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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21623

Source
NTR

Brief title
Sleep Well 3.0

Health condition

NA

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI) questionnaire (PSQI)
The number of tones produced by the SmartSleep during deep sleep

Secondary outcome

Sleep characteristics as measured by the SmartSleep,
Speed of cortisol increase in saliva following wake-up.
Stress level as measured by DASS-42 questionnaire

Study description

Background summary

Rationale: A good night of sleep is well recognized as being beneficial for overall health and well-being. Therefore, sleep disturbances being as high as about 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.
Objective: The primary objective is to investigate whether the intervention product increases sleep quality compared to placebo intervention, and to assess the effectiveness of audio intervention delivery(SmartSleep; Philips Respironics, Murrysville, PA) during deep sleep. Secondary objectives are to investigate the effect of the intervention on improvement of sleep efficiency, sleep duration, and stress reduction. The tertiary objective is to get insight in the possible changes in the intestinal microbiota/microbiome in relation to intake of the intervention product.
Study population: Healthy female and male human volunteers, 30-50 y old, with sleep disturbances according to their PSQI (≥9).
Intervention: In a cross-over, double-blind randomized controlled study, the subjects receive an IP and placebo product, each for 3 weeks (Figure 1). 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 intervention using the SmartSleep. The intervention product 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.

Main study parameters/endpoints: The primary outcomes are sleep quality as estimated by the Pittsburgh Sleep Quality Index (PSQI) questionnaire, and the effectiveness of audio intervention delivery (SmartSleep) during deep sleep measured by the number of audio tones delivered during deep sleep. 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 and differences in NREM sleep characteristics during audio intervention nights. 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 as studied in faecal samples during the 1st treatment period. Daily a short questionnaire on bedtime, wake-up, some life-style habits, and fitness and mood at waking up has to be filled in. A short questionnaire on product tolerability will be offered together with the PSQI questionnaire. With regard to data evaluation, first of all the differences between the IP and placebo product will be studied, at the end of each treatment period and after taking the 1st and 2nd treatment periods together. Evaluations will be done based on changes in parameters as well as for the absolute values. Secondly, within product groups changes will be evaluated for each of the treatment periods. Finally, the effectiveness of the audio intervention delivery will be studied in the 3rd treatment period looking at the difference of the audio intervention delivery between product group.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
1. 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:
2. Collection of fecal spot sample at 2 time points
3. Collection of 5 saliva samples at 5 time points.
4. Intake of study product during 8 weeks
5. Completing daily questionnaires during 8 weeks and other questionnaires including PSQI (on 9 time points) and DASS-42 (on 5 time points)
6. Sleeping with SmartSleep device during 35 days

Study objective

The PSQI score is significant lower in the intervention group as compared to the placebo group after 3 weeks of oral intake of the test product.

Study design

August-September 2019: recruitment
September-December 2019: intervention
January 2020: data clean and lock
February-April 2020: data analysis and evaluation

Oktober-December 2020: report and manuscript writing

Intervention

Whey protein based product fortified with tryptic casein hydrolysate, galactooligosaccharides, vitamins and minerals.

Contacts

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Eligibility criteria

Inclusion criteria

- Age 30-50y
- BMI 19.5-25 kg/m2 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 down-load/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 anonymized 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 study physician
- 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 subjects themselves)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2019
Enrollment:	70
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	31-07-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48159
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7919
CCMO	NL70673.081.19
OMON	NL-OMON48159

Study results

Summary results

Schaafsma et al., The Effect of A Whey-Protein and Galacto-Oligosaccharides Based Product on Parameters of Sleep Quality, Stress, and Gut Microbiota in Apparently Healthy Adults with Moderate Sleep Disturbances: A Randomized Controlled Cross-Over Study. Nutrients 2021;13 (7)