**Participant Information Statement**

***Use of an electric fan to improve sleep quality in hot overnight environments***

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1. **What is this study about?**

We are conducting a research study to determine if increasing air velocity with electric fans affects thermal strain (e.g., core body temperature, skin temperature, sweat rate, heart rate etc.), thermal comfort, and sleep quality in overnight temperatures ~35°C and 40% relative humidity. Taking part in this study is voluntary.

Please read this sheet carefully and ask questions about anything that you don’t understand or want to know more about.

1. **Who is running the study?**

The study is being carried out by the following researchers:

* Dr Yorgi Mavros, Senior Lecturer, The University of Sydney
* Dr Delwyn Bartlett, Associate Professor, The University of Sydney
* Dr Anthony Capon, Professor, Monash University
* Dr Nicole Vargas, Lecturer, Australian National University
* Dr James Smallcombe, Senior Research Associate, The University of Sydney
* Dr Ollie Jay, Professor, The University of Sydney
* Dr Christopher Gordon, Associate Professor, Macquarie University
* Dr Nathan Morris, Assistant Professor, University of Colorado Colorado Springs
* Dr Edward Ashworth, Postdoctoral Researcher, The University of Sydney
* Lily Hospers, Research Assistant, The University of Sydney

This study is being funded by a 2022 National Health and Medical Research Council (NHMRC) Ideas Grant (ID#2020782).

1. **Who can take part in the study?**

We are seeking young healthy adults that meet the following inclusion/exclusion criteria.

### **Inclusion criteria**

* Between the ages of 18-40 years
* Able to understand the demands of the protocol, has had any questions answered and has voluntarily signed the participant consent form prior to any study procedures
* Must have a usual sleep time before midnight, a self-reported sleep latency (time it takes to fall asleep) of 30min or less, and a usual waketime between 5am and 8am

### **Exclusion criteria**

* + Poor sleep quality or known sleep disorders
	+ Sensitivity to noise, especially with trying to sleep
	+ Taking any medication(s) known to affect sleep or thermoregulation
	+ Mood disorders known to affect sleep, such as depression, anxiety, and stress
	+ Known cardiovascular/heart or pulmonary/lung disease
	+ Neurodiversity (e.g., ADHD, autism)
	+ If you have problems with drugs and/or alcohol
	+ Type I or Type II Diabetes
	+ If you have difficulty controlling your bowel movementsor rectal prolapse
	+ A contraindication to the telemetric temperature pill
		- * Weigh less than 40 kg
			* Stomach or intestine problems that can cause blockages
			* If your digestive system has problems moving food through
			* If you've had surgery on your digestive system or have a history of such surgeries
			* If you have difficulties with swallowing
			* Chron’s disease or irritable bowel syndrome
			* If you have a pacemaker or other electronic medical device in your body
			* If you might need to have a strong magnetic imaging test like an MRI during the study
			* Pregnancy

To help establish your eligibility you will be asked to complete an initial eligibility questionnaire online (REDcap) and record 7 consecutive days of at-home sleep using a GENEActiv activity and sleep monitor, and by filling in a sleep diary.

1. **What will the study involve for me?**

If you are found eligible and decide to take part in this study, you will be asked to attend the Thermal Ergonomics Laboratory located in the Susan Wakil Health Building on 4 separate occasions to sleep overnight. On two occasions you will stay overnight in warm conditions (35°C and 40% relative humidity) for the experimental trials and on two occasions in thermoneutral conditions (~18°C) for the habituation trials.

Experimental conditions will involve a fan facing forwards you with an air velocity of ≥0.8 m/s (Fan) on one occasion or away from you (No-Fan) on a separate occasion. The conditions will occur in a randomised order.

Each experimental sleep will be separated by 7 days and will be preceded by a habituation sleep that will take place in the climate chamber under thermoneutral (~18°C) conditions.

The time commitment for the study will be approximately 1 hour for preliminary screening questionnaires and experimental and habituation sessions will take approximately 15 hours each (arrive at 530pm, leave at ~830am). The total time commitment is therefore ~61 hours.

**Screening**To help establish your eligibility you will be asked to complete an initial eligibility questionnaire online (REDcap). If are you are not excluded during the initial eligibility questionnaire, you will be asked to record 7 consecutive days of at-home sleep using a GENEActiv activity and sleep monitor (supplied), and by filling in a sleep diary.

**Experimental Trials**

If you satisfy all inclusion/exclusion criteria after screening, you will be scheduled for habituation sleeps and experimental trials, with experimental trial order randomised.

**Habituation Sleep #1** – You will sleep in the climate chamber in thermoneutral conditions ~18°C, 60% relative humidity and undertake all experimental measures (except for blood draw) to familiarise yourself to the measures and habituate to the environment.

**Experimental Trial #1** – On the night directly after the habituation sleep you will sleep in the climate chamber with night-time temperature ~35°C, 40% relative humidity under either the fan or no-fan condition.

**Habituation Sleep #2** – After at least four weeks at home, you will return for a second habituation sleep, identical to the first.

**Experimental Trial #2** – On the night directly after the second habituation sleep participants will return for their second experimental trial with night-time temperature ~35°C, 40% relative humidity under either the fan or no-fan condition.

You will be provided with a standardized dinner, catering to your specific dietary requirements, during each experimental and habituation visit.

You will be contacted by phone 7 days after each visit to check for the occurrence of any adverse (unexpected) events that may be related to your participation in the study. Each phone call will take ~5 minutes where you will be asked questions about your health status in the past week. This is standard practice in clinical trials.

**The following measures will be taken:**

**Heat strain:** Core temperature will be recorded before and during sleep by a telemetric core temperature pill sensor (E-celcius, BodyCap™), which will be supplied by BMedical under the Clinical Trial Notification (CTN) scheme, and orally ingested at 330pm on the day of each trial. It is a single-use pill, roughly the size and shape of a large vitamin pill.

NOTE: In April 2023, the Therapeutic Goods Association (TGA) reclassified the e-Celsius Core Body Temperature Monitoring Pills as an unapproved class 2a medical device. As such, this study which you are participating is classified as a clinical trial and has gone through the appropriate University of Sydney Clinical Trial approvals and processes (registration number: x/x). To comply with this classification, we are required report any adverse events that are considered possibly or probably related to the temperature pill to BMedical (as the supplier) and/or BodyCAP (as the manufacturer). The reclassification from the TGA is not related to any safety concerns regarding the use of these temperature pills which have been used in humans around the world with no reported incidents directly or indirectly related to the use of these monitoring devices.

**Presence of phthalates**: Based on the toxicological evaluation, there is the presence of an acceptable phthalate level in the e-Celsius telemetric temperature pills. An acceptable level without toxicological risk for the subject of di – (2 – ethylhexyl) DEHP under the number CAS 117-81-7, diisobutyl DIBP under the number CAS 84-69-5, and dinonyl under CAS number 84-76-4.

**Thermal comfort:** You will be asked at several points before going to sleep and upon waking to mark how thermally comfortable you are feeling or felt overnight.

**Objective sleep quality:** This will be measured using polysomnography, which uses an EEG (electrocephalogram) that measures brain activity and eye movements while you sleep, a belt around the waist and chest to monitor respiration, and an oximeter to monitor blood oxygen levels. Facial hair may need to be removed for the placement of electrodes, and some electrodes may need to be applied using glue. The room will be monitored for experimental and safety purposes throughout the night.

Secondary measures will also be obtained using GENEActiv wrist watches (Activinsights, United Kingdom), and a Withings mat that is placed under the mattress, that provide objective measures of overall sleep quality.

The watch is worn on your non-dominant wrist throughout the night, and will also be worn for one week leading up to the experimental trial to provide a record of your habitual sleep.

**Subjective sleep quality**: In the morning after waking, you will be asked to record your subjective sleep quality by marking in response to several questions along a visual analogue scale.

**Cognitive function and alertness**: In the morning after waking, you will be asked to complete a series of cognitive tasks, designed to assess changes in alertness associated with sleep loss, extended wakefulness, circadian misalignment and time on task. The tasks involves pressing a button in response to a red light on a screen, designed to test simple reaction time, a task that requires remembering items in a list (n-back task), a Stroop test to measure selective attention capacity as well as processing speed and a psychomotor vigilance task that evaluates sustained attention. The tests will take less than 30 minutes in total.

**Skin temperature:** Wireless skin temperature sensors will be taped to the skin surface with hypoallergenic tape. These sensors give an indication of skin temperature. Some hair may need to be shaved (by the use of disposable razors) in order to secure the sensors adequately to the skin surface.

**Cardiovascular strain:** Blood pressure will be collected using a wireless Ambulatory Blood Pressure Monitor (SunTech Medical, USA). The unit will be programmed to take a reading every 30 minutes while you are awake, and every 60 minutes while asleep. Heart rate will be measured and recorded using a Polar chest strap and heart rate monitor watch worn on the wrist.

**Dehydration:** To estimate your sweat losses overnight, we will weigh you at night before you go to sleep and again in the morning. Your weight will be taken nude, but you will be behind a privacy screen. While the researcher will not be able to see you behind the screen, a same-sex chaperone will be offered for additional comfort. You will also be asked to provide a small first pass, mid-stream urine sample in the morning to assess hydration status. All overnight voids will also be weighed to avoid error in estimating sweat losses.

**Blood draw:** A small blood sample will be taken prior to the exposure and upon waking during each experimental trial. As such, two blood draws will be taken via venepuncture (needlestick) during each experimental trial. The volume of blood that will be taken is 20mL per occasion, a total of 80mL in total for the study. We will measure Full Blood Count (FBC) which provides haematocrit, and urea, electrolytes and creatinine (UEC).
*Measurement only done during experimental sleeps, not habituation sleeps.*

1. **Can I withdraw once I’ve started?**

Being in this study is completely voluntary and you do not have to take part.

Your decision will not affect your current or future relationship with the researchers or anyone else at The University of Sydney.

If you decide to take part in the study and then change your mind you can withdraw by informing any member of the study team. You may withdraw at any time, for any reason.

If you choose to withdraw, we will not collect any more information from you. Please let us know at the time you withdraw what you would like us to do with information we have collected about you up to that point.

If you choose to withdraw during a study visit, we can organise transportation home for you, or if you prefer to remain overnight, we can adjust the room temperature to your desired neutral sleeping temperature before organising your transportation home the following the morning.

If you completed both experimental studies and wish to have your data withdrawn, you can do so up until the data have been published.

There may be circumstances where your participation is terminated by the trial sponsor or by the researchers.

1. **Are there any risks or costs?**

**Elevation of core body temperature:** There are typically certain risks that accompany a marked elevation in core temperature. These include: headache, extreme weakness, dizziness, nausea, hyperventilation, hypotension, confusion, diarrhoea, vomiting and loss of consciousness. Throughout all experimental protocols, your body temperature (gastro-intestinal pill) will be continually monitored. The test will be terminated immediately if a core body temperature of 39.0 degrees Celsius is reached in any of the participants. However, if you feel uncomfortable at any time during testing, you are free to stop and withdraw from that session at any point, irrespective of your core temperature. If symptoms of heat illness are severe chronic, or at the participants request, our heat stress safety protocol will be implemented, which involves rapid cooling with ice packs that are readily available, rehydration with an electrolyte replacement drink and continuous monitoring of core temperature until values of <38.0 degrees Celsius have been attained.

**Venepuncture/Blood Draw:** There are risks of infection associated with any blood work if stringent safety protocols are not in place. Accordingly, to minimise any risk to researcher or participant we have in place strict procedures pertaining to blood draws. The surface used to rest the participants arm on is stable, and the researcher will wear gloves except when palpating for the appropriate vein. The area of the arm where venepuncture will occur will be thoroughly sterilised with an alcohol swab prior to insertion. Additionally, as is standard procedure, new needles will be used for all blood draws and any used needle will be disposed of in a biohazard sharps bin and any material that comes into contact with blood will be disposed of in a biohazard waste bin. Moreover, all blood draws are carried out by a researcher with venepuncture certification. You may also feel some slight discomfort during needle insertion this is normal, the discomfort should subside within seconds of the blood draw being complete, however sensitivity in the area may remain for ~24-48 hours.

**Lack of/poor sleep:** The study includes a habituation sleep to help familiarise you to sleeping in the climate chamber overnight, and while this will help minimize potential sleep disturbances experienced during the experimental trials that could arise from sleeping in an unfamiliar environment, you may still experience poor sleep or a lack of sleep during your overnight stays. You may also feel uncomfortable at night as a result of the higher than usual air temperatures during the experimental trials. Upon waking you will be given the option to shower at our facilities before going home, and we will provide transportation for you to and from the laboratory.

There are no costs involved with participating in this study, and you will be reimbursed for your time and any associated travel costs as set out in section 9.

1. **What if injury or complications happen?**

If any injuries or complications occur as a result of this study, you should contact the study co-ordinator or study doctor as soon as possible. They will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by the drugs or procedures, or by the negligence of any of the parties involved in the study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

1. **What happens when the study ends?**

When data collection is complete the researchers will analyse the data and attempt to disseminate the findings via conference proceedings, peer-reviewed journals etc.

1. **Are there any benefits?**

As compensation for your time, you will receive $600 in Coles-Myer gift cards upon completion of all four overnight visits. Additionally, travel to and from the laboratory for the experimental sessions will be organised and supplied at no cost to you.

We anticipate that this research will contribute to the scientific community and the body of research in the areas of human thermoregulation and public health,but we cannot guarantee that you will receive any direct benefits from being in the study.

1. **What will happen to information that is collected?**

By providing your consent, you are agreeing to us collecting information about you for the purposes of this study.

Any information you provide us will be stored securely and identifiable information will only be disclosed with your permission, unless we are required by law to disclose material. We anticipate study findings will be published, but you will not be individually identifiable in these publications.

Your information will be stored securely, and your identity/information will be kept strictly confidential, except as required by law. Study findings may be published, but you will not be individually identifiable in these publications*.*

With your permission, we would like to keep the information we collect for this study, and we may use it in future projects. By providing your consent you are allowing us to use your de-identified information in future projects. We don’t know at this stage what these other projects will involve. We will seek ethical approval before using the information in these future projects.

1. **What will happen to my samples after the study?**

The blood or tissue sample/s you provide during the study will be destroyed at the completion of the study.

Overnight voids will be immediately disposed of after being weighed, and the small midstream urine sample provided in the morning after waking will be assessed immediately to yield a single value and is then disposed of immediately.

1. **Will I be told the results of the study?**

You have a right to receive feedback about the overall results of this study. You can indicate your interest in receiving feedback by providing your contact details on the consent form. This feedback will be in the form of a brief lay summary.

1. **What if I would like further information?**

When you have read this information, the following researcher/s will be available to discuss it with you further and answer any questions you may have:

* Dr Edward Ashworth, edward.ashworth@sydney.edu.au
* Dr Yorgi Mavros, yorgi.mavros@sydney.edu.au
1. **What if I have a complaint or any concerns?**

The ethical aspects of this study have been approved by the Human Research Ethics Committee (HREC) of The University of Sydney [2023/633] according to the *National Statement on Ethical Conduct in Human Research (2007).*

If you are concerned about the way this study is being conducted or you wish to make a complaint to someone independent from the study, please contact the University:

Human Ethics Manager

human.ethics@sydney.edu.au

+61 2 8627 8176

***This information sheet is for you to keep***

**Participant Consent Form**

***Use of an electric fan to improve sleep quality in hot overnight environments***

Dr. Yorgi Mavros (Responsible Researcher)

Faculty of Medicine and Health
Email: yorgi.mavros@sydney.edu.au

|  |  |
| --- | --- |
| **Participant Name** |  |

I agree to take part in this research study. In giving my consent, I confirm that that:

* The details of my involvement have been explained to me, and I have been provided with a written Participant Information Statement to keep.
* I understand the purpose of the study is to investigate the impact of electric fan use during sleep in hot overnight environments.
* I acknowledge that the risks and benefits of participating in this study have been explained to me to my satisfaction.
* I understand that in this study I will be required to sleep inside a climate-controlled chamber on four occasions while physiological and subjective data is collected.
* I understand that my information may be used in future research, deidentified.
* I understand that being in this study is completely voluntary.
* I am assured that my decision to participate will not have any impact on my relationship with the research team or the University of Sydney.
* I understand that I am free to withdraw from this study at any time and that I can choose to withdraw any information I have already provided (unless the data has already been de-identified or published).
* I have been informed that the confidentiality of the information I provide will be protected and will only be used for purposes that I have agreed to. I understand that information identifying me will only be told to others with my permission, except as required by law.
* I understand that the results of this study may be published, and that publications will not contain my name or any identifiable information about me.
* I confirm the following:

**I consent to** **being contacted for future studies** Yes [ ]  No [ ]

**I consent to my data being used in future research** Yes [ ]  No [ ]

**I would like feedback on the overall results of this study** Yes [ ]  No [ ]

If you answered **yes**, please provide your preferred contact details (email/telephone/postal address):

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* I understand that after I sign and return this consent form it will be retained by the researcher, and that I may request a copy at any time.

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| **Participant Name** |  |
| **Participant Signature** |  |
| **Date** |  |
|  |  |
| **Witness Name** |  |
| **Witness Signature** |  |
| **Date** |  |

**Revocation of Consent Form**

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| **Participant Ref** |  |

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| **Participant Name** |  |
| **Participant Signature** |  |
| **Date** |  |
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| **Witness Name** |  |
| **Witness Signature** |  |
| **Date** |  |

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| **Reason for withdrawal (optional):** |
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