

DBBO Night Shift Support Study

No registrations found.

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

Summary

ID

NL-OMON20803

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Not applicable

Sponsors and support

Primary sponsor: none

Source(s) of monetary or material Support: No funding sources

Intervention

Outcome measures

Primary outcome

The primary outcome measure of the current study is need for recovery, as measured with the 11-item Need for Recovery Scale from the Dutch Questionnaire on the Experience and Evaluation of Work (Van Veldhoven, & Broersen, 2003). Higher scores indicate an increased need for recovery.

Secondary outcome

Secondary outcome measures include fatigue, motivation, concentration, and physical activity, measured with the Checklist Individual Strength (Beurskens et al., 2000). A higher compound score refers to an increase in fatigue, and a decrease in motivation, concentration, and physical activity. Furthermore, indications of stress and (lack of) physiological recovery are measured using the parameters Stress Level and Body Battery from the Garmin Vivo Smart 4 fitness tracker (Firstbeat, 2019). These parameters are derived from a combination of heart rate, heart rate variability, respiratory rate, and duration and intensity of body movements. As a covariate, chronotype is measured using one item of the reduced Morningness–Eveningness Questionnaire (Adan & Almirall, 1991).

Study description

Background summary

In this study, the effectiveness of blue light glasses in night shifts of security guards from the Netherlands Armed Forces Security Agency is evaluated. A randomised controlled cross-over trial is performed, with half of the study population using light glasses in a 5-week work shift schedule (comprising approx. 7 night shifts), and half of the study population using the light glasses during the following 5-week block schedule. Primary outcome is the need for recovery (validated questionnaire); secondary outcome measures include fatigue, motivation, concentration, and physical activity (validated questionnaire), as well as indications of stress and lack of physiological recovery as measured with a fitness tracker. The trial will be performed in the first half of 2021.

Study objective

Blue light glasses can manipulate (i.e., inhibit) body melatonin production to re-adjust the circadian rhythm of shift workers, thereby having the potential to enhance vigilance, cognitive function, and positive mood during night shift work.

Study design

Baseline, week 5 (after 1st shift work block schedule), and week 10 (after 2nd shift work block schedule)

Intervention

Wearing blue light glasses for 30 minutes in the first half of a night shift

Contacts

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Eligibility criteria

Inclusion criteria

Healthy volunteers from the Netherlands Armed Forces Security Agency aged 18 to 67 years.

Exclusion criteria

Individuals with diseases of the retina (e.g., macular degeneration) were excluded from the study, as were security guards who were not capable of fulfilling their duty tasks without wearing their own glasses.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped

Start date (anticipated):	22-02-2021
Enrollment:	98
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description

N/A

Ethics review

Positive opinion

Date: 11-05-2021

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 49280

Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9458
CCMO	NL76088.028.20
OMON	NL-OMON49280

Study results

Summary results

N/A