Detailed Summary of the Study Findings

Effectiveness of Sanna Formulation A ("Sanna Sleep", Sanna Brands, LLC) on Sleep Quality
and Health-related Quality of Life of Adults with Poor Sleep Quality: A Pilot Study

Introduction

To promote optimal health and well-being, experts recommend adults get at least seven hours of sleep each night. A recent report from the Centers for Disease Control and Prevention (CDC) estimated that over one-third of the adult population in the U.S. sleeps less than the recommended minimum hours each night; this equates to an estimated 83.6 million U.S. adults sleeping less than 7 hours on any given night.

Sleeping less than seven hours per night is associated with increased risk for obesity, diabetes, high blood pressure, coronary heart disease, stroke, mental distress, and all-cause mortality. Insufficient sleep impairs cognitive performance, which can increase the likelihood of motor vehicle and other transportation accidents, industrial accidents, medical errors, and loss of work productivity that could affect the wider community. The National Safety Council estimates that sleepy employees cost their employers $136 billion a year (NSC, 2018).

A common intervention to re-establish sleep patterns are over-the-counter and prescription drugs. At present, however, no professional sleep organizations have issued consensus statements or recommendations about the efficacy or safety of either over-the-counter or prescription sleep aids for improving sleep duration in the general adult population. In addition, prescription sleep aids have been criticized regarding their side effects, short- and long-term efficacy, and dependency. Research is needed examining the effectiveness of alternative interventions to improve sleep quality and quantity.

In particular, cannabidiol (CBD) and other cannabinoid compounds found in cannabis have been purported to have calming and anti-anxiety effects resulting in improved sleep quality. Despite the interest and marketing of CBD related products few studies exist on its effectiveness on health-related quality of life, anxiety, and sleep quality, in particular with nonclinical populations.

Study Purpose

Conduct a pilot study on adults with poor sleep quality (i.e., sleeplessness) to examine the effectiveness of "Sanna Sleep" (Sanna, LLC). The primary outcomes were sleep quality. The secondary outcomes were health-related quality of life (HRQoL), perceived stress, anxiety, and product usability/feasibility.

Methods

Participants

Participants were 24 male (n = 13) and female (n = 11) adults (M age = 49.20, SD = 13.30, range = 27 to 67 years) with poor sleep quality. Most of the participants were White (n = 22), followed by Asian (n = 1) and Hispanic/Latino (n = 1). Regarding education level, nine participants graduated from high school, nine graduated from college, and six had a graduate degree. Most of the participants worked full-time (n = 20) and had an income greater than $100,000 ($n$ = 14). All participants reported insomnia symptoms as determined by the Insomnia Severity Index (i.e., score of 8 or greater on the index; see Table 1).

Procedures and Design

Participants who met the inclusion criteria (based on responses to the Prescreen Survey) were contacted to discuss the intervention. Interested participants signed an Informed Consent and then the supplement was delivered to their home address.

Participants were instructed to take 1 to 2 capsules 30 minutes prior to nighttime sleep for 7 consecutive days. They were sent a Daily Diary to complete that assessed their supplement adherence, adverse events, sleep quality, and mood. As well, the participants completed assessments of their sleep quality, anxiety, health-related quality of night, and perceived stress at Day 0 (Pre) and Day 7 (Post).

A total of 26 adults were enrolled and 24 completed the study, representing an adherence rate of 92%. The reasons for dropout were: $n = 1$ did not receive the capsules in time to participate, and $n = 1$ stopped due to adverse events (see Figure 1). Data were collected electronically via secured links.

Measures

Demographic Information (Baseline only): The following demographic items were assessed: age, gender, education level, work status, family income, ethnicity, physical and mental health status, and sleep quality.

The following measures were completed at Day 0 (Baseline: Pre) and Day 7 (Post).

- **Insomnia Severity Index:** The Insomnia Severity Index is a 7-item self-report questionnaire assessing the nature, severity, and impact of insomnia. The usual recall period is the "last month" and the dimensions evaluated are: severity of sleep onset, sleep maintenance, and early morning awakening problems, sleep dissatisfaction, interference of sleep difficulties with daytime functioning, noticeability of sleep problems by others, and distress caused by the sleep difficulties. A 5-point Likert scale is used to rate each item (e.g., 0 = no problem; 4 = very severe problem), yielding a total score ranging from 0 to 28. The total score is interpreted as follows: absence of insomnia (0–7); sub-threshold insomnia (8–14); moderate insomnia (15–21); and severe insomnia (22–28).

- **Bergen Insomnia Scale**: The Bergen Insomnia Scale includes six items that correspond to the DSM-IV-TR diagnostic criteria for insomnia (American Psychiatric Association, 2000). Each item is given a score of between 0 and 7, reflecting the frequency of various insomnia symptoms in terms of days per week. The BIS has good psychometric properties (Pallesen et al., 2008).

- **Anxiety Inventory:** The Trait Anxiety Inventory is widely used to measure anxiety (Spielberger, 2010). The short version of Anxiety Inventory contains 6 four-point Likert scale items. Trait anxiety items assess how subjects generally feel. Higher scores indicate more severe anxiety levels.

- **Perceived Stress Scale:** The Perceived Stress Scale (PSS) is the most widely used psychological instrument for measuring the perception of stress (Cohen et al., 1983). It is a measure of the degree to which situations in one's life are appraised as stressful. Items assess how unpredictable, uncontrollable, and overloaded respondents find their lives. The scale also assesses current levels of experienced stress.

- **Health-related Quality of Life:** The CDC Health-related Quality of Life measure was used to assess health-related quality of life (e.g., mental and physical health, sleep quality, pain level; Andresen et al., 2001). This scale has excellent psychometric properties (Zack et al., 2014).

Daily Diary: The participants also completed a brief daily diary regarding their nighttime sleep quality, mood, adherence, adverse events, and the dosing amount.

Intervention

The capsules contained 3mg THC, 6mg CBN,10mg CBD and 90mg proprietary terpene blend. To increase adherence and compliance to the intervention (i.e., consuming the supplement nightly) the participants received a nightly reminder to take the supplement 30 minutes prior to their nighttime sleep. Adherence to the supplement was monitored daily via the Daily Diary. Participants who were not complying with the intervention were contacted for feedback and further instruction. To maintain adherence to the assessments, multiple reminders were sent to participants who did not complete the surveys within 12 hours.

Lifestyle Behaviors

Participants were asked to maintain their current lifestyle behaviors and to not engage in any new forms of structured exercise or begin a new diet or health intervention for the duration of their participation in the pilot study.

Data Analysis

Data were analyzed for normality using Shapiro-Wilk Test and the skewness and kurtosis values of the scales. Descriptive statistics were expressed in Mean (SD) and percentage/count formats. Paired t-tests were used to analyze mean differences between PRE (Day 0) and POST (Day 7) scores (p's ≤ .05). The data were also analyzed categorically via nonparametric statistical tests (e.g., Chi-square analyses) and expressed as percentages and counts where appropriate. The data were analyzed using EXCEL and SPSS (Version 24).

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Results

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Health-related Quality of Life: Significant improvements from Pre to Post intervention were evidenced for general health, mental health, depressive symptoms, anxiety symptoms, sleep quality and feeling healthy and full of energy, $p < .05$ (see Table 2). There was an 83% positive change from Pre to Post intervention for sleep quality and a 75% positive change from Pre to Post intervention for feeling healthy and full of energy.

Insomnia Severity Index: Significant improvements in insomnia symptoms from Pre to Post intervention were evidenced, $p < .001$. More specifically, 83% of the participants had a positive change in insomnia symptoms from Pre to Post intervention (see Table 3). A significant improvement in participants

improving on the insomnia symptoms categories from Pre to Post intervention was also found, *p* = .01 (see Table 5).

Anxiety Inventory: Significant improvements in anxiety symptoms from Pre to Post intervention were evidenced, *p* = .001. More specifically, 75% of the participants had a positive change in anxiety symptoms from Pre to Post intervention (see Table 3).

Perceived Stress Scale: Significant improvements in perceived stress from Pre to Post intervention were evidenced, *p* = .008. More specifically, 67% of the participants had a positive change in perceived stress from Pre to Post intervention (see Table 3).

Bergen Insomnia Scale: Significant improvements in insomnia symptoms from Pre to Post intervention were evidenced, *p* < .001. Specifically, significant improvements were evidenced for night awakening between sleep periods, awakening earlier than wanted, getting enough sleep, feeling that sleep issues interfered with personal life, and sleep dissatisfaction, *p*'s < .05. A trend was evidenced for improved ability to fall asleep within 30 minutes of nighttime sleep, *p* = .06 (see Table 4).

Qualitative Post Responses: Most of the participants indicated that they plan to continue taking the capsules (*n* = 22, 92%) and felt that the capsules helped with their sleep (*n* = 22, 92%). See Table 6 for the qualitative responses to the question regarding *how the capsules helped their sleep*. See Table 7 for the open-ended Post feedback regarding Sanna.

Daily Diary Responses: Improvements were found for sleep quality, mood, energy level, productivity, and stress level by Day 2 of the intervention (See Table 8). See Table 10 for the open-ended feedback responses to the Daily Diary.

Adherence and Adverse Events: Adherence to taking the supplement daily was 99% and the adverse events were minimal (2%). Most participants took one capsule each night (70%) and reported not taking any other cannabis products (74%; see Table 9).

Tables

Table 1: Demographic Information

Item	Participants *N* = 24
Age	*M (SD)*
Average	49.20 (13.30)
Min Age	27.25 (13.30)
Max Age	67.63 (13.02)
Race/Ethnicity	**Number of participants**
Asian	1 (4%)
Hispanic/Latino	1 (4%)
White	22 (92%)
Educational Level	**Number of participants**
Graduated from high school	9 (37.5%)
Graduated from college	9 (37.5%)
Completed graduate school (master's, doctorate, MD, etc.)	6 (25%)
Employment Status	**Number of participants**
Working full-time	20 (83%)
Working part-time	1 (4%)
Retired	3 (13%)
Income	**Number of participants**
Less than $50,000	3 (13%)
$50,000 to $100,000	7 (29%)
Greater than $100,000	14 (58%)
Gender	**Number of participants**
Female	11 (46%)
Male	13 (54%)
Insomnia Scores	**Number of participants**
<8	0 (0%)
≥ 8	24 (100%)

Table 2: Descriptive and Statistical Information for the Health-related Quality of Life Measure

Item	Pre M (SD)	Post M (SD)	% Improve	Positive Change	Statistic: Paired Sample t-test
HRQoL-1 General Health	3.63 (1.01)	4.00 (0.78)	22%	33%	$t(23)$= -2.10, p = .047*
HRQoL-2 Physical Health Not Good	1.5 (1.93)	1.08 (2)	28%	38%	$t(23)$= 1.16, p = .260
HRQoL-3 Mental Health Not Good	3.13 (2.35)	1.83 (2.28)	34%	58%	$t(23)$= 2.26, p = .034*
HRQoL-4 Poor Health Prevented Activity	2.42 (2.57)	1.46 (2.6)	28%	42%	$t(23)$= 2.42, p = .024*
HRQoL-5 Pain Made Activities Hard	2.33 (2.87)	1.42 (2.45)	23%	38%	$t(23)$= 1.63, p = .116
HRQoL-6 Felt Sad, Blue, Depressed	2.67 (2.3)	1.46 (2.28)	50%	54%	$t(23)$= 2.17, p = .041*
HRQoL-7 Felt Worried, Tense, Anxious	4.04 (2.46)	2.38 (2.26)	36%	50%	$t(23)$= 3.47, p = .002*
HRQoL-8 Felt Did not Sleep Enough	5.33 (1.69)	2.33 (2.41)	55%	83%	$t(23)$= 5.96, p < .001#
HRQoL-9 felt Healthy/Full of Energy	1.71 (1.63)	4.17 (2.44)	155%	75%	$t(23)$= -4.85, p < .001#

Note: Higher scores on HRQoL-1 and HRQoL-9 = improvements in general health and number of days the person felt healthy and full of energy. Lower scores on HRQoL-2 to HRQoL-8 = improvements in health outcomes.

* = significant differences from Pre to Post at p < .05 level

= significant differences from Pre to Post at p < .01 level

Table 3: Descriptive and Statistical Information for the Insomnia Severity Index, Trait Anxiety Inventory, and Perceived Stress Scale

Item	Pre M (SD)	Post M (SD)	% Improve	Positive Change	Statistic: Paired Sample *t*-test
Insomnia Index	15.71 (4.16)	10.83 (5.67)	32%	83%	*t*(23)= 5.17, *p* < .001#
Anxiety	54.31 (10)	41.94 (15.1)	22%	75%	*t*(23)= 5.96, *p* = .001*
Perceived Stress	7.29 (2.9)	5.54 (2.86)	19%	67%	*t*(23)= 5.96, *p* = .008*

Note: Lower scores indicate improvements for insomnia, anxiety, and perceived stress levels.

* = significant differences from BL to Post at p < .05 level

= significant differences from BL to Post at p < .01 level

Table 4: Descriptive and Statistical Information for the Bergen Insomnia Scale

Item "How many days in the past week…"	Pre M (SD)	Post M (SD)	% Improv	Positive Change	Statistic: Paired Sample *t*-test
…has it taken you more than 30 min to fall asleep after the light was switched off?	2.96 (2.35)	1.63 (2.41)	22%	67%	*t*(23)= 2.75, *p* = .064
…have you been awake for more than 30 min between periods of sleep?	4.92 (2.48)	2.71 (2.2)	41%	67%	*t*(23)= 3.87, *p* = .001*
…have you awakened more than 30 min earlier than you wished without managing to fall asleep again?	4.83 (2.44)	2.75 (2.71)	49%	67%	*t*(23)= 3.52, *p* = .002*
…have you felt that you have not had enough rest after waking up?	5.29 (2.03)	3.04 (2.53)	24%	75%	*t*(23)= 3.10, *p* = .005*
…have you been so sleepy/tired that it has affected you at school/work or in your private life?	3.58 (2.28)	1.71 (2.1)	52%	75%	*t*(23)= 3.30, *p* = .003*
…have you been dissatisfied with your sleep?	5.29 (1.73)	2.5 (2.34)	39%	79%	*t*(23)= 5.43, *p* < .001#
Total Score	27.91 (8.66)	13.43 (11.90)	52%	79%	*t*(22)= 5.95, *p* < .001#

Note: Lower scores indicate an improvement in insomnia symptoms.

* = significant differences from BL to Post at p < .05 level

\# = significant differences from BL to Post at p < .01 level

Table 5: Descriptive and Statistical Information for the Insomnia Severity Index Categories

Insomnia Categories	Pre	Post	Statistic: Chi Square
No Clinical Insomnia (≤7)	0 (0%)	8 (33%)	
Subthreshold Insomnia (8-14)	9 (38%)	10 (42%)	Pre to Post: X^2=df(1), p = 0.005*
Moderate Clinical Insomnia (15-21)	13 (54%)	4 (17%)	
Severe Clinical Insomnia (22-28)	2 (8%)	2 (8%)	

* = significant differences from Pre to Post at $p < .05$ level

Table 6: Qualitative Post Responses Regarding the Capsules

Item (Participant Number)	Response
Plan to keep taking capsules	
Yes	22 (92%)
No	2 (8%)
Felt capsules helped sleep	
Yes	22 (92%)
No	2 (8%)
If yes, how did the capsules help with sleep?	
278	Fell asleep faster on most nights and stayed asleep
1122	I just felt my sleep was really good, and I was actually able to do through things that would normally wake me up or keep me awake
1198	I fell asleep faster. But did not stay asleep.
1209	The days after I started or increased dosage I felt worse than not taking it. A couple of days I slept slightly longer but felt worse during the day than usual.
1697	I felt the effect within the last 3 days of taking the capsules. I woke up later than I did before and felt better after waking up than usual.
1741	They made it so I was able to fall asleep faster and actually stay asleep for the whole night. I love these things
1866	I felt I was able to fall asleep quickly and stay asleep but still had trouble staying asleep throughout the night or waking up ealier than intended
2689	Stayed asleep and able to fall back asleep much easier.
3188	It seemed as though the first two or three nights it really helped. The dreams were crazy. Then… I don't know what happened. I think my life and what I am experiencing is just way larger than the effects your probably very helpful medication, provide.
4992	Definitely helped me aleep
5020	They are great
5154	Na
5177	I feel like they did have a slight positive effect. I'm going to start trying 3 instead of 2. Thinking the dosage is to weak for me
5639	Helped me sleep through the night. When I woke up to go to bathroom, I was able to go back to sleep quickly.
5834	I definitely noticed a difference in being able to stay asleep for much longer periods through the night. Normally I wake up 4 to 6 times a night to adjust to to back pain or lay in bed and worry about why details but even when I occasionally woke up in the night this past week, I was able to fall back asleep within a short time. For me it worked best to make sure I was going to have at least 7 to 8 hours to sleep and when this happened, I did not wake up feeling drowsy at all, which is a concern when taking any sleep aid.
5990	Slept great all but the last night for some reason.

6161	The first night of the test I didn't feel as much benefit as the last 5. As the test progressed I was feeling better and more rested. There was a night that I drank some beers and that didn't have a good outcome.
6443	The Sanna Sleep capsules were very helpful in my ability to fall asleep and to stay asleep. I plan to keep taking Sanna asleep after the study concludes.

Table 7: Additional Post Open Ended Feedback

ID Number	Additional Feedback Provided
278	Really like the product
1122	You guys should make an A.M capsule
1198	Make them a little more potent
1209	I would be curious to know if this product worked in a positive way for the others in the study.
2689	I do feel generally better since taking Sanna Sleep.
3188	No. I just feel guilty that Sanna didn't change my life.
5020	Love these!
5639	Some of the capsules exploded in my mouth before I could swallow them.
7951	Fantastic product!! Am telling all my friends!! We all have sleep issues!!!
8281	They were great! Thanks so much!

Table 8: Daily Diary Descriptive Statistics for Sleep Quality, Productivity, ad Mood-related Items

Item	Day 1 N = 21 M (SD)	Day 2 N = 20 M (SD)	Day 3 N = 23 M (SD)	Day 4 N = 22 M (SD)	Day 5 N = 17 M (SD)	Day 6 N = 19 M (SD)	Day 7 N = 4 M (SD)	Total N = 145 M (SD)
Sleep quality	5.29 (2.17)	6.25 (2.27)	7.14 (2.12)	6.62 (1.83)	7 (2.37)	7.06 (2.01)	5.5 (3.7)	6.64 (2.24)
Mood	6.05 (1.88)	6.45 (2.28)	6.86 (1.86)	6.67 (1.93)	7 (1.94)	7.11 (1.84)	6.5 (3.87)	6.8 (2.04)
Energy level	5.52 (1.78)	6.3 (1.78)	6.32 (1.96)	6.76 (1.76)	6.76 (1.99)	6.5 (2.5)	5.25 (3.77)	6.41 (2.1)
Productivity	6.19 (1.5)	6.35 (1.66)	6.91 (1.6)	6.81 (1.69)	7.12 (2.06)	6.39 (2.66)	5.75 (3.5)	6.7 (1.95)
Stress level	4.71 (1.93)	4.35 (2.08)	3.82 (2.36)	3.95 (2.06)	4.18 (2.04)	4 (2.22)	5.75 (4.03)	4.13 (2.2)

Note: Higher scores for sleep quality, mood, energy level, and productivity indicate an improvement.
Lower scores on stress level indicate an improvement.

Table 9: Daily Diary Adherence, Adverse Events, Cannabis Product Use, and Sleep Improvement

Took Capsules	
Yes	143 (99%)
No	2 (1%)
Number of capsules took at night	
0	2 (1%)
1	102 (70%)
2	40 (28%)
3	1 (1%)
Adverse Events	
Yes	3 (2%)
No	142 (98%)
Took other cannabis products	
Yes	37 (26%)
No	108 (74%)
Sleep improved since taking product	
Yes	110 (76%)
No	35 (24%)

Table 10: Daily Diary feedback

| Open-Ended Response		Open-Ended Response
What is you ID number?	Date	Is there any feedback you would like to provide regarding the Sanna Sleep capsules?
Participant 1		
278	10/19/20	Sleep more sound!!
	10/20/20	Wow. Much better sleep —- fall asleep faster and stay asleep
	10/21/20	All good
Participant 2		
1122	10/18/20	Very good product
	10/19/20	Good product
	10/21/20	Good Product
Participant 3		
1198	10/20/20	Last night was my best sleep yet. I only woke up once to go to the head. And fell back a sleep quickly.
	10/21/20	I only woke up once and fell back asleep more quickly and slept a extra hour.
	10/22/20	I have had 2 good nights of sleep so far. Last night was rough only 3 good hours.
	10/23/20	I get dry mouth
Participant 4		
1209	10/20/20	I have not seen improved sleep quality or quantity since I started taking the product.
	10/22/20	I took two capsules for the first time. I did sleep an extra hour, but I didn't wake up naturally as the dog woke me. I didn't feel good upon waking. I will try two capsules again.
Participant 5		
1697		I felt like the capsules makes it difficult for me to get out of bed in the morning.
Participant 6		
1741	10/18/20	I notice that I wake up way less throughout the night and wake up later which is good
Participant 7		
1866	10/23/20	Vivid dreams
	10/28/20	I fall asleep great, but still have some trouble staying asleep for a long time.
Participant 8		
2689	10/20/20	Capsules were stuck together so probably sat in a hot spot during transport.
Participant 9		
3188	10/18/20	The dreams are crazy. But, I still wake up in the middle of the night, but instead of being awake for two hours that has easily been cut in half. I go back to sleep much more easily. It seems to me.
	10/18/20	I said this already but… The dreams are crazy. The biggest thing I notice is when I wake up I am not awake for two or more hours. I am only awake an hour to maybe an hour and 15 minutes.

	10/19/20	I still wake up in the middle of the night but I'm not awake as long. The capsule also makes me feel a little trippy. But that's OK. But it makes me feel a little nervous about taking two. I'll probably do that tomorrow night.
	10/19/20	The dreams are crazy. Some nightmares. I've had them before but.. I'm living movies every night. Some good, some bad. A little gastrointestinal
	10/21/20	I tried 2 capsules. Left a little out of it when I woke up. I'll go back to one. The dreams are crazy.
	10/23/20	The last 2 nights I had a noticeable change. I don't know that it is a result of your product. But I awoke at 1 AM both nights and was awake until at least four or 430. That has not happened to me before. Lot of other variables… My life… But still it was very different from the first two or three nights of the study.
Participant 10		
4992	10/18/20	The only adverse effect was being very thirsty
Participant 11		
5154	10/20/20	I feel drowsy when I wake up.
Participant 12		
5639	10/21/20	Bad night. Woke up at 3 and didn't get back to sleep, which is my old sleep pattern.
Participant 13		
5834	10/18/20	Usually I wake up multiple times a night and last night I slept 5 hours, woke up once, then slept 4 more hours!
Participant 14		
6161	10/22/20	Starting to notice a more restful, full nights sleep....encouraging.
	10/23/20	I am experiencing results that are making me pleased with the product. I will want to continue with them past the 7 day study.
	10/24/20	I have a beer or two to many in the evening and feel the alcohol massed with my sleep.
Participant 15		
7575	10/21/20	I feel less anxious in the morning.
Participant 16		
7951	10/18/20	When I take the capsules 30 minutes prior to sleep I fall asleep and stay asleep for at least 6 hours. This has never happened since I had children. My kids are grown but always still had sleep issues. This is a game changer for me
	10/19/20	Feeling better.
	10/20/20	2 seemed to help a bit better. Will try that again tonight!!
Participant 17		
8281	10/18/20	I slept a little lighter than usual taking melatonin or other products. But it did help me feel sleepy about 30 minutes after taking it.
	10/19/20	Unfortunately, I put my back out playing pickle ball yesterday so I had to take a little bit of pain pills as well.
	10/20/20	I smoked a little sativa dominant hybrid Cannabis about three hours before bed. So I am saying that I did not take it before bed I had a bad reaction to some pain medication yesterday and was ill all day. I also took a Tylenol p.m.

		to help with pain during the night. But I had the best night sleep so far! Tylenol p.m. doesn't usually help me sleep very well.
	10/21/20	This is the first night I took only the sauna sleep capsule. I went to bed around 1130 and woke up at around 4 AM could not get back to sleep.
	10/22/20	I also took a Tylenol p.m. for back pain.
Participant 18		
9344	10/18/20	It had the opposite impact. I was wired and tripping hard from this product. I was up most of the night and am still stoned.. no longer tripping my face off but high none the less. With some assistance I was able to manage to make it a somewhat ok experience but this could really Cause harm to someone who has had less life experience or less support in their life. W/o my late night call to a friend who I've known for decades and who was able to recalibrate my unexpected medicine journey I would have been quite fucked honestly.

FIGURE 1: Participant Flow Chart
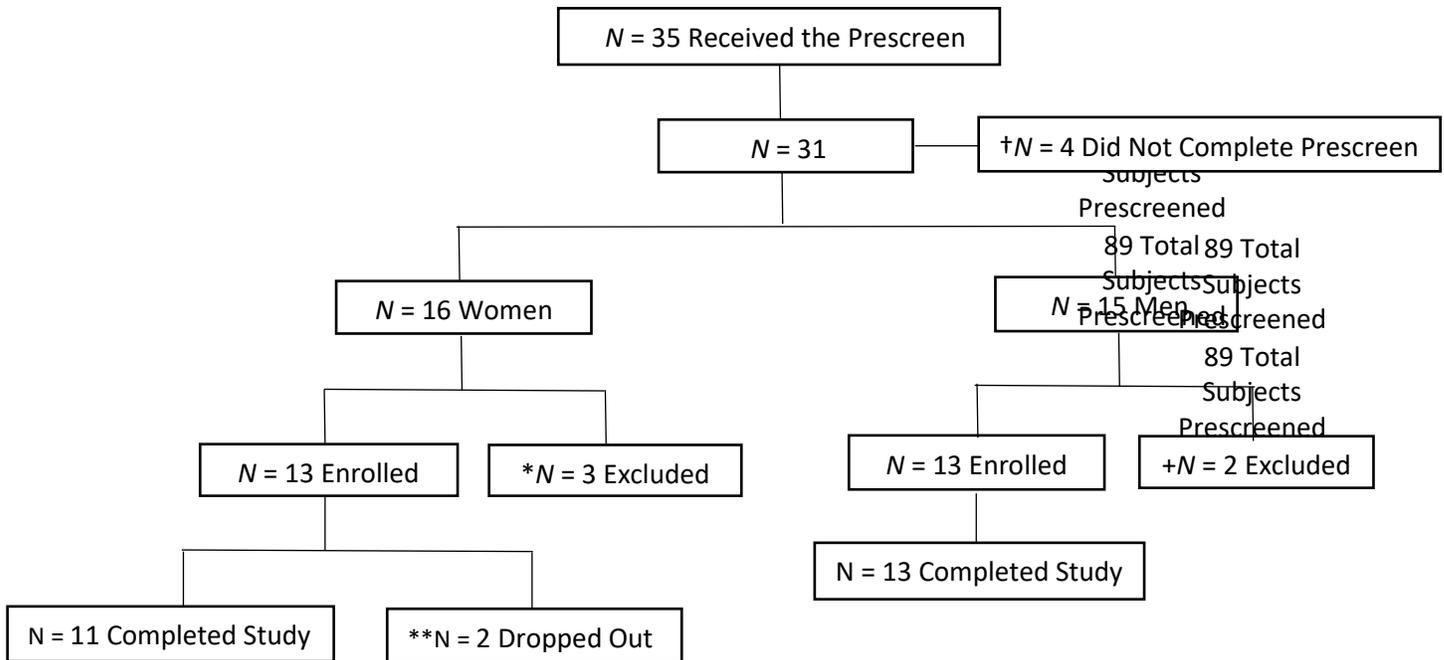
Note: †N = 4 (n =2 women, n = 2 men) did not complete the prescreen survey

*N = 3 excluded because they did not meet the inclusion criteria or declined to participate (N = 1 excluded due to high BMI, N = 1 excluded for scoring too low on insomnia index, N = 1 decided not to participate)

** N = 2 dropped out (N = 1 due to delayed capsule delivery, N = 1 had an adverse event from taking capsules)

+ N = 2 excluded or declined (N = 1 excluded because stopped responding after prescreen, N = 1 decided not to participate)