The effects of a nutritional supplement on sleep efficiency, sleep duration and stress, and the effect of audio intervention on deep sleep, in apparently healthy adults with sleep disturbances: a randomized controlled cross-over study

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

Summary

ID

NL-OMON48159

Source
ToetsingOnline

Brief title
Sleep Well in adults with sleep disturbances

Condition

- Other condition

Synonym
Insomnia, sleep disturbances

Health condition

Slaapproblematiek

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Keyword: Nutritional supplement, Sleep duration, Sleep efficiency, Stress reduction

Outcome measures

Primary outcome

The primary outcomes are sleep quality as estimated by the Pittsburgh Sleep Quality Index (PSQI) questionnaire, and the effect of audio intervention (SmartSleep) on deep sleep.

Secondary outcome

Secondary outcomes are: sleep characteristics (total sleep time, REM, NREM, Wake ups After Sleep Onset, sleep onset/latency) as measured with the SmartSleep in monitoring modus. Stress, anxiety and depression are measured by the DASS-42 questionnaire, whereas also the rate of increase in wake-up cortisol levels will be monitored. Finally, tertiary outcomes are changes in microbiota composition and gut functionality as studied in faecal samples during the 1st and 2nd treatment periods.Daily a short questionnaire on bedtime, wake-up and some life-style habits has to be filled in. A short questionnaire on product tolerability will be offered together with the PSQI.

Study description

Background summary

A good night of sleep is well recognized as being beneficial for overall health and well-being. Therefore, sleep disturbances being 20% in 12-65 y old persons in The Netherlands are worrisome. A nutritional supplement could help in improving sleep quality in healthy adults with sleep disturbances.

Study objective

The primary objective is to increase sleep quality, and to assess the effect of audio intervention (SmartSleep; Philips Respironics, Murrysville, PA) on deep sleep. Secondary objectives are to improve sleep efficiency, sleep duration, and to reduce stress. The tertiary objective is to get insight in the possible changes in the intestinal microbiota/microbiome

Study design

Double-blind randomized placebo-controlled cross-over trial

Intervention

In a cross-over, double-blind randomized controlled study, the subjects receive an intervention and placebo product, each for 3 weeks. The two treatment periods are separated by a washout periods of 2 weeks. Directly after the 2nd treatment period a 3rd treatment period of 2 weeks will take place in which the participants receive the same products as in treatment period 2 but additionally will undergo an audio-sonic intervention using the SmartSleep (Philips Respironics, Murrysville, PA). The intervention product (per serving) consists of whey protein, tryptic casein hydrolysate, magnesium, zinc, vitamins B6, niacin, vitamin D, and galacto-oligosaccharides (GOS). The placebo product is skimmed milk powder. Products will be supplied as powders in a sachet, have to be dissolved in luke warm water (100-150 ml) just before consumption, and have to be consumed daily in the evening about 1 hour before going to bed. Participants will be asked to collect the emptied and remaining sachets

Study burden and risks

For this study healthy volunteers are selected with sleep disturbances. When the IP is effective, the participants will have a direct benefit during the period the IP is consumed. Volunteers will be reimbursed for their time investment which is estimated to be about 25 hours in total (including information meeting, visits and phone calls). Subjects will visit the clinical facilities 2 times, whereas questionnaires will be filled in on-line. There are

no known risks associated with the consumption of the IP or placebo, nor with regard to the (non-invasive) data collection procedures. Subjects have to perform the following study activities: * Collection of fecal spot sample at 2 time points * Collection of 5 saliva samples at 5 timepoints. * Intake of study product during 8 weeks * Completing daily questionnaires during 8 weeks (on 9 timepoints PSQI and on 5 timepoints DASS-42) * Sleeping with SmartSleep device during 35 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

-Age 30-50 years -BMI 19.5 - 25 kg/m^2, as measured by the NIZO health and lifestyle questionnaire -PSQI * 9 - willing and being able to consume a dairy based product on a daily basis - Understand Dutch - Having access to the

internet and access to a mobile device for app download/function (phone or tablet) - Apparently healthy according to the participant - Being available during the study period (telephone and internet) - Willing to sign the written informed consent - Accept use of all encoded data, including publication, and the confidential use and storage of all encoded data.

Exclusion criteria

-Use of medicines to improve sleep (e.g. Benzodiazepines and benzodiazepine ago-nists such as Temazepam, Zolpidem, Lormetazepam and Zopiclon, and Barbiturates such as Fenobarbital) or supplements (protein, vitamins, herbs) in general which im-prove sleep as assessed by the principal investigator. - Sleep apnea or other diagnosed sleep diseases - Being allergic to dairy products or any of the ingredients of the product - Being intolerant for prebiotics - Those involved in shift working - Having a serious risk on a jetlag at the time of starting or during the study period: re-turn (*1 week before a treatment period) from an intercontinental flight and from a time-zone with >3 hours difference. - Pregnant or breastfeeding women - Being treated by psychologist for sleep or burnout - Diseases of the respiratory tract that cause serious sleep issues, as assed by the medical arts - No use of soft and hard drugs during the study period. - Having a history of medical or surgical events that may significantly affect the intes-tine and/or digestion (e.g including: Inflammatory bowel disease, hepatitis, pancreatitis, ulcers, gastrointestinal or rectal bleeding; major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, or bowel resection; known or suspected gastrointes-tinal disorders, colon or GI tract cancer - Mental status that is incompatible with the proper conduct of the study (judgement is based on the personal view of the researcher) - Alcohol consumption for men > 28 consumption units/week and >4/day; for women: >21 units/week and >3/day - Reported weight loss or weight gain of > 3 kg in the month prior to pre-study screen-ing, or intention to lose weight during the study period - Reported slimming or medically prescribed diet - Personnel of FrieslandCampina Research, NIZO and Philips Research, their partners and their first and second degree relatives - Having a hearing impairment (preventing hearing of tones of 80dB)'
- Peri- or postmenopausal women. Perimenopausal women will be defined based on the criteria of hot flushed, irritability, irregular menstrual cycle and mood swings (judgement is based on personal view of the subject themselves)

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-08-2019
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-09-2019
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21623
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70673.081.19
Other	NL7919
OMON	NL-OMON21623