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Carryover effects in melatonin suppression

Submission date
20/06/2025

Recruitment status
No longer recruiting

Registration date
30/06/2025

Overall study status
Ongoing

Last Edited
27/08/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Exposure to light in the evening or at night can reduce how much melatonin your body produces. Melatonin is a hormone that helps you feel sleepy. Evening light can also shift your body clock, making it harder to fall asleep and possibly affecting your sleep quality. However, we still don't fully understand how melatonin levels vary from day to day, or how light exposure on the days before affects this.
This study aims to learn how different levels of evening light affect the body and behaviour. We are studying this in healthy adults between 18 and 40 years old.

Who can participate?
Healthy adults aged 18 to 40 years who are in good physical and mental health and have healthy vision can participate. Participants can be men, women with a natural menstrual cycle, or women who take a specific type of birth control pill.

What does the study involve?
Each participant goes through all parts of the study and serves as their own control. The study has three parts:

Week at home – Participants follow their usual routine for one week while we record their sleep, physical activity, light exposure, and glucose levels.

Ten days in the laboratory – Participants come to the laboratory for six hours each evening. They are exposed to different light levels (dim or bright light). We collect saliva samples every 30 minutes to measure melatonin. Participants also complete short questionnaires every 30 minutes about how sleepy they feel and how comfortable they find the room temperature. Every hour, they take a short attention test. We also measure their skin and core body temperature during the laboratory visits.

Week at home again – After the laboratory period, participants return to their normal routine for one more week while we continue to collect data.

What are the possible benefits and risks of participating?
Participants will receive personal health feedback, including insights into their sleep and glucose patterns. They will receive EUR540 for completing the full study.

There are no major medical risks. However, some people may feel tired from the laboratory visits. The glucose sensor may also cause mild skin irritation.

Where is the study run from?
The study is run by the Technical University of Munich, in collaboration with the Professorship for Chronobiology and Health and the Chair for Engineering and Design.

When is the study starting and how long is it expected to run for?
The study was planned in January 2025. Recruitment started in May 2025, after ethics approval. We expect to complete the last experiments by August 2025.

Who is funding the study?
This work is funded by internal sources and by the TUM Institute for Advanced Study (IAS), Focus Group Human-Centric Building Performance (Germany)

Who is the main contact?
Letizia Wörrlein, letizia.woerrlein@tum.de

Contact information

Type(s)
Public

Contact name
Ms Letizia Wörrlein

ORCID ID
https://orcid.org/0009-0001-3104-1249

Contact details
Department Health and Sport Sciences
Technical University of Munich
Am Olympiacampus 11
Munich
Germany
80809
+49 (0)89 289 - 24544
letizia.woerrlein@tum.de

Type(s)
Scientific, Principal Investigator

Contact name
Prof Manuel Sptischan

ORCID ID
https://orcid.org/0000-0002-8572-9268

Contact details
Department Health and Sport Sciences
Technical University of Munich

Am Olympiacampus 11
Munich
Germany
80809
+49 (0)89 289 - 24544
manuel.spitschan@tum.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Carryover effects in melatonin suppression during repeated light exposure in healthy adults: a within-subject controlled trial

Acronym
AFTERGLOW

Study objectives
Primary hypotheses:
H1: Light exposure (1000 lx) leads to greater melatonin suppression compared to dim light (10 lx).
H2: The impact of light exposure on melatonin suppression is modulated by prior light history.
H3: Individual variability in melatonin suppression is significant.

Secondary hypotheses:
H4: Bright light exposure reduces subjective sleepiness compared to dim light.
H5: Bright light exposure enhances psychomotor vigilance.
H6: Core body temperature follows a different trajectory under bright vs. dim light.
H7: Distal-proximal skin temperature gradient follows a different trajectory under bright vs. dim light.
H8: Bright light exposure influences glucose metabolism.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 07/05/2025, Ethics Committee at the Technical University of Munich (Grillparzerstraße 16, Munich, 81675, Germany; +49 89 4140-7737; ethikkommission@mri.tum.de), ref: 2025-164-S-SB

Study design
Interventional randomized cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home, Laboratory

Study type(s)
Other, Prevention, Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Chronobiology, melatonin suppression

Interventions
This ten-day in-laboratory within-subject study in healthy adults aged 18-40 years examines melatonin suppression and potential carryover effects of repeated evening light exposure (dim light 10 lx, bright light 1000 lx), with light exposure sequence determined by a 2-label, 3-level counterbalanced De Bruijn sequence with no masking applied.

After successful screening, participants are invited to visit the laboratory to sign the informed consent and collect the study devices. They will begin with a 7-day ambulatory pre-laboratory period, during which they follow their regular routines while wearing an ActiGraph (to monitor physical activity and sleep), an ActLumus (to measure light exposure), and a continuous glucose monitor (CGM) for interstitial glucose levels. During this period, participants complete a daily sleep questionnaire each morning upon waking and roughly record their food and drink intake as well as physical activity. This is followed by a 10-day sequential laboratory stay. Participants arrive at the laboratory 6.5 hours before their habitual bedtime, where they receive a standardized meal tailored to their anthropometric measurements. After a 60-minute rest, they spend 3 hours in dim light conditions (10 lx), followed by a 1.5-hour exposure period to either 10 lx or 1000 lx lighting. Skin and core body temperature are continuously measured throughout the laboratory stay. Participants leave the laboratory 30 minutes before their habitual bedtime. To address potential evening hunger, an optional snack is provided for the way home. This is intended to prevent compensatory overeating later in the evening, which could negatively impact sleep onset and overall sleep quality. During the laboratory stay, saliva samples are collected every 30 minutes to assess melatonin levels. Every 30 minutes, participants complete sleepiness and visual comfort questionnaires, and every 60 minutes, they perform a psychomotor vigilance test (PVT). The laboratory period is concluded by a final 7-day post-laboratory period at home.

Intervention Type
Mixed

Primary outcome measure
Melatonin concentrations (pg/mL) are determined from saliva samples collected at 30-minute intervals throughout each of the ten evenings in the laboratory.

Secondary outcome measures
1. Subjective sleepiness measured using Karolinska Sleepiness Scale (KSS) scores at 30-minute intervals throughout each of the ten evenings in the laboratory.
2. Reaction time (ms) measured using the psychomotor vigilance test (PVT) at 60-minute intervals throughout each of the ten evenings in the laboratory.
3. Core body temperature measured continuously during each of the ten evenings in the laboratory using indigestible pills by BodyCap.
4. Skin temperature measured continuously during each of the ten evenings in the laboratory using iButtons attached to the ankle (distal) and neck (proximal).
5. Interstitial glucose levels measuring using the continuous glucose monitor during the ambulatory pre-laboratory, laboratory and post-laboratory period.

Overall study start date
30/01/2025

Completion date
31/08/2025

Eligibility

Key inclusion criteria
1. Age: ≥ 18, ≤ 40 years of age
2. Biological sex: men / women with a natural menstrual cycle / women taking monophasic combined oral contraceptives
3. Good physical health
4. Good mental health
5. Good ocular health
6. Normal color vision
7. Ability to comprehend and communicate in basic Englisch

Participant type(s)
Healthy volunteer, Learner/student

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex

Both

Target number of participants
16

Total final enrolment
9

Key exclusion criteria
1. Biological sex: women taking any other type of hormonal contraception
2. BMI: <18 / >30 years
3. Any use of medications
4. Habitual smoking
5. Diagnosis of epilepsy
6. Excessive alcohol use
7. Poor sleep quality
8. Extreme chronotype
9. Shift work in the past 3 months
10. Inter-time zone travel in the past 3 months
11. Currently pregnant and <12 months postpartum
12. Any hormonal imbalances
13. Any drug detected
14. Any alcohol in breath

Date of first enrolment
12/05/2025

Date of final enrolment
30/06/2025

Locations

Countries of recruitment
Germany

Study participating centre
University (TUM SenseLab)
Arcisstr. 21
Munich
Germany
80333

Sponsor information

Organisation

Technical University of Munich Professorship for Chronobiology and Health

Sponsor details
Department Health and Sport Sciences
Technical University of Munich
Am Olympiacampus 11
Munich
Germany
80909
+49 (0)89 289 - 24544
info.chronobiology@mh.tum.de

Sponsor type
University/education

Website
https://www.hs.mh.tum.de/en/chronobiology/home/

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
The results of this study will be published without any reservations as a peer-reviewed article. The article will be preprinted on bioRxiv.

Intention to publish date
31/08/2026

Individual participant data (IPD) sharing plan
All data to be published will be stored in anonymized form in the Professorship´s GitHub repository at github.com/tscnlab. Data will be available under an open licence, and after informed consent is obtained from participants. A permalink will be generated on Zenodo, and this information updated here.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/06/2025	No	Yes
Protocol file			30/06/2025	No	No