The effect of citrus extract on sleep and mental wellbeing

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The aim of the present study is to investigate the effect of a citrus extract rich in the flavonoids hesperidin and naringin on sleep quality and mental wellbeing in healthy subjects with sleep (minor) disturbance.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON53237

Source
ToetsingOnline

Brief title
Citrus extract, sleep and mental wellbeing

Condition

- Other condition

Synonym
night rest, sleep

Health condition

slaap

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: BioActor BV

Intervention

Keyword: citrus, mental wellbeing, sleep

Outcome measures

Primary outcome

The primary objective is to assess the effect of 8 weeks of supplementing daily 500 mg citrus extract rich in the flavonoids hesperidin and naringin on parameters of sleep quality.

Secondary outcome

The secondary objectives are to study the effects on mental wellbeing (depression, anxiety and stress outcomes). Exploratory study objectives are to study the effect on faecal microbiota composition, faecal short-chain fatty acid (SCFA) concentrations, blood biomarkers related to mental wellbeing (BDNF, dopamine, serotonin) and blood biomarkers of metabolic health (total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, CRP, glucose, insulin and HOMA-IR).

Study description

Background summary

Based on epidemiological data, a substantial number of people report to have sleeping problems. This is of major concern, as poor sleep quality has been associated with impaired mental and physical health. Several pre-clinical studies have shown that treatment with the citrus flavonoids hesperidin and naringin may improve sleep and mental wellbeing. However, evidence from human

studies is still limited.

Study objective

The aim of the present study is to investigate the effect of a citrus extract rich in the flavonoids hesperidin and naringin on sleep quality and mental wellbeing in healthy subjects with sleep (minor) disturbance.

Study design

A randomized, double-blind, placebo-controlled, cross-over trial

Intervention

Participants will ingest daily before dinner, in random order, 500 mg of citrus extract or placebo (maltodextrin) capsules for 8 weeks, separated by a 4-week wash-out.

Study burden and risks

The total study duration will be maximal 21 weeks, including the wash-out period of 4 weeks. During the study, blood samples will be collected (< 500 mL in total), which occasionally may cause a hematoma or bruise. Other measurements are not expected to cause side effects. Subjects will have a time investment of ± 12,5 hours (screening, six test days).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

men and women, 40-70 years old, BMI 18,5-30 kg/m2, (mild) sleep disturbance (PSQI score >5), willingness to give up being a blood donor from 4 weeks before the start of the study until 4 weeks after completion of the study.

Exclusion criteria

• Excessive caffeine use (>400 mg/day)
• Major psychiatric/mental health disorders (e.g. major depression, post-traumatic stress disorder, bipolar disorder, schizophrenia).
• Chronic sleep disorders (e.g. sleep apnea, restless leg syndrome, periodic limb movement disorder)
• Severe sleep disturbance for more than 1 year
• Other clear causes for poor sleep quality, stress, depression or anxiety (e.g. stressful situation or life event, excessive noise, snoring partner, infants/children regularly awakening, shift-work, chronic/acute pain)
• Use of medication or supplements that can affect outcomes (e.g. anti-depression medication, sleeping pills, melatonin)
• Use of medication that can be affected by intake of grapefruit (juice)
• Nonpharmacological treatment for sleep disorders (cognitive behavioural therapy, relaxation therapy)
• Flight from a time-zone with >3 h difference <=1 week before an intervention period
• Administration of investigational drugs or participation in any scientific intervention study which may interfere with this study, to be decided by the principal investigator, in the 180 days prior to the study
• Use of pre-, pro- or synbiotics within 1 month prior to the start of the study
• Reported weight loss or weight gain of >3 kg in the month prior to pre-study

screening, or intention to lose weight during the study period
• Smoking
• Abuse of products (> 20 alcoholic consumptions per week and drug usage)
• Current use of (antioxidant) dietary supplements and not willing to quit for the duration of the study duration
• Known allergy to citruses
• Known pregnancy or lactation

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2023
Enrollment:	70
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	26-09-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	20-08-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT06239168
CCMO	NL84076.068.23