

# Impact of a simulated multiday heatwave on nocturnal physiology, behavior, and sleep

<b>Submission date</b> 17/05/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

This study looks at how a multiday heatwave affects nighttime physiology, behavior, and sleep under controlled conditions, with careful monitoring of the environment and participant activities. The study aims to enhance our knowledge regarding the impact of heatwaves on human physiology, cognition, behavior, and sleep. Currently, there are no physiological studies investigating the impact of this unique weather phenomenon in laboratory settings that enable comprehensive and precise assessment of multiple physiological and behavioral responses in humans.

### Who can participate?

Healthy young men with no history of sleep disorders or medication use

### What does the study involve?

Participants will be kept in a controlled environment for ten days. The temperature will be hot-to-warm (day: 35.4°C, night: 26.3°C) during nights 4-6 and moderate (day: 25.4°C, night: 22.3°C) before (nights 1-3) and after (nights 7-10) the heatwave. Measurements to be taken include core and skin temperatures, heart rate, balance between sympathetic and parasympathetic nervous systems, indicators of skin blood flow, urine samples, blanket usage, subjective sleep quality assessments, and partial sleep monitoring.

### What are the possible benefits and risks of participating?

The benefits of this study for our participants are that (i) they will learn more about the physiology of their bodies and, most importantly, (ii) they will have the opportunity to contribute to a unique state-of-the-art physiological study that will expand current knowledge on the impact of heatwaves on humans.

Regarding the risks of participating, the present study simulates a frequent weather phenomenon that participants have already experienced many times in their lives. The safety of the laboratory settings ensures that there will be no negative impacts on the health of the participants, although they may feel more tired during the heatwave simulation.

Where is the study run from?  
Jožef Stefan Institute

When is the study starting and how long is it expected to run for?  
June 2020 to November 2020

Who is funding the study?  
1. Horizon 2020  
2. Slovenian Research and Innovation Agency

Who is the main contact?  
Dr Leonidas Ioannou, ioannoulg@gmail.com

## Contact information

**Type(s)**  
Public, Scientific, Principal Investigator

**Contact name**  
Dr Leonidas Ioannou

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## Additional identifiers

**EudraCT/CTIS number**  
Nil known

**IRAS number**

**ClinicalTrials.gov number**  
Nil known

**Secondary identifying numbers**  
Horizon Grant No. 668786, Slovenian Research and Innovation Agency grant no. P2-0076

## Study information

**Scientific Title**  
Impact of a simulated multiday heatwave on nocturnal physiology, behavior, and sleep: A 10-day confinement study

**Acronym**  
HEATWAVE

**Study objectives**

This study hypothesizes that prolonged exposure to heatwave conditions will significantly alter nocturnal physiology, thermoregulatory behavior, and sleep, including changes in the thermoregulatory mechanisms of skin vasomotion and sweating rate (reflected in urine dehydration markers), as well as variations in blanket coverage and sleep quality indicators, compared to neutral conditions.

**Ethics approval required**  
Ethics approval required

**Ethics approval(s)**

Approved 20/10/2020, National Committee for Medical Ethics of the Republic of Slovenia (Štefanova ulica 5, Ljubljana, 1000, Slovenia; +386 01 478 60 01; gp.mz@gov.si), ref: 0120-402/2020/4

**Study design**  
Interventional study

**Primary study design**  
Interventional

**Secondary study design**  
Non randomised study

**Study setting(s)**  
Laboratory

**Study type(s)**  
Quality of life, Safety

**Participant information sheet**  
See study outputs table

**Health condition(s) or problem(s) studied**  
Impact of a simulated heatwave on physiology, behavior, and sleep.

**Interventions**

This study will monitor physiological and behavioral responses to a 3-day heatwave throughout the day and over ten days. During this period, three days (days 5 to 7) are dedicated to a heatwave (day: 35.4 °C; night: 26.3 °C) simulation, while days 1 to 4 and 8 to 10 are thermally neutral (day: 25.4 °C; night: 22.3 °C).

**Intervention Type**  
Behavioural

**Primary outcome measure**

1. Core body temperature measured using telemetric pills continuously
2. Skin temperature from four sites measured using iButtons continuously
3. Heart rate measured using heart rate monitors continuously
4. Sleep quality measured using a partial polysomnography device continuously
5. Sleep thermoregulatory behavior measured using photographs taken once per night, and with a questionnaire once per day
6. Dehydration measured using urine-specific gravity once per day

### **Secondary outcome measures**

There are no secondary outcome measures

### **Overall study start date**

01/06/2020

### **Completion date**

01/11/2020

## **Eligibility**

### **Key inclusion criteria**

1. Non-heat acclimatized
2. Healthy, young males
3. Without a history of sleep disorders or medication use

### **Participant type(s)**

Healthy volunteer

### **Age group**

Adult

### **Lower age limit**

18 Years

### **Sex**

Male

### **Target number of participants**

7

### **Total final enrolment**

7

### **Key exclusion criteria**

1. Unhealthy
2. Non-adult

### **Date of first enrolment**

21/10/2020

**Date of final enrolment**

22/10/2020

## Locations

**Countries of recruitment**

Slovenia

**Study participating centre**

Institut "Jožef Stefan": IJS

Jamova Cesta 39

Ljubljana

Slovenia

1000

## Sponsor information

**Organisation**

Jožef Stefan Institute

**Sponsor details**

Jamova cesta 39

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**Sponsor type**

Research organisation

**Website**

<https://www.ijs.si/ijsw>

**ROR**

<https://ror.org/05060sz93>

## Funder(s)

**Funder type**

Government

**Funder Name**

Horizon 2020

**Alternative Name(s)**

EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location****Funder Name**

Slovenian Research and Innovation Agency

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/07/2024

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

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Leonidas Ioannou, ioannoulg@gmail.com. The type of data that will be shared will be a spreadsheet file with physiological responses, which will be available five years after the data collection. Written informed consent was obtained from participants. Data are fully anonymized and stored in an encrypted format. No participant data that may affect the confidentiality (anonymity) of our participants will be shared.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		24/08/2020	22/05/2024	No	Yes
<a href="#">Results article</a>		25/06/2024	16/07/2024	Yes	No