if an individual is stressed or anxious, they are likely to have sleep-related issues. However, it is also possible that people who are not getting enough sleep are likely to feel more stressed and anxious. If people are able to get better sleep, they are likely going to have lower rates of stress and anxiety.

Research today highlights that getting adequate amounts of sleep each night is one of the most important things that can be done for overall health (Wells & Vaughn, 2012). Sleep is connected to everything from immunity to stress and anxiety. Therefore, supplements that can support healthy sleep habits would likely be well received by consumers.

ASYSTEM developed a line of supplementation to specifically address challenges with sleep in the modern world. The Complete Calm supplement consists of the "De-stress Gummies" and "Sleep Gummies". Both products contain a blend of adaptogens, terpenes, and Safr'Inside. The overall goal of these supplements is that users experience improved sleep quality and duration, as well as reduce their stress and anxiety. The key ingredient in both supplements are Safr'Inside which combines adaptogens, lion's mane, Rhodiola, lemon balm, and terpene blends. The de-stress gummies also have Panax ginseng. The Sleep Gummies also have l-tryptophan, melatonin, chamomile extract, passionflower extract, and holy basil. These ingredients have previously been shown to be effective in helping reduce stress and aid in sleep.

This trial is an exploratory look at the Complete Calm supplement with the main goal of understanding how Complete Calm supports healthy sleep habits, reduces stress and anxiety, as well as lifting mood.

PURPOSE:

The overall purpose of this exploratory observational trial is to gather information on a multi-supplement intervention. Specifically, this trial will provide evidence for marketing claims and will provide information about whether a randomized controlled trial is warranted in the future.

Specifically, this study has two overarching objectives:

- The primary objective of this study is to assess the efficacy of Asystems' Complete Calm products consisting of de-stress gummies and sleep gummies and their effects on sleep quality and duration, stress, and anxiety
- The secondary objective is to examine if Asystem's Complete Calm products work synergistically and enhance the participants' quality of life.

It is hypothesized that the dietary supplement marketed as Asystems Complete Calm (consisting of De-Stress Gummies and Sleep Gummies) will improve subjective wellbeing in trial participants, through promoting restful sleep (looking at sleep quality and duration), and reducing stress and anxiety, while lifting up the participants' mood.

SUBJECTS AND METHODS:

This is an open-label observational single-arm clinical trial to study the efficacy of a commercial dietary supplement and its effect on sleep quality, sleep duration, anxiety, mood, and stress.

A total of 33 men and women were recruited for this trial. Each of the participants was screened and deemed eligible to participate based on inclusion and exclusion criteria. The trial was run virtually using a technology platform. The participants in the trial took the Complete Calm Product, consisting of both the De-Stress Gummies (during the day) and the Sleep Gummies (at night) for four weeks. 28 participants finished the entire study and completed the questionnaires at all measurement points.

The sequence of events followed the bullet points below:

- Eligibility pre-screening (inclusion/exclusion criteria including relevant demographic and medical information)
- Informed consent
- Test product distribution
- Onboarding participants on technology platform that captures data
- Participants to complete the baseline survey
- Participants start to take Complete Calm (De-Stress Gummies during day, Sleep Gummies at night) for four weeks
- Participants to complete questionnaires at weeks two and four
- Participants to write down any adverse or ill effects at any time during the intervention
- Participants to complete exit survey and note any final adverse and positive events

The questionnaires that were provided to the participants examined perceptions of sleep, sleep improvement, anxiety, stress, overall mood, and other variables related to psychological well being.

RESULTS
Understanding Improvements in Sleep, Anxiety, and Stress Across the Trial
Participants were asked questions that focused on stress, sleep, and anxiety at baseline, study midpoint, and the conclusion of the trial. With the three-time point measurement and a single group design, a repeated measures statistical approach is most appropriate to understand improvement in the questions asked to participants. Due to the comprehensive nature of the data collected for this trial, the subsections below will focus on stress, anxiety, and sleep separately, even though the data were collected in the same survey, at the same time.

Stress
Participants were asked about the frequency and severity of the stress they experience at baseline, midpoint, and the conclusion of the trial. Below are the repeated measures ANOVA results and the means at each time point for each of the questions asked.

Table 1. Stress Symptoms Across the Four Week Trial

Question	Baseline Mean	Midpoint Mean	End Mean	P-Value
How often do you experience stress?	5.89	5.75	4.93	< .001*
How severe would you rate your stress?	4.86	4.71	4.25	.007*
How often do you feel nervous	5.36	4.86	4.29	.001*
How severe would you rate the nervousness?	4.82	4.29	3.75	< .001*
How often do you feel under pressure?	5.29	5.29	4.43	.001*
If you feel under pressure sometimes, how severe would you rate this symptom?	4.79	4.39	3.71	< .001*
How often do you feel rested?	2.75	3.43	3.79	< .001*
How often do you feel calm?	3.29	3.86	4.04	.002*

*Indicates a statistically significant RM ANOVA result.

As noted above in the table, participants had significant improvements on each of the measures used to capture stress in this trial. This demonstrates that Complete Calm is effective in improving stress significantly across a 4 week period.

Additional measures were used at the same time points to capture feelings and perceptions related to anxiety. The average responses from participants are included in the Table 2 below:

Table 2. Anxiety Symptoms Across the Four Week Trial

Question	Baseline Mean	Midpoint Mean	End Mean	P-Value
How often do you experience anxiety?	5.50	5.14	4.68	.003*
If you experience anxiety, how severe would you rate your anxiety?	4.89	4.75	4.29	.004*
How often do you experience panic attacks?	3.00	2.92	2.50	.06
If you experience panic attacks, how severe would you rate these attacks?	4.18	3.93	3.54	.13
How often do you feel irritated?	5.11	5.07	4.61	.06
If you feel irritated, how severe would you rate our irritation?	4.61	4.64	3.82	.001*
How often do you feel upset?	4.50	4.61	4.25	.45
If you feel upset sometimes, how severe would you rate this symptom?	4.14	4.39	3.79	.04*
How often do you worry about different things?	5.89	5.46	4.89	.002*
If you worry about different things sometimes, how severe would you rate this symptom?	4.57	4.50	3.79	.005*

How often do you feel restless?	4.71	4.71	3.96	.02*
If you feel restless sometimes, how severe would you rate this symptom?	4.21	4.07	3.68	.09
How often do you feel to be in a good mood?	3.89	4.14	4.36	.14

*Indicates a statistically significant RM ANOVA.

Results from the anxiety symptoms were more mixed than the previous section. There were clear, statistically significant reductions in anxiety, anxiety severity, irritation, feeling upset, worry, worry severity, and feeling restless. Although the other questions were not statistically different from baseline to conclusion, there were improvements in all of the mean values. This means that if another trial with a larger sample was conducted, it is reasonable to expect some of the questions would be statistically distinct from baseline to conclusion.

The last major section of questions asked at all three time points were focused on sleep. The results from the sleep-related questions can be seen in Table 3 below:

Table 3. Sleep Symptoms Across the Four Week Trial

Question	Baseline Mean	Midpoint Mean	End Mean	P-Value
Hours of Sleep Per Night	2.67	3.11	3.11	.009*
How often do you experience sleep disturbances?	5.46	4.86	4.36	.001*
How often do you have difficulties falling asleep?	4.61	3.89	3.61	.008*
How often do you have difficulties getting back to sleep once you wake up in the middle of the night?	4.39	4.00	3.54	.01*
How often do you feel refreshed after sleep?	2.64	3.36	3.61	< .001*
How often would you like to continue sleeping after you woke up the next morning?	5.57	5.39	4.86	.048*

How often do you toss and turn?	5.39	4.61	4.04	< .001*
How often does poor sleep make you irritated?	4.89	4.68	4.25	.11
How often does poor sleep let you lose interest in work or other activities?	4.50	4.50	4.00	.10
How often do you feel distracted because of poor sleep?	4.68	4.68	4.18	.16
How often are your sleep hours enough?	2.82	3.71	3.82	< .001*
How often do you fall into deep sleep?	3.50	3.96	4.18	.01*

*Indicates a statistically significant RM ANOVA. Note. The hours of sleep variable has been recoded. Therefore the hours of sleep on average are likely between 6-7 hours if the mean value above is a 3, between 7-8 hours if the value in the table above is 4, and 6 hours or less if the value is 2.

Overall, the Complete Calm system was very effective in helping participants get more sleep, have deeper sleep, experience fewer issues falling back asleep after waking up, have fewer difficulties falling asleep, and feeling more refreshed after sleeping.

Questions Asked in Weeks 2 and 4
At the end of week 2 and week 4 (week 2 being the study midpoint and week 4 being the conclusion), participants were asked to rate how improved they felt on a variety of variables compared to before they were taking the Complete Calm Supplement. In Table 4 the percentage of participants who either agreed or strongly agreed they experienced improvement is reported.

Table 4. Percentage Improvement After Two Weeks of Complete Calm.

Question	Number of Participants Who Felt an Improvement	Percentage of Participants who Felt an Improvement
Improvement in Sleep	18	64%
Felt Asleep Faster	21	75%

Stay Asleep Longer	14	50%
Able to Get More Restful Sleep	18	64%
Woke up Feeling More Refreshed	16	57%
Mood Improved	16	57%
Felt More Calm	19	68%
Reduced Feelings of Mind Racing	11	39%
Reduced Anxiety	15	54%
Reduced Stress Levels	16	57%

*The number of participants included in this calculation either marked agree or strongly agree on the questionnaires.

Participants were asked the same questions again at the conclusion of the study. The results can be seen below in Table 5.

Table 5. Percentage Improvement After Four Weeks of Complete Calm.

Question	Number of Participants Who Felt an Improvement	Percentage of Participants who Felt an Improvement
Improvement in Sleep	23	82%
Fell Asleep Faster	22	79%
Stay Asleep Longer	17	61%
Able to Get More Restful Sleep	20	71%
Woke up Feeling More Refreshed	16	57%
Mood Improved	23	82%
Felt More Calm	24	86%
Reduced Feelings of Mind Racing	18	64%

Reduced Anxiety	18	64%
Reduced Stress Levels	22	79%

*The number of participants included in this calculation either marked agree or strongly agree on the questionnaires.

Participants were also asked how likely they would be to recommend ASYSTEM's Complete Calm combination to a friend on a scale of 1 (not at all likely) to 10 (very likely). On average participants were likely to recommend ASYSTEM's Complete Calm to a friend (Mean = 7.39, SD = 2.06). 24 of the 28 participants (86%) rated a 6 or above on the question about recommending the supplement to a friend.

Participants were also asked if they would be interested in continuing to take the gummies after the trial and 22 of 28 (79%) of the participants said they either agree or strongly agree. This indicates that participants were largely in favor of continuing the product and feel they received value from the product.

Lastly, participants were asked if they enjoyed the taste of the gummies. 15 of the 28 (54%) participants either strongly disagreed or disagreed that they enjoyed the taste of the gummies. 10 out of 28 (36%) participants agreed or strongly agreed that they enjoyed the taste of the gummies. Three participants were neutral about the taste.

DISCUSSION:
The purpose of this study was to examine the effectiveness of the Complete Calm product in being able to help with stress, anxiety, and sleep issues that are common today. Participants followed the guidelines outlined by the product and took the two gummies each day. Participants experienced substantial improvements in anxiety, stress, and sleep. These improvements demonstrate the efficacy of Complete Calm for helping individuals with the daily stressors experienced today.

Participants in this trial had a marked decrease in both the amount of stress and the severity of the stress. These reductions in stress could lead to substantial improvements in overall quality of life and it appears the Complete Calm system is effective at bringing positive changes to stress levels. Participants taking complete calm also felt like they were under less pressure and they felt more rested. Also, participants reported feeling more calm. Overall, it appears that participants had substantial and meaningful improvements in stress across the trial.

As previously mentioned in the introduction, people today appear to have more anxiety than previous generations. Complete Calm demonstrated efficacy at alleviating some symptoms related to anxiety in this trial. Specifically, Complete Calm helped reduce perceptions of anxiety, anxiety severity, feelings of irritation, being upset, worry, worry severity, and feeling restless.

These reductions are in the symptoms that are commonly reported as issues for individuals. This trial provides support for Complete Calm helping reduce some of the symptoms associated with high levels of anxiety.

Sleep is another major issue for people today. Complete Calm was able to help improve the amount of sleep participants received. Very few products can actually support the claim that they positively impact the amount of sleep participants are able to get. Complete Calm was also effective at helping participants have fewer sleep disturbances, fewer difficulties falling asleep, fewer issues getting back to sleep after waking up in the night, and less tossing and turning. These are common sleep complaints that can have an impact on overall well-being. Also, participants reported feeling more refreshed after sleep and felt they were getting enough sleep. This is likely because participants were getting more deep sleep and letting their bodies and minds recover more at night.

Not only were there differences between the pre-mid-post measurement of the primary variables of this study, participants clearly noted they could feel the improvement in most of the areas of their lives. These improvements were considered quite large and, on average, participants largely felt much better at the end of the trial after taking Complete Calm for a month.

Overall, it appears that Complete Calm is an effective supplement at helping reduce stress, reduce anxiety, and promote healthy sleep patterns. These results suggest that Complete Calm would likely hold up well in a double-blind trial in the future.

REFERENCES:

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Hamilton, N. A., Nelson, C. A., Stevens, N., & Kitzman, H. (2007). Sleep and psychological well-being. *Social Indicators Research, 82,* 147-163.

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APPENDIX:

Supported product claims:

- 82% of study participants saw an improvement in sleep.
- 79% of study participants fell asleep faster.
- 61% of study participants stayed asleep longer.
- 82% of study participants were able to get more restful sleep.
- 57% of study participants woke up feeling more refreshed.
- 82% of study participants saw an improvement in mood
- 86% of study participants felt more calm.
- 64% of study participants saw reduced feelings of mind racing.
- 64% of study participants saw a reduction in anxiety levels.
- 79% of study participants saw reduced stress levels.

Study Participants: 28 study subjects, between 24 and 48 years of age, presenting (self-perceived) one or several of the following: mild to moderate sleep issues, mild to moderate anxiety, stressful lifestyle.