PREREGISTRATION

Working Title

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1 Introduction

1.1 Background

Description: The background section contains description of the existing scientific literature, as well as a justification of the research question. Special care should be taken to make sure that the section is even-handed and bias-free. It should also present the rationale for the study.

1.1.1 Prior evidence

Description: We recommend providing a systematic overview of the prior evidence of a given phenomenon, effect or mechanism. This can be any data from any model system. We recommend displaying this information in a table (Table 1)

Table 1

Prior literature

Reference	Species	Level of analysis	Findings
Placeholder (1000)	Humans	??	??

1.2 Objectives

List any implicit and explicit eligibility criteria used to determine if a participant is included in the study. This could include age ranges, sex, chronotype, visual function, consumption of substances, and any participant-level characteristics precluding them from inclusion in the study. Include inf

2 Methods and Materials

2.1 Sample

2.1.1 Inclusion and Exclusion Criteria

Description: List any implicit and explicit eligibility criteria used to determine if a participant is included in the study. This could include age ranges, sex, chronotype, visual function, consumption of substances, and any participant-level characteristics precluding them from inclusion in the study. Include information about the aspect (e.g., age), assessment modality (e.g. self-report), exclusion cut-off, the timing of assessment (e.g. during screening visit, . . .). If only the table is used, this section needs to explain the table and what is said in the table. We recommend not duplicating information.

2.1.2 Participant-level Characteristics

Description: Define data that is collected to describe the characteristics of the population.

2.1.3 Participant Recruitment

Description: Method of recruitment, such as by referral or self selection (for example, through advertisements). Describe screening procedure. The steps could include:

- Telephone or physical interview (Volunteers are informed in detail about the study and questions they might have will be answered. Inclusion and exclusion criteria are screened as far as possible)

Table 2

Inclusion and exclusion criteria

Aspect	Assessment modality	Exclusion criterion and cut-off	Timing of Screening
Age	Self-report	< 18 years > 35 years	Initial screening survey
Gender			
Diseases			
Sleep disorders			
Drug/ alcohol use			
Body Mass Index (BMI)			
Visual acuity			
Shift word < 3 months prior to study			

- Questionnaires (e.g. consent form, General Medical questionnaire, the Horne-Östberg (Morningness-Eveningness) Questionnaire, the Pittsburgh Sleep Questionnaire (PSQI), the Epworth Sleepiness Scale (ESS), and the Beck Depression Inventory (BDI-II), Munich Chronotype Questionnaire (MCTQ)). How will the participants fill in the questionnaires (e.g. via an online-platform (REDcap)).
- Physical examination
- Ophthalmologic Screening (e.g. Visual acuity, contrast sensitivity, colour vision (100 Hue, Ishihara, . . .), stereoscopic vision)
- Adaptation night

Provide information under which circumstances volunteers will be excluded from the study, e.g. if compliance to this outpatient segment of the study is verified using wrist actigraphs and self-reported sleep logs, what is the maximum deviation allowed. Report if and how a toxicological analysis will be carried out. Describe how volunteers will be compensated for participating in the study.

2.1.4 Stopping guidelines

Description: Describe the condition which has to be achieved to stop data collection (e.g. number of participants). Also name adverse events which would lead to termination of the study before completion on a study level. On a participants level, state what will lead to exclusion of the participant in the course of the study.

2.2 Protocol

2.2.1 Study Design

Description: e.g. Field study or lab study, within or between-participant design, cross-over, etc. Describe the type of study, e.g. if it is a clinical trial and if it belongs to a certain risk category. Intervention-controlled design or observation study? If an intervention is administered, describe potential group allocation processes, potential cross-over, etc. Within- or between-participant or mixed study design? Describe if the study is a within or between (or a mix of a within and between) subject design. How will the participants be assigned to the conditions that are tested? Illustration recommended.

2.2.2 Environment and Context

Table 3

Measurement schedule

Measurement modality	Sampling frequency	Timing of sampling	N
Salivary melatonin	10 measurements per evening	Every 30 minutes	10
PVT	10 measurements per evening	Every 30 minutes	10
KSS	10 measurements per evening	Every 30 minutes	10

Description: Define the physical context of the study. For laboratory and field interventions this can look very different. In the laboratory this should be done in greater detail concerning the spatial properties. If you use multiple rooms, these should be described separately to avoid confusion. We recommend that you include pictures and describe them in text. The environment could include:

- Season, location, time zone, multicenter vs. single location
- Settings (home, workplace, outdoors)
- Description of room (qualitative: windows, surface colours, quantitative: dimensions, orientation, air temperature)
- Lighting (position and size of the luminaires, windows and daylighting systems, position of the observer), optional: include table of the room measurements (e.g., alpha-opic irradiance values in reference to the participants eye position)
- Pictures/Illustration of the set-up

2.2.3 Screening

Description: Describe the mode (online questionnaire, phone call, etc) and timing of the screening. By referring to Table Table 2, specify the instruments and cut-off used in a screening process according to inclusion/ exclusion criteria.

2.2.4 Procedure

Description: Give an overview of the entire procedure, from the ambulatory part (if applicable) to the end of the study. E.g. numbers of conditions, different stages in each condition (ambulatory/ laboratory), numbers of each stage in each condition, the detailed timeline of all the intervention administration, tasks and measurements taking places from the arrival till the end of the study. A gantt chart showing the study schedule should be included.

2.2.5 Timeline

Description: Rough overview of all study appointments, start and end of the project. Refer to section "procedure" for detailed description.

2.2.6 Randomization

Description: Explain how the randomisation is conducted. Disclose if a non-random procedure is required (e.g. in order to balance back the matching samples). In addition, if the sample size does not allow a counterbalanced randomisation (e.g. 3 conditions forming 6 types of sequences, but only 20 participants are recruited), the samples of each sequence should be described.

2.3 Statistical Analysis

2.3.1 Power Analysis

Description: Preliminary power analyses that is either based on data extracted from the literature or synthetic data. Discuss whether the sample size is justified using the power analysis, or given by fixed and limited resources.

2.3.2 Pre-processing

Description: This section should contain any details on processing, filtering, and other data transformations. This also includes any data exclusion and rejection rules (e.g., blinks in pupillometry data). This section should describe in unambiguous terms how raw data were processed. Code and algorithms used for preprocessing should be named and ideally made available.

2.3.3 Confirmatory Analysis

Description: This section includes descriptions of any confirmatory analyses that are performed, how they are performed (i.e., which statistical test and which criterion used to accept a hypothesis), and how results from the statistical test would be interpreted.

2.3.4 Exploratory Analysis

Description: This section should include any ringfenced analyses, i.e. analyses that are exploratory but not confirmatory.

2.3.5 Data Storage and Privacy

Table 4

Hypotheses and associated tests

Confirmatory or exploratory	Hypothesis	Outcome measure	Sampling plan	Analysis plan	Interpretation
Confirmatory	H1	Circadian phase shift (difference between DLMO)	fixed N ($n = 20$)	Linear mixed model	
	H2				
Exploratory					

Description: Describe how you anonymize the data (referring the participant with unrecognized numbers, using data sets for sensitive and non-sensitive information etc.), where to store, how long the data will be stored. In the case of promoting open science, describe when and how the data will be made available to the public.

2.4 Outcomes

2.4.1 Primary Outcomes

Description: Define all primary measurements in detail that are monitored according to research questions. The primary outcomes should be explicitly determined and also could be Linked to hypothesis or exploratory analysis .The informations of outcomes could include (Table 5) :

- Measurement modality
- Derived outcome measure and unit
- Number of measurements per participant

- Preprocessing
- Linked hypothesis or exploratory analysis

Table 5

Primary outcome measures

Measurement modality	Derived outcome measure and unit	Definition	Number of measurements per participant	Preprocessing	Linked hypothesis or exploratory analysis
Salivary melatonin	Dim-light melatonin onset (DLMO) [local hour]	Rise in DLMO time based on some criterion	n=2 (one per evening)		H1
	Acute melatonin suppression		n=2 (one per evening)		H2
PVT reaction time test	Median RT				
	Fastest 10% RT				
	Error rate				
KSS					

2.4.2 Covariates

Description: Measurements which are not directly linked to the research question, but they are used in the analyses with primary factors to gain the precision of data interpretation. The addition of covariates should be justified by evidence. E.g.

2.4.3 Other Measurements

Description: Measurements which are not directly linked to the research question, but they can provide information about the quality of the study. The instruments and the purpose of the measurements should be addressed. Such as:

- Baseline demographic and clinical characteristics for each group [CONSORT 15%]
- Baseline demographic and clinical characteristics for each group [CONSORT 15%]
- Adverse events [CONSORT 19; Expectancy (if blinded]
- Measurements which monitor the compliance of the participants to restrictions (e.g. caffeine levels; SOMETHING FOR LIGHT STUDIES?)
- Adverse events [CONSORT 19; expectancy (if blinded)]

2.5 Intervention

2.5.1 Description and Delivery of Intervention

Description: This section describes the intervention, including a name, rationale, materials and procedures, delivery of the intervention (modes, location, dose, personalised tailoring), and any planned evaluation of adherence and fidelity to the intervention. For light stimuli, the stimuli need to be well described as given in CIE TN 011:2020.

2.5.2 Placebo or Control Condition

Description: This section describes any control or reference measurements along with the active intervention. This could be e.g. dim light measurements.

Ethics Approval

Description: Responsible Ethics committee; if proposal has been reviewed, cite ethics approval code.

Funding

Description: Include all sources of funding and role of the funder(s) in the investigation. Where applicable, report how they were involved in design, conduct, analysis and reporting of the study, otherwise state that they were not involved in those processes. Further include any additional sources of support (e.g., providing equipment, drugs, analyses, location etc.).

Conflicts of Interest

Description: Provide information on possible conflicts of interest of any of the authors. List circumstances that could create a conflict of interest, which among other things could be of financial nature (e.g., financial gain when the study succeeds), involving any other personal gain related to the study's results, or else.

References

Placeholder, N. A. (1000). This is the title. *Some Journal*, *1*(1).

Appendix

The following appendix contains supplementary figures and tables.

Figure A1

Here comes the figure caption.