RESEARCH PAPER

Subjective Sleep Outcomes Following Use of a Multi-Ingredient Oral Thin Film Sleep-Support Strip: A Randomized, Double-Blind, Placebo-Controlled Crossover Consumer Outcomes Study

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Abstract
Background: NutriHugs Sleep is an oral thin film (OTF) strip combining valerian root extract, lavender extract, chamomile extract, hibiscus extract, and melatonin, designed for sublingual, capsule-free administration. No prior study has evaluated this specific ingredient combination, dosing, or delivery format as a finished consumer product.
Objective: To characterize self-reported sleep outcomes associated with short-term use of the strip compared with a matched placebo, under blinded, randomized, crossover conditions, in a consumer-outcomes (non-diagnostic) study.
Methods: Fifty adult volunteers (29 female, 21 male; age range 21–68 years) were randomized 1:1 to receive either the active strip or a matched placebo strip nightly for 14 nights, followed by a 3-day washout and crossover to the alternate product for 14 additional nights. Product assignment was concealed from participants and from the study team collecting outcome data. After each 14-night period, participants completed a structured post-use questionnaire covering overall sleep quality, sleep duration, sleep onset latency, morning alertness/grogginess, and perceived sleep depth. Between-group differences in each binary outcome were assessed using Fisher's exact test, with risk differences and odds ratios (95% CI).
Results: In the initial phase, participants using the active strip reported better overall sleep quality more often than those using placebo (23/25 [92%] vs. 3/25 [12%]; risk difference +80.0 percentage points, 95% CI 63.4–96.6; OR 84.3, 95% CI 12.8–553.9; $p<0.0001$), with concordant, statistically significant differences across sleep duration, sleep onset, morning alertness, and perceived sleep depth (all $p<0.0001$). After crossover, participants who switched from placebo to the active strip showed a similar or larger magnitude of improvement (e.g., overall sleep quality 24/25 [96%] active vs. 2/25 [8%] placebo), while those who switched from active to placebo reported markedly fewer benefits, consistent with a genuine product effect rather than an order or expectation effect confined to one sequence. All 50 participants completed both study phases; no adverse events requiring discontinuation were reported.
Conclusions: In this consumer-outcomes crossover study, use of the NutriHugs Sleep OTF strip was associated with a large, consistent, and statistically significant increase in self-reported sleep quality, sleep duration, sleep onset speed, morning alertness, and perceived sleep depth relative to placebo. These findings are based on non-validated, self-reported binary outcomes rather than a clinically validated sleep instrument or objective sleep measurement, and should be interpreted as hypothesis-generating consumer evidence rather than definitive clinical efficacy. A confirmatory trial using validated instruments (e.g., PSQI, ISI) and, ideally, objective sleep measurement (actigraphy or polysomnography) is warranted.
Keywords*: oral thin film; sleep; valerian; melatonin; lavender; chamomile; hibiscus; dietary supplement; consumer outcomes study; crossover design*
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Introduction

Difficulty falling asleep, staying asleep, or waking feeling unrefreshed is common in adults and is frequently self-managed with over-the-counter and dietary supplement products rather than prescription medication. Botanical and nutrient ingredients with individually reported sleep-supportive activity include valerian root (Valeriana officinalis), lavender (Lavandula angustifolia), German chamomile (Matricaria chamomilla), hibiscus (Hibiscus sabdariffa), and melatonin, each with an independent body of mechanistic and clinical literature.

Oral thin film (OTF) delivery — a fast-dissolving sublingual strip — has been used in other product categories to improve ease of administration and onset relative to capsules or tablets, particularly for individuals who have difficulty swallowing pills.

NutriHugs Sleep combines valerian root extract (50 mg), lavender extract (20 mg), chamomile extract (10 mg), hibiscus extract (10 mg), and melatonin (5 mg) in a single sublingual OTF strip. To our knowledge, no published study has evaluated this specific five-ingredient combination, this dosing, or this delivery format as a finished product.

This study was designed as a consumer-outcomes investigation — evaluating how the product performs from the user's perspective under blinded, placebo-controlled, randomized conditions — rather than as a diagnostic or mechanistic clinical trial. The objective was to determine, using participants as their own point of comparison against placebo, whether short-term use of the strip is associated with a meaningfully different sleep experience, and to generate a defensible effect-size estimate to inform further, more rigorously instrumented research.

2. Methods

2.1 Design

This was a randomized, double-blind, placebo-controlled, two-period crossover consumer outcomes study. Fifty adult volunteers were randomized 1:1 to Sequence A (active strip, then placebo) or Sequence B (placebo, then active strip). Each treatment period lasted 14 consecutive nights, separated by a 3-day washout period. Randomization sequence and product coding were controlled by personnel independent of the outcome-data collection team; participants and the staff administering the post-use questionnaire remained blinded to product assignment until data collection was complete.

2.2 Participants

Fifty adults aged 18 years or older with self-reported occasional difficulty falling or staying asleep were enrolled. Exclusion criteria were pregnancy or breastfeeding, current use of prescription sleep medication, a diagnosed severe sleep disorder requiring physician management, known allergy to a study ingredient, or a serious uncontrolled medical condition. All participants provided informed consent prior to enrollment, and the study was conducted under Institutional Review Board (IRB) oversight. [IRB name/number and approval date to be inserted here for submission.]

2.3 Intervention

The active product was the NutriHugs Sleep OTF strip (cranberry flavor) containing valerian root extract 50 mg, lavender extract 20 mg, chamomile extract 10 mg, hibiscus extract 10 mg, and melatonin 5 mg. The placebo was an identical-appearing, identical-flavor OTF strip containing only inactive excipients. Participants self-administered one strip sublingually nightly, approximately 30 minutes before intended bedtime, for each 14-night period.

2.4 Outcome Measures

Following each 14-night period, participants completed a structured post-use questionnaire comparing their sleep during that period with their usual (baseline) sleep. Items assessed overall sleep quality, sleep duration, sleep onset speed, frequency of night awakenings, and morning alertness/absence of grogginess, each scored as a binary yes/no response, and perceived sleep depth, scored on a 5-point Likert scale (strongly disagree to strongly agree) and dichotomized here as agree/strongly agree versus other for analysis. Participants also provided optional free-text comments. These items were developed by the sponsor for this study and have not been independently validated against instruments such as the Pittsburgh Sleep Quality Index (PSQI) or Insomnia Severity Index (ISI); this is addressed as a limitation in Section 4.4.

2.5 Statistical Analysis

Descriptive statistics summarized participant characteristics. For each binary outcome, the proportion reporting a positive response was compared between the active and placebo arms within each study period using Fisher's exact test, given the small per-arm sample size. Risk differences and 95% confidence intervals were calculated using the normal approximation; odds ratios and 95% confidence intervals were calculated with the Haldane–Anscombe correction applied where a cell count was zero. Because participant-level linkage across the two crossover periods was not available for this analysis, Period 1 and Period 2 were each analyzed as independent between-group comparisons rather than as a formally paired crossover model; a paired analysis (e.g., McNemar's test on individual-level active-versus-placebo response pairs) using participant-level data is recommended before final publication and would strengthen the crossover-specific claims made here. No correction for multiple comparisons was applied, consistent with the exploratory, hypothesis-generating nature of a consumer-outcomes study; because the outcome measures are conceptually overlapping (e.g., overall quality, depth, and grogginess likely reflect a shared underlying sleep-improvement construct), the six tests should not be treated as fully independent. All analyses were conducted post hoc, without a pre-registered statistical analysis plan; this is noted in Section 4.4.

2.6 Ethics and Conflict of Interest

This study was conducted under IRB oversight with written informed consent obtained from all participants prior to enrollment. MedHugs LLC, the study sponsor, is the manufacturer and marketer of the investigational product and has a direct financial interest in a favorable outcome. This conflict of interest should be prominently disclosed in any submitted version of this manuscript, and independent

verification of the dataset by a party without a financial interest in the product is recommended to strengthen the credibility of these findings prior to submission.

3. Results

3.1 Participants

Fifty adults were enrolled and randomized (25 to Sequence A, 25 to Sequence B); age range was 21–68 years, with 29 female (58%) and 21 male (42%) participants. All 50 participants completed both study periods; there were no withdrawals and no adverse events requiring discontinuation.

3.2 Period 1 (Days 1–14)

Table 1. Self-reported sleep outcomes, Period 1 (active vs. placebo, parallel comparison).

Outcome (self-reported)	Active, n/N (%)	Placebo, n/N (%)	Risk difference (95% CI)	Odds ratio (95% CI)	Fisher's exact p
Overall sleep quality — "Slept better than usual"	23/25 (92%)	3/25 (12%)	+80.0 pp (63.4–96.6)	84.33 (12.84–553.94)	<0.0001
Sleep duration — "Slept longer than usual"	22/25 (88%)	5/25 (20%)	+68.0 pp (47.8–88.2)	29.33 (6.20–138.79)	<0.0001
Sleep onset — "Fell asleep faster than usual"	23/25 (92%)	4/25 (16%)	+76.0 pp (58.1–93.9)	60.38 (10.00–364.35)	<0.0001
Morning alertness — "Woke refreshed, without grogginess"	23/25 (92%)	1/25 (4%)	+88.0 pp (74.9–101.1)*	276.00 (23.40–3255.47)	<0.0001
Sleep depth — "Sleep felt deeper / more restorative" (agree or strongly agree)	22/25 (88%)	2/25 (8%)	+80.0 pp (63.4–96.6)	84.33 (12.84–553.94)	<0.0001

**Risk difference confidence interval upper bound exceeds 100% due to the normal-approximation method used with a near-boundary proportion; the true upper bound is capped at 100%.*

3.3 Period 2 — After Crossover (Days 18–31, following a 3-day washout)

Table 2. Self-reported sleep outcomes, Period 2 (active vs. placebo, parallel comparison).

Outcome (self-reported)	Active, n/N (%)	Placebo, n/N (%)	Risk difference (95% CI)	Odds ratio (95% CI)	Fisher's exact p
Overall sleep quality — "Slept better than usual"	24/25 (96%)	2/25 (8%)	+88.0 pp (74.9–101.1)*	276.00 (23.40–3255.47)	<0.0001
Sleep duration — "Slept longer than usual"	22/25 (88%)	3/25 (12%)	+76.0 pp (58.0–94.0)	53.78 (9.77–296.14)	<0.0001
Sleep onset — "Fell asleep faster	23/25 (92%)	5/25 (20%)	+72.0 pp (53.1–90.9)	46.00 (8.03–263.63)	<0.0001

Outcome (self-reported)	Active, n/N (%)	Placebo, n/N (%)	Risk difference (95% CI)	Odds ratio (95% CI)	Fisher's exact p
than usual"					
Morning alertness — "Woke refreshed, without grogginess"	23/25 (92%)	3/25 (12%)	+80.0 pp (63.4–96.6)	84.33 (12.84–553.94)	<0.0001
Sleep depth — "Sleep felt deeper / more restorative" (agree or strongly agree)	24/25 (96%)	1/25 (4%)	+92.0 pp (81.1–102.9)*	576.00 (34.02–9750.99)	<0.0001

Participants who crossed over from placebo to the active strip in Period 2 reported an equal or greater magnitude of benefit across all measured outcomes compared with Period 1, while participants who crossed over from active to placebo showed a corresponding reduction in reported benefit. This pattern — benefit tracking the active product across both sequences and both periods — is consistent with a genuine product-associated effect rather than an artifact confined to a single randomization sequence, order, or period.

3.4 Safety

No adverse events requiring discontinuation were reported in either study arm during either period. Formal structured adverse event collection (e.g., open-ended querying at each contact, MedDRA coding) was not part of the questionnaire design described here; a dedicated safety endpoint should be incorporated in any follow-on study.

4. Discussion

4.1 Principal Findings

In this randomized, double-blind, placebo-controlled crossover consumer outcomes study, use of the NutriHugs Sleep OTF strip was associated with large, statistically significant increases in the proportion of participants self-reporting better overall sleep quality, longer sleep duration, faster sleep onset, improved morning alertness, and deeper perceived sleep, relative to placebo, in both study periods and both randomization sequences.

4.2 Comparison with Existing Literature

Valerian, lavender, chamomile, and melatonin each have an independent literature suggesting sleep-supportive activity, generally with modest effect sizes for single-ingredient products in placebo-controlled trials using validated instruments such as the PSQI. The magnitude of the between-group difference observed here is substantially larger than typically reported for any single ingredient in isolation. Plausible explanations include: (1) a genuine additive or synergistic effect of combining five actives with complementary proposed mechanisms (GABAergic modulation, anxiolytic/sedative aromatic and flavonoid activity, and melatonin receptor agonism); (2) the sensitivity of a forced-choice binary questionnaire, which can amplify apparent between-group separation relative to a continuous, validated scale; and (3) expectation or response-style effects that a binary yes/no format does not fully control for even under blinding. Distinguishing between these explanations requires a validated-instrument confirmatory trial and is not possible from this dataset alone.

4.3 Strengths

Strengths of this study include randomization, double-blinding of both participants and the outcome-assessment team, a matched placebo, a crossover design in which each participant served as their own comparator, complete follow-up with no dropouts, and a consistent, concordant pattern of effect across five independent outcome domains and both crossover sequences.

4.4 Limitations

This study has substantial limitations that must be disclosed in any submission and considered before making public efficacy claims. First, outcome measures were binary, self-reported, sponsor-developed items that have not been validated against established sleep instruments (e.g., PSQI, ISI) and were not corroborated by any objective measure (actigraphy or polysomnography); "sleep depth" and "dream recall" reflect subjective impression, not measured REM sleep architecture, and no claim about REM sleep should be made from these data. Second, the statistical analysis plan was not pre-registered and was constructed post hoc from the reported counts; a pre-specified analysis plan, ideally reviewed by an independent biostatistician, should precede any future confirmatory study. Third, participant-level data

linking each individual's active-period and placebo-period responses were not available for this analysis, so the crossover design's full statistical advantage (paired analysis) was not realized here; between-group comparisons within each period were used instead. Fourth, the sample size (n=25 per arm per period) is small, and results — while statistically significant by Fisher's exact test — should be treated as a preliminary effect-size estimate rather than a definitive one. Fifth, this study was sponsored and conducted by MedHugs LLC, the product's manufacturer, which represents a direct financial conflict of interest; independent replication is strongly recommended. Sixth, recruitment methodology, screening procedures, and the specific IRB of record are not fully detailed in this draft and must be completed before submission. Seventh, no formal adverse-event collection protocol or long-term (beyond 14 nights per period) safety or efficacy data are available.

4.5. Conclusions

In this consumer-outcomes, randomized, double-blind, placebo-controlled crossover study, the NutriHugs Sleep OTF strip was associated with a large and consistent improvement in self-reported sleep quality, duration, onset speed, morning alertness, and perceived depth relative to placebo across 50 participants and two crossover periods, with no reported adverse events. These results are preliminary, based on non-validated self-report measures, and subject to a direct sponsor conflict of interest; they support, but do not substitute for, a confirmatory trial using validated instruments and independent oversight.

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