Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of Clear Blue-Light–Filtering Versus Anti-Reflective Coated Lenses on Sleep Timing and Sleep Quality: A Triple-Masked, Randomized Crossover Clinical Trial

Protocol summary

Study aim

To compare clear blue-light-filtering spectacle lenses with conventional anti-reflective lenses for sleep timing and sleep quality in adults who habitually use digital devices after sunset.

Design

Single-centre, triple-masked, randomized, two-period crossover trial involving 24 participants, allocated equally to two sequences using computer-generated permuted blocks of four. Allocation is concealed using sequentially numbered, opaque, sealed envelopes. Drug-development phase is not applicable.

Settings and conduct

The trial is coordinated by Tehran University of Medical Sciences, with recruitment and clinic assessments at The All Vision Center, Suq Al-Shuyukh, Dhi Qar, Iraq. Participants record sleep, exposures, adherence, and adverse effects daily. Identical frames and visually matched coded lenses mask participants and the outcome examiner; the statistician remains masked until final analysis.

Participants/Inclusion and exclusion criteria

Adults aged 18–40 years using digital devices for at least one hour after sunset on at least five evenings weekly, with stable sleep schedules and normal or corrected-to-normal vision. Major exclusions are diagnosed sleep disorders, shift work, sleep-affecting medications, significant ocular disease, and uncontrolled systemic conditions affecting sleep.

Intervention groups

Each participant receives both lens types in randomized order. Each is worn from 6:00 PM until bedtime for 10 consecutive days, separated by a 10-day washout without study lenses.

Main outcome variables

Primary: mean nightly sleep onset time from daily sleep diaries. Secondary: subjective sleep quality, sleep-onset latency, total sleep time, sleep efficiency, final wake time, wake after sleep onset, and Pittsburgh Sleep Quality Index score. Adherence to spectacle wear and the frequency, type, and severity of adverse effects are also assessed as secondary outcomes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250902067089N3**
Registration date: **2026-11-07, 1405/08/16**
Registration timing: **prospective**

Last update: **2026-11-07, 1405/08/16**
Update count: **0**

Registration date

2026-11-07, 1405/08/16

Registrant information

Name

Masoud Khorrami Nejad

Name of organization / entity

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-01-01, 1405/10/11

Expected recruitment end date

2027-01-28, 1405/11/08

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of Clear Blue-Light–Filtering Versus Anti-Reflective Coated Lenses on Sleep Timing and Sleep Quality: A Triple-Masked, Randomized Crossover Clinical Trial

Public title
Effects of clear blue-light-filtering glasses compared with anti-reflective glasses on sleep timing and sleep quality
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18–40 years. Ability to understand study procedures and provide written informed consent. Habitual digital-device use for at least one hour after sunset on at least five evenings per week. Stable habitual sleep schedule during the preceding month, with bedtime and wake time varying by no more than two hours on most days. Willingness to wear each assigned study lens from 6:00 PM until bedtime for 10 consecutive days and complete the 10-day washout period. Willingness to complete the daily sleep diary, exposure log, adherence record, and adverse-effect form. Normal or corrected-to-normal visual acuity and no clinically significant ocular disease affecting visual function. No uncontrolled systemic, psychiatric, or neurological condition likely to affect sleep or participation. Agreement to maintain usual sleep habits, evening activities, caffeine intake, and digital-device use throughout the study.
Exclusion criteria:
Self-reported physician-diagnosed sleep disorder, including chronic insomnia, delayed sleep–wake phase disorder, obstructive sleep apnoea, restless legs syndrome, or narcolepsy. Current night-shift or rotating-shift employment. Travel across more than two time zones during the previous month or planned during the study. Current use of melatonin, hypnotics, sedatives, stimulants, or other medications or supplements known to substantially affect sleep or circadian rhythms. Uncontrolled psychiatric, neurological, endocrine, cardiovascular, or systemic disease that could influence sleep. Significant ocular disease, uncorrectable reduced visual acuity, severe colour-vision deficiency, or ocular surgery during the previous three months. Current use of tinted, photochromic, or blue-light-filtering spectacles that cannot be discontinued during the intervention periods. Hazardous alcohol use, defined as more than 14 standard drinks per week, or recreational drug use. Participation in another clinical study that could influence sleep outcomes. Inability or unwillingness to comply with the lens-wearing schedule or complete the required records.
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each participant contributes measurements under two lens conditions in a two-period crossover design. Both eyes receive the same lens condition in each period. The unit of randomization is the individual participant.
Randomization (investigator's opinion)
Randomized
Randomization description
The unit of randomization is the individual participant. After eligibility confirmation and baseline assessment, 24 participants will be randomly allocated in a 1:1 ratio to the A-to-B or B-to-A lens sequence, with 12 participants per sequence. An independent researcher will generate the allocation sequence using computer-generated permuted blocks of four, without stratification. This researcher will not participate in recruitment, outcome assessment, data entry, or statistical analysis. Allocation will be concealed using sequentially numbered, opaque, sealed envelopes prepared by the independent researcher. After enrolment, the next envelope will be opened by the unblinded lens dispenser to assign the coded lens sequence.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Participants, the outcome examiner, and the statistician will remain blinded to the identity of the study lenses. An independent researcher will code the clear blue-light-filtering and conventional anti-reflective lenses as Lens A and Lens B and retain the confidential code. Both lens types will be mounted in identical frames, have the same optical prescription, and be matched as closely as possible in material, refractive index, visible-light transmission, and surface appearance, including the same visible violet residual reflection of the anti-reflective coating. The unblinded researcher responsible for preparing and dispensing the coded lenses will not participate in recruitment, outcome assessment, data entry, or statistical analysis. At the end of each intervention period, participants and the outcome examiner will independently guess the lens identity and rate their confidence to assess masking success. The lens-identity code will be released only after database lock and completion of the final statistical analysis, except when emergency unmasking is required for participant safety.
Placebo
Not used
Assignment
Crossover
Other design features
Two-period, two-sequence crossover design. Each

participant receives both lens conditions for 10 consecutive days each, separated by a 10-day washout. Study spectacles are worn from 6:00 PM until bedtime. Both lens conditions use identical frames, the same optical prescription, and visually matched anti-reflective coatings. The total intervention and washout duration is 30 days per participant.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee, School of Nursing and Midwifery & Rehabilitation, TUMS

Street address
Dr. Mirkhani Street (East Nosrat), Towhid Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1419733171

Approval date
2026-10-08, 1405/07/16

Ethics committee reference number
IR.TUMS.FNM.REC.1405.132

Health conditions studied

1

Description of health condition studied
Sleep timing and sleep quality in adults who habitually use digital devices after sunset

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Mean nightly sleep onset time during each lens condition, expressed as minutes elapsed from 6:00 PM.

Timepoint
Recorded each morning for the preceding night throughout both 10-day intervention periods (study nights 1–10 and 21–30), and averaged separately for each lens condition.

Method of measurement
Daily sleep diary recording the participant-reported estimated clock time of falling asleep in 24-hour format. Clock times are converted to minutes elapsed from 6:00 PM to account for sleep onset after midnight.

Secondary outcomes

1

Description
Mean nightly subjective sleep quality score during each lens condition, measured on a scale from 0 to 10, with higher scores indicating better sleep quality.

Timepoint
Each morning for the preceding night during study nights 1–10 and 21–30, with scores averaged separately for each intervention period.

Method of measurement
Participant self-report in the daily sleep diary, rating the preceding night's sleep quality from 0 (worst sleep quality) to 10 (best sleep quality).

2

Description
Mean sleep onset latency during each lens condition, expressed in minutes.

Timepoint
Each morning for the preceding night during study nights 1–10 and 21–30, with values averaged separately for each intervention period.

Method of measurement
Participant self-report in the daily sleep diary of the time taken to fall asleep after attempting to sleep, recorded in minutes.

3

Description
Mean nightly total sleep time during each lens condition, expressed in minutes.

Timepoint
Each morning for the preceding night during study nights 1–10 and 21–30, with values averaged separately for each intervention period.

Method of measurement
Calculated from participant-reported daily sleep diary entries as the interval between sleep onset and final awakening, minus the total time spent awake during that interval, expressed in minutes.

4

Description
Mean sleep efficiency during each lens condition, expressed as a percentage.

Timepoint
Each morning for the preceding night during study nights 1–10 and 21–30, with values averaged separately for each intervention period.

Method of measurement
Calculated from participant-reported daily sleep diary entries as total sleep time divided by time in bed, multiplied by 100.

5

Description

Mean final morning awakening time during each lens condition.

Timepoint

Each morning for the preceding night during study nights 1–10 and 21–30, with values averaged separately for each intervention period.

Method of measurement

Participant self-report in the daily sleep diary of the clock time of final morning awakening, recorded in 24-hour format.

6

Description

Mean wake after sleep onset during each lens condition, expressed in minutes.

Timepoint

Each morning for the preceding night during study nights 1–10 and 21–30, with values averaged separately for each intervention period.

Method of measurement

Participant self-report in the daily sleep diary of the total time spent awake after initial sleep onset and before final awakening, recorded in minutes.

7

Description

Pittsburgh Sleep Quality Index global score, ranging from 0 to 21, with higher scores indicating poorer sleep quality.

Timepoint

At baseline and at the end of each 10-day intervention period, on study days 10 and 30.

Method of measurement

Self-administered Pittsburgh Sleep Quality Index using the standard one-month recall period at baseline and a modified recall period covering the corresponding 10-day intervention at each post-intervention assessment, as specified in the protocol. The global score is calculated by summing the seven component scores.

8

Description

Mean percentage adherence to study spectacle wear during each intervention period.

Timepoint

Daily during study days 1–10 and 21–30, with percentage adherence averaged separately for each intervention period.

Method of measurement

Calculated from participant-reported spectacle donning and removal times and non-wear interruptions in the daily exposure and adherence log. Adherence equals actual wear time divided by prescribed wear time from 6:00 PM until bedtime, multiplied by 100.

9

Description

Frequency, type, and severity of adverse effects and visual complaints during each study lens condition.

Timepoint

Recorded daily during study days 1–10 and 21–30 and reviewed at the end of each intervention period, on days 10 and 30.

Method of measurement

Participant self-report in the daily exposure and adherence log, reviewed by the researcher using the end-of-intervention evaluation form. Adverse effects are recorded by presence and type, including visual discomfort, headache, visual disturbance, colour-perception complaints, or other effects, with severity classified as mild, moderate, or severe.

Intervention groups

1

Description

Intervention group: Clear blue-light-filtering spectacle lenses worn daily from 6:00 PM until bedtime for 10 consecutive days. In this crossover trial, each participant receives both the blue-light-filtering lenses and the conventional anti-reflective coated comparator lenses in a randomly assigned order, separated by a 10-day washout period. The two pairs of spectacles are matched for prescription, frame, lens material and refractive index, visible light transmission, and appearance. During washout, the study spectacles are not worn; ordinary clear spectacles without blue-light filtering may be used if refractive correction is required.

Category

Treatment - Devices

2

Description

Control group: Conventional clear anti-reflective coated spectacle lenses without a blue-light-filtering feature, worn daily from 6:00 PM until bedtime for 10 consecutive days. Each participant receives this comparator and the blue-light-filtering lenses in a randomly assigned order, separated by a 10-day washout period. The two pairs of spectacles are matched for prescription, frame, lens material and refractive index, visible light transmission, and appearance. During washout, the study spectacles are not worn; ordinary clear spectacles without blue-light filtering may be used if refractive correction is required.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

The All Vision Center

Full name of responsible person

Alhasan Jalil Imran

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Doctors Street, The All Vision Center (Private Clinic), Suq Al-Shuyukh, Dhi Qar, Iraq

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Vice Chancellor for Research, Tehran University of Medical Sciences
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Central Administration Building, 6th Floor, Vice Chancellor for Research and Technology, Corner of Ghods Street, Keshavarz Boulevard, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available