The effects of a colon-delivered multivitamin supplement on vigilance and cognitive performance under stressful working conditions in military subjects

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This current study aims to examine the effects of a 6-week colon-delivered multi-vitamin supplement intervention on cognitive performance and stress levels in military under real-life, stressful working conditions.

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

Summary

ID

NL-OMON52332

Source
ToetsingOnline

Brief title
VIT for vigilance study

Condition

- Other condition

Synonym
cognitive functioning

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: De studie is onderdeel van een PPS project (publiek private samenwerking) gefinancierd door LNV en een consortium van partijen,DSM,Ministerie van Defensie,Thales

Intervention

Keyword: cognitive performance, colon-delivered multivitamin supplement, vigilance

Outcome measures

Primary outcome

The main study outcome is the backward digit span (DS) score, during the field

exercise as compared to the start of the 6-week supplementation period.

Secondary outcome

Secondary parameters are other cognitive test scores and a combined (z-scored)

cognitive performance score. Stress levels will be measured in salivary

cortisol and self-perceived stress levels will be derived from the HADS and

PSS-10 questionnaire. Other stress biomarkers (e.g. heart rate variability)

will be measured by a wearable.

Study description

Background summary

A growing number of professionals work in a type of job that brings psychological or physical stress while requiring optimal alertness and cognitive control, so called vigilance. These professionals are for example found in military contexts. Even a tiny lapse in alertness can carry large risks for themselves and others.

Study objective

This current study aims to examine the effects of a 6-week colon-delivered multi-vitamin supplement intervention on cognitive performance and stress levels in military under real-life, stressful working conditions.

Study design

Randomized, double-blind, placebo-controlled, parallel trial in a real-life setting (field exercise or intensive training).

Intervention

The intervention product is a nutritional supplement, composed of vitamins B2, B3, B6, B9, C and D3. These vitamins will be delivered in the colon where most of these vitamins can be utilized by the gut microbiota, as they act as cofactors for important cellular functions.

Study burden and risks

This study is performed in military subjects, but the findings can be generalized to a larger group of professionals that work in stressful jobs that require optimal alertness. There are minor risks for the research subjects of this study. There are no direct benefits for the research subjects. Doses of the vitamins in the multivitamin supplement are all below the tolerable upper intake levels (UL) as set for these vitamins. Subjects that will participate in the study will invest approximately 7 hours during the trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* Healthy men and women
* Aged between 18-50 years old
* Participating in military field exercise
* BMI between 18.5 - 30 kg/m2
* Stable body weight (< 5 kg change) over the past 3-months

Exclusion criteria

• Food allergies or other issues with foods that would preclude intake of the study products
• History of gastro-intestinal surgery or gastro-intestinal complaints or gastrointestinal diseases (i.e., diarrhoea, Crohn's disease, ulcerative colitis, irritable bowel syndrome, diverticulosis, stomach or duodenal ulcers)
• Suffering from metabolic, neuro-psychiatric disease (i.e., diabetes, hepatitis, HIV, cancer, epilepsy, major depression, AD(H)D, schizophrenia, etc.)
• Taking medication related to gut diseases or stress
• Being severely immunocompromised (HIV positive, transplant patient, on antirejection medications, on a steroid for >30 days, or chemotherapy or radiotherapy within the last year);
• Use of antibiotics within the previous 3 months
• Not willing to refrain from taking other supplements during the intervention period
• Pregnant, lactating or having a wish to become pregnant during the study
• History of drug and/or alcohol abuse at the time of enrolment
• Using doctor described drugs related to gut or neurological/psychiatric diseases
• Alcohol intake > 3 servings of alcoholic beverages per day
• Planned major changes in lifestyle (i.e. diet, dieting, exercise level,

travelling) during the duration of the study
• Suffering from an eating disorder
• Vegetarian/vegan diet or other issues with foods that would preclude intake of the study products
• High fibre diet (i.e. >30 g) based on our fibre intake screening tool;
• Receiving treatment involving experimental drugs. If the subject has been in a recent experimental trial, these must have been completed not less than 60 days prior to this study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-10-2022
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
Other	het traject loopt
CCMO	NL75954.091.20