<table>
<tr><th colspan="2">Study Summary</th></tr>
<tr><td>Title</td><td>A Study to Evaluate the Effects of Relaxium in Subjects with Sleep Disorders</td></tr>
<tr><td>Protocol Number</td><td>ABRI-002</td></tr>
<tr><td>Sponsor</td><td>American Behavioral Research Institute</td></tr>
<tr><td>Clinical Site</td><td>Center For Wellness, 4242 North Federal Hwy B-C, Fort Lauderdale, FL</td></tr>
<tr><td>Methodology</td><td>Double-blind, randomized, placebo-controlled, parallel group</td></tr>
<tr><td>Objective</td><td>To evaluate the efficacy of a nutritional supplement to improve sleep patterns and related sequelae.</td></tr>
<tr><td>Number of Subjects</td><td>40 (planned to complete); 37 were randomized and 35 completed the study. Two subjects left the study and could not be reached for follow-up.</td></tr>
<tr><td>Population</td><td>Male and Female subjects</td></tr>
<tr><td>Duration</td><td>2 Weeks (Screening/ Baseline Week 1; Blinded Week 2)</td></tr>
<tr><td>Study Drug/Frequency/Reference</td><td>• Relaxium Sleep, 2 capsules at bedtime x 1 week
• Placebo, 2 capsules at bedtime x 1 or 2 weeks</td></tr>
<tr><td>Study Design</td><td>This was a randomized, double blind, placebo controlled, parallel group study in subjects with insomnia. After qualifying for the study, subjects had a 1-week lead-in period with placebo, and subjects completed daily sleep diaries [each morning for the quality of their sleep for the previous night (QoN), each evening the overall quality of day (QoD), including levels of daytime energy and concentration] and completed the Leeds Sleep Evaluation Questionnaire (LSEQ) which was a visual analog scale (VAS on an 80 mm line) to indicate their quality of sleep (QoS), getting to sleep (GTS), behavior following awakening (BFW), awake following sleep (AFS) on the last 3 days of the treatment period. Subjects were then randomized 1:1 to placebo or Relaxium in a double-blind manner for another week (Week 2). The daily diaries and LSEQ evaluations were repeated as in the Lead-in period (Week 1). As an exploratory endpoint subjects had wrist actigraphy (Fitbit Inspire) daily during sleep to assess quality and sleep duration over each period.</td></tr>
<tr><td>Statistical Methodology</td><td>Descriptive statistics reported for diary responses, LSEQ and sleep time [total, time in bed, time awake, light, deep and rapid eye movement (REM)] for subjects with data in both treatment periods for diary responses and LSEQ, analysis of variance was done to evaluate the statistically differences between placebo and Relaxium. Fisher's exact time was used to evaluate the number of days with no difficulty in concentration during blinded medication. Statistical significance was declared at $p \leq 0.05$.</td></tr>
<tr><td>Results</td><td>Based on the LSEQ, a validated test for sleep, Relaxium treatment resulted in improved sleep, compared to placebo treatment. The mean differences the treatments expressed as changes from baseline are shown in the following table. Higher scores represent better quality of sleep (calmer, less wakeful periods), easier time getting to sleep, easier to awake, and more alert following wakening.

Changes in LSEQ

<table>
<tr><th>Parameter</th><th>Mean Treatment Difference (mm) From Baseline (Lead -in Period Week 1) to Blinded Treatment (Week 2) Between Relaxium and Placebo Groups</th><th>P value</th></tr>
<tr><td>QoS</td><td>12.3</td><td>0.002</td></tr>
<tr><td>GTS</td><td>12.2</td><td>0.006</td></tr>
<tr><td>BFW</td><td>10.2</td><td>0.028</td></tr>
<tr><td>AFS</td><td>10.4</td><td>0.034</td></tr>
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The significantly higher scores indicate better sleep and easier awakening with Relaxium compared to placebo.

The daily diary responses on a 5-point severity for level of daytime energy and ability to concentrate were also improved with Relaxium compared to placebo, but only the difference in daytime concentration was statistically significant.

The changes in quality of sleep or mood were not statistically different between the two treatments.

Changes in Daily Diary Responses

Parameter	Mean Treatment Differences From Baseline in Diary Scores Between Relaxium and Placebo Groups	P value
QoN	-0.36	0.162
QoD Q1	0.1621	0.089
QoD Q2	-0.53	0.058
QoD Q3	0.79	0.002

QoD Q1 = level of daytime energy today; QoD Q2 = mood level
QoD Q3 = level of difficulty in concentration; QoN= quality of sleep last night

The number of days that subjects reported no difficulty in concentration was 21% for placebo and 38% on Relaxium treatment during blinded treatment. The difference between the 2 groups was statistically significant ($p = 0.013$). Thus, there was about an 80% increase in the number of days the subjects reported no difficulty in concentration, compared to placebo.

For the wearable technology (Fitbit Inspire) there were no changes from baseline in time in bed, time asleep, time awake, light sleep, deep sleep, and REM sleep) for placebo and Relaxium treatments.

Summary

In subjects with insomnia, Relaxium treatment improved various parameter related to sleep, compared to subjects treated with placebo. The improvements included:

- easier time to fall asleep
- sleep was calmer with less wakeful periods
- awakening following sleep, was easier
- improved alertness after awakening

Furthermore, subjects had less difficulty in concentration during the day. All of these changes were statistically significant.

No adverse events were reported in this study.