Understanding sleep deprivation effects on cognitive performance through comprehensive characterization

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49165

Source
ToetsingOnline

Brief title
Sleep deprivation effects on cognition

Condition

- Other condition

Synonym
cognitive resilience

Health condition

cognitieve prestatie(verlies) door slaapdeprivatie

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: ERP Brain Body Interactions (TNO)

Intervention

Keyword: Cognition, Inflammation, Sleep deprivation

Outcome measures

Primary outcome

Main study parameters/endpoints are inflammatory responses. These will be

assessed using capillary blood samples obtained from finger pricks.

The main primary endpoints of cognitive resilience will be defined as the

difference between cognitive performance measures before and after the night.

Cognitive resilience to SD refers to the extent to which a sleep deprived

individual maintains cognitive performance while sleep deprived.

Secondary outcome

- Cognitive performance determined based on the PVT

- HR and EDA during Psychological Synchrony

- Stanford Sleepiness Scale (SSS)

- Rating Scale of Mental Effort (RSME)

Study description

Background summary

Our understanding of why sleep deprivation (SD) affects cognitive performance, and why it does so to such different extents in different people, is limited. Given that SD is unavoidable in certain professions and under certain

circumstances, a better grasp on the mechanisms underlying cognitive decline through SD, and better prediction of cognitive decline, would be valuable to intervene and cope with negative effects of SD. A promising, recent explanation links SD and its effects on cognitive performance to increased levels of inflammation. In the proposed research, we focus on this possible explanation of SD induced cognitive decline, by examining the association between decreases in cognitive performance after a night of SD and inflammatory responses. We take a comprehensive approach to study inflammation, including metabolic inflammatory mediators in addition to cytokines. More broadly, it is clear that to understand and predict cognitive effects of SD, we have to include measures from multiple domains, which is why we also include autonomic and psychological measures. Besides this, we will test a recently developed measure of attention (physiological synchrony in electrodermal activity (EDA) and heart rate (HR)) can predict upcoming cognitive performance of a repeated cognitive task in the SD participants.

Study objective

The primary objective is to determine whether SD-induced cognitive decline is associated with comprehensively measured inflammatory processes as well as other possibly relevant markers. We will investigate whether these markers explain inter-individual variations in SD induced cognitive decline.

As secondary objective, we aim to determine whether intra-individual variations in SD-induced decrease in cognitive performance over the course of the night are associated with physiological synchrony in EDA and HR.

Study design

A mixed between- and within group, randomized controlled trial. One group will undergo a night of sleep deprivation and the other group (control) will have a normal night of sleep at home. Both groups will perform and undergo a number of tests (cognitive, subjective and immunological, endocrine and psychophysiological stress responsiveness) before and after the (sleep deprived) night.

Intervention

N/A

Study burden and risks

There are small (SD group) to minimal (control group) burden and risks associated with participation, and there is no risk for any serious (adverse) event.
The burden consists of the following:

1) Having to stay awake during a single night (SD group only)
2) A trained experimenter will collect blood via finger pricks (two on day 1, and two on day 2). This can cause a mild pain.
3) Performing cognitive tasks, questionnaires and physiology recorded through wearables in the lab.
4) Keeping a log of activities done during the day that precedes the sleep-deprived (or control) night.
5) Collect a fecal sample using a swab (a do-it-yourself procedure) twice at home.
Participants are informed on all of these elements of the study, except for the second one, in the recruitment phase.
Participants from both groups spend approximately 140 minutes in the research institute to perform the various test; once on day 1, and once on day 2. They also visit the research institute before for a two hour training visit.
Participants in the SD group additionally spend the night in the research institute (from 21:00 until 8:00, immediately followed by the second 140 minutes measurement session).

Contacts

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TNO

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. The potential participant has given informed and written consent and is able to comply with all study assessments scheduled in the protocol.
2. All subjects need to be between 18 and 55 years of age.
3. All subjects has computer skills.
4. All subjects need to be in good health, and may not have any chronic diseases.
5. BMI between 18 and 30 kg/m2.
6. No alcohol the day before the start of a test day.
7. No drugs used in the last 3 months.
8. Subjects must be able to communicate, participate, and comply with the requirements of the entire study.
9. One week prior to starting every trial day, all subjects need to be (and remain) in the same time zone as the CET time zone in which the research center lies. (GMT+1, daylight savings GMT+2). This to exclude jet lags that might confound the test results.
10. No signs of flue or viral infection in the last 10 days before the start.

Exclusion criteria

1. Smoking
2. Pregnant
3. A history of psychiatric illness; this including sleeping disorders.
4. Autoimmune disease and/or hyperactive thyroid
5. People with known heart, kidney or liver disease or neurological complaints.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2021
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	09-12-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74961.028.20