

Evaluation of a cosmetic cream to improve skin tone, barrier function and hydration in adults with long-term insufficient or delayed sleep

Submission date 09/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 13/10/2026	Overall study status Completed	☐ Protocol
Last Edited 12/10/2026	Condition category Skin and Connective Tissue Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☒ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Public, Scientific, Principal investigator

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Study information

Scientific Title

Skin effects of a cream containing α -arbutin, ethyl ascorbic acid, and madecassoside in adults with chronic sleep insufficiency and circadian disruption: a two-phase study of acute sleep deprivation challenge and real-world home use

Study objectives

The study recruits a single cohort of adults with chronic sleep insufficiency and circadian disruption, drawn from two groups: non-lactating mothers of infants and toddlers, and professional live-stream broadcasters. Participants complete a two-phase study. Phase I is a randomised, evaluator-blinded split-face challenge: one hemiface receives the test cream immediately before a 12-hour supervised acute sleep deprivation (ASD) challenge, and the contralateral hemiface remains untreated; after the challenge, a single application is made to the previously untreated hemiface. Phase II is an open-label period of twice-daily home use of the test cream for 28 days. The main objectives are as follows:

1. To evaluate whether pre-application of the test cream attenuates the deterioration in skin colour and gloss observed on the untreated hemiface during the 12-hour supervised ASD challenge.
2. To quantify the immediate change in skin colour and gloss 5 minutes after a single post-challenge application to the previously untreated hemiface.
3. To evaluate changes in skin barrier function (TEWL), hydration, pigmentation, skin colour, gloss, and participant-reported appearance during 28 days of twice-daily real-world home use.
4. To assess the cutaneous tolerability of the test cream throughout the study.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 31/10/2025, Intertek China Healthcare & Beauty Products Ethics Committee (4F, No.5 lane 2028, Changzhong Road, Shanghai, 200435, China; +86 (0)21 53397896; bill.zeng@intertek.com), ref: 017

Primary study design

Interventional

Allocation

N/A: single arm study

Masking

Open (masking not used)

Control

Uncontrolled

Assignment

Single

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied

Adults with chronic sleep insufficiency and circadian disruption

Interventions

This is a single-cohort study comprising a randomised, evaluator-blinded split-face challenge followed by an open-label single-arm treatment phase. The study design is classified according to the single-assignment phase because all participants remain in one cohort and the main outcomes come from Phase II.

Test product: a cosmetic face cream containing alpha-arbutin, ethyl ascorbic acid and madecassoside.

Phase I (split-face challenge): Participants attended the study centre individually between 18:00 and 23:00. After baseline (T0) assessments, performed following standardised facial cleansing and a 30-minute acclimation period, 0.3 ml of the test cream was applied to one randomly assigned hemiface with gentle circular massage until complete absorption; the contralateral hemiface received no product. Participants then remained awake at the centre under continuous supervision for 12 hours. Post-deprivation assessments (T1) were performed the following morning with the cream remaining on the treated hemiface. Immediately after T1, 0.3 ml of the cream was applied to the previously untreated hemiface, and final assessments (T2) were performed 5 minutes later.

Phase II (28-day real-world home use): Phase II commenced immediately after Phase I with no washout period; the Phase II baseline (D0) coincided with the Phase I baseline (T0). Participants self-applied the test cream to the entire face twice daily (morning and evening) after routine cleansing for 28 consecutive days. Only habitual facial cleanser, the test cream and habitual sunscreen were permitted; all other functional skincare products and interfering topical medications were prohibited. Participants attended visits at D0, D7 and D28; assessments were performed after standardised cleansing, with no skincare products applied on the day of each visit until all assessments were completed.

Randomisation method (within-subject, split-face): The hemiface allocation sequence was prepared in advance by an independent statistician who was not involved in participant recruitment or outcome assessment. According to the pre-generated sequence, one hemiface received the test cream and the contralateral hemiface remained untreated. This within-subject randomisation minimises inter-individual variability and hemiface-related bias when comparing the treated and untreated sides.

Blinding: The study was open-label with respect to Phase II. In the Phase I split-face comparison, outcome assessors were blinded to hemiface allocation; participants were aware of which hemiface was treated.

Intervention Type

Other

Primary outcome(s)

1. Transepidermal water loss (TEWL) measured using a Tewameter TM300 (Courage + Khazaka, Germany) at baseline (D0), 7 days (D7) and 28 days (D28) after product application
2. Melanin index (MI) measured using a Mexameter MX18 (Courage + Khazaka, Germany) at baseline (D0), 7 days (D7) and 28 days (D28) after product application

Key secondary outcome(s)

1. Skin colour parameters (lightness L*, redness a*, yellowness b*, individual typology angle [ITA°]) measured using spectrophotometer CM-26dG (Konica Minolta, Japan) at baseline (T0), after the 12-hour supervised acute sleep deprivation challenge (T1) and 5 minutes after product application (T2) in Phase I, and at baseline (D0), 7 days (D7) and 28 days (D28) after product application in Phase II
2. Skin gloss measured using Glossometer GL200 (Courage + Khazaka, Germany) at baseline (T0), after the 12-hour supervised acute sleep deprivation challenge (T1) and 5 minutes after product application (T2) in Phase I, and at baseline (D0), 7 days (D7) and 28 days (D28) after product application in Phase II
3. Skin hydration measured using Corneometer CM825 (Courage + Khazaka, Germany) at baseline (D0), 7 days (D7) and 28 days (D28) after product application
4. Skin smoothness (SEsm) measured using Visioscan VC20plus (Courage + Khazaka, Germany) at baseline (D0), 7 days (D7) and 28 days (D28) after product application
5. Skin translucency (K value) measured using Translucency Meter TLS850 (Dia-Stron, United Kingdom) at baseline (D0) and 28 days (D28) after product application
6. Dermatologist-graded skin tone evenness, gloss, yellowness, smoothness and complexion measured using ordinal grading scales at baseline (D0), 7 days (D7) and 28 days (D28) after product application
7. Participant-reported moisturization, skin tone evenness, gloss, smoothness, dullness and yellowness measured using 10-point numeric rating scales at baseline (D0), 7 days (D7) and 28 days (D28) after product application

Completion date

31/12/2025

Eligibility

Key inclusion criteria

1. Healthy participants aged 18 to 55 years
2. Chronic sleep insufficiency and circadian disruption for at least the preceding 6 months, defined as habitual late bedtime (sleep onset at or after 00:00 on ≥ 5 nights per week) and/or insufficient sleep duration (< 6 hours per night)
3. Membership of one of two prespecified subgroups: (a) non-lactating mothers of infants and toddlers (children aged ≤ 2 years) with nocturnal sleep fragmentation attributable to child care; or (b) professional live-stream broadcasters with chronic late bedtime, irregular sleep schedules, or insufficient sleep duration attributable to occupational demands
4. Self-perceived facial dullness or uneven skin tone
5. Screening cheek-site measurements within predefined thresholds: individual typology angle (ITA°) 20° – 40° , transepidermal water loss (TEWL) ≥ 15 g/m²/h, and stratum corneum hydration ≤ 60 Corneometer units (c.u.)
6. Willingness to maintain habitual sleep patterns throughout the study
7. Completion of structured baseline sleep questionnaires, including the Pittsburgh Sleep

Quality Index (PSQI) and the Perceived Stress Scale-10 (PSS-10)

8. Able to understand the trial procedures, take part voluntarily and provide written informed consent

Healthy volunteers allowed

Yes

Age group

Adult

Lower age limit

18 Years

Upper age limit

55 Years

Sex

All

Total final enrolment

38

Key exclusion criteria

1. Pregnant or lactating women
2. Systemic medical conditions contraindicating overnight wakefulness, such as uncontrolled hypertension, coronary artery disease, cardiac arrhythmia, insulin-dependent diabetes mellitus, or autoimmune disease
3. Active facial dermatosis, allergic skin disease, known hypersensitivity to cosmetic ingredients, or photosensitivity disorders
4. Use of topical or systemic agents affecting skin colour, barrier function, or inflammation (e.g., retinoids, hydroxy acids, corticosteroids, depigmenting agents) within the previous 4 weeks
5. Facial aesthetic procedures within the previous 3 months, or within 6 months for injectable or energy-based resurfacing procedures
6. Concurrent participation in another interventional clinical trial
7. Any condition judged unsuitable for enrolment by the investigator, including inability to comply with protocol requirements

Date of first enrolment

01/12/2025

Date of final enrolment

03/12/2025

Locations

Countries of recruitment

China

Study participating centre

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Room 301 (Self-compiled), Workshop 2, No. 1 Yuhong Street, Zhongcun Sub-district, Panyu District
Guangzhou
China
511400

Sponsor information

Organisation

Shenzhen Hujia Technology Co., Ltd

Funder(s)

Funder type**Funder Name**

Shenzhen Hujia Technology Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available