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Influence of sleep restriction on health, and analysis of the effect of the weekend catch-up sleep

Submission date	**Recruitment status**	[X] Prospectively registered
09/08/2023	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/09/2023	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/01/2025	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims

One-third of the population of Western countries do not achieve the daily sleep recommendations (7 hours per night). Sleep has become a critical factor in the development of chronic diseases. Thus, there is strong evidence between insufficient sleep and cardiometabolic disorders, such as high blood pressure, diabetes and obesity. The underlying mechanism by which this association seems to be associated with hedonic factors and increased opportunity to eat. This fact highlights the need to address the role of sleep in the development of these pathologies in public health. In addition, people who have a short sleep duration on weekdays tend to increase their sleep duration on weekends, "catching up" with the sleep loss of the previous days. Few studies have analyzed the effect of both sleep patterns on health, obtaining disparate results depending on the methodological design studied. Furthermore, none of the existing studies that have analyzed the difference in weekly sleep have been carried out in the Mediterranean population. For this reason, this study aims to analyze the changes in blood markers, eating patterns and health factors after sleep restriction plus sleep recovery ad libitum (as much sleep as they want) compared to a habitual sleep situation.

Who can participate?

Healthy adults aged 18-60 years with a body mass index (BMI) of 20 to 33 kg/m², with daytime work schedules, with a habitual sleep of 7-9 hours at night and with an intermediate chronotype evaluated with a validated questionnaire.

What does the study involve?

Two interventions are compared in a crossover design (each participant receives both interventions in a random order): a) sleep restriction (SR) plus a catch-up period and b) habitual sleep [HS] (7-9 hours per night). This study consists of two sleep phases [RS and HS] of 5 days each, followed by 2 days of sleep recovery ad libitum during the weekend, and separated by a 2-week period. During both phases at baseline, day 5 and after the recovery period, information about lifestyle (sleep, diet and physical activity) will be gathered through questionnaires, and blood samples will be taken for tests.

What are the possible benefits and risks of participating?
Participants will be informed that there are no benefits and risks expected. Potential risks may be caused by the blood samples and the drowsiness produced in the reduced sleep phase. For this reason, to ensure the safety of the participants and the general population, the participants included in this study will be advised not to drive any type of vehicle during the time of sleep restriction.
The potential benefits of the study would be to increase research knowledge about the effects of reduced sleep and recovery at the weekend. With this knowledge, it is intended to carry out more individualized treatments in people with insufficient sleep, a very common practice in current research.

Where is the study run from?
University of Valencia (Spain)

When is the study starting and how long is it expected to run for?
October 2022 to June 2025

Who is funding the study?
1. Generalitat Valenciana (Spain)
2. University of Valencia (Spain)

Who is the main contact?
Prof. Rocío Barragán Arnal, rocio.barragan@uv.es

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
PCT1E-19

Study information

Scientific Title
Effect of sleep restriction and weekend catch-up sleep on cardiometabolic phenotypes, dietary intake, and omic markers: a randomized clinical trial

Acronym
SUMICS

Study objectives
An experimental model that mimics real conditions of sleep restriction (5.5 h/night) produces modifications in factors associated with dietary consumption, as well as in gene expression, epigenetic marks and in the level of metabolites, and all of this is associated with an unfavorable cardiometabolic profile. In addition, the weekend catch-up sleep could recover the clinical disturbances induced by the experimental sleep restriction in a Mediterranean population.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/01/2023, Institutional review board of Valencia University (Avda. Blasco Ibanez 13, Valencia, 46010, Spain; +34 (0)963864109; vicerec.investigacio@uv.es), ref: 2440618

Primary study design
Interventional

Study design
Interventional randomized cross-over trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of intermediate chronic disease phenotypes in the general population

Interventions
This is a short-term cross-over randomized trial including 50 participants. Participants will be randomly assigned 1:1 to the order of the two interventions by simple random assignment through a computer program:
1. Habitual sleep during weekdays and weekends (7-9 h/night)
2. Sleep restriction + weekend catch-up period
During the HS phase, the sleep duration will be the regular hours in which the participants usually go to bed and wake up. For the SR phase, the sleep duration will be -1.5 h in relation to HS. During SR, participants will maintain their wake-up time but delay their bedtime to reflect time differences between individuals with short sleep durations and normal sleepers.
The intervention will be 5 weekdays and 2 weekend days for each treatment in a crossover design. A "wash-out" period of 2 weeks between treatments will be undertaken.

Intervention Type
Behavioural

Primary outcome(s)

Expression level (Clariom™ S Assays Human and RT-PCR) and methylation pattern measured using (Methylation EPIC 850K array and MALDI-TOF) after a sleep restriction period plus a weekend catch-up period compared to habitual sleep at baseline, 5 and 7 days

Key secondary outcome(s)
1. Biochemical measurements (glucose, cholesterol, triglycerides and inflammatory markers), hormones and metabolites measured in fasting plasma by standard procedures at baseline, 5 and 7 days in both phases
2. Blood pressure measured using an automatic sphygmomanometer (OMRON HEM-705CP)] at baseline, 5 and 7 days in both interventions
3. Weight, waist circumference and body composition by bioimpedance measured at baseline, 5 and 7 days in both phases
4. Food intake, food timing using a phone application and adherence to the Mediterranean diet, measured using the 14-item Mediterranean diet adherence PREDIMED scale at baseline, 5 and 7 days in both phases
5. Physical activity measured using the short form of the Minnesota and RAPA physical activity questionnaire and an actigraph wGT3X-BT model at baseline, 5 and 7 days in both phases
6. Sleep characteristics measured using the Pittsburgh Sleep Quality Index questionnaire, Epworth and actigraph wGT3X-BT model at baseline, 5 and 7 days in both interventions
7. Taste and odor perception using a validated test at baseline, day 5 of sleep restriction and day 7 after the weekend catch-up sleep period
8. Chronotype measured using the Horne and Östberg questionnaire at baseline

Completion date
30/06/2025

Eligibility

Key inclusion criteria
1. Volunteers recruited from the general population
2. Adults between 18 and 60 years old
3. BMI between 20 and 33 kg/m²
4. Habitual good sleepers (7-9 h/nights)
5. Intermediate chronotype

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Does not meet the inclusion criteria
2. Shift or rotating workers
3. Travelers across time zones during the month prior to the start of the study
4. Present the following situations: consumption of drugs and alcohol on a regular basis, treatment with anxiolytics, corticosteroids or hypnotics, pregnant women, lactating women or with hormonal treatment, infectious, neurological, psychological, renal or hepatic diseases, cancer or other relevant pathologies that could bias the study
5. Any other condition that may interfere with sleep

Date of first enrolment
01/10/2023

Date of final enrolment
01/12/2024

Locations

Countries of recruitment
Spain

Study participating centre
University of Valencia
School of Medicine
Avda. Blasco Ibanez 15
Valencia
Spain
46010

Study participating centre
CIBER OBN
Instituto de Salud Carlos III. Calle Sinesio Delgado 10
Madrid
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Sponsor information

Organisation
University of Valencia

ROR
https://ror.org/043nxc105

Funder(s)

Funder type
Government

Funder Name
Generalitat Valenciana

Alternative Name(s)
Regional Government of Valencia, Consell del País Valencià, Generalitat Valenciana Government, Generalidad Valenciana, Spain, Generalitat de la Comunidad Valenciana, Generalitat, GVA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Universitat de València

Alternative Name(s)
University of Valencia, UV

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan

Data will not be available outside the core research group as the informed consent form signed by participants stated that individual-level data will not be publicly available. Researchers who are interested in this study can contact the main investigator (Dra. Rocío Barragán, rocio.barragan@uv.es) if they have any questions regarding the data or if they are interested in further collaborations. The participants will receive written information about what the study involves and sign a consent form before entering the study.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available