Biomarker based intervention strategies to combat adverse effects of shift work

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

Summary

ID

NL-OMON53661

Source
ToetsingOnline

Brief title
GRIP

Condition

- Other condition
- Appetite and general nutritional disorders
- Sleep disorders and disturbances

Synonym
metabolic health, sleep

Health condition

slaap, vermoeidheid, wellbevinden

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: NWO

Intervention

Keyword: intervention, nutrition, shift work, sleep

Outcome measures

Primary outcome

The primary outcomes are the quality and quantity of sleep and stability and

levels of (continuous) glucose patterns.

Secondary outcome

Secondary outcomes include a set of relevant clinical biomarkers (of metabolic

health, epigenetic DNA methylation profiles in blood, and stress markers in

hair, and anthropometrics), and alertness during night shifts. For the

nutritional intervention, metabolic flexibility and inflammatory resilience

will be measured with the PhenFlex test.

Study description

Background summary

Night work interferes with the timing of daily activities and disturbs the circadian rhythms of multiple physiological processes in the human body. This is associated with detrimental health effects, such as disturbances in sleep (shorter, less consolidated sleep) and insulin regulation (due to altered eating behaviour). Night shift work is prevalent and difficult to limit in many job types, yet there is currently limited evidence on effective interventions to prevent the health consequence of shift work in a real life context. Therefore more research on tools for the prevention of negative health effects is warranted.

Study objective

The current study aims to investigate two types of preventive interventions in night shift workers: a personalised sleep intervention and a personalised nutritional intervention. It will assess the effects of the two interventions on sleep and on (continuous) glucose patterns.

Study design

A non-blinded controlled intervention study, consisting of a run-in period with baseline levels, an intervention of ~ 3 months including measurements at the start of the intervention, a post-intervention measurement and a follow up after 12 months. There are three study arms: control group (no advice), personalised sleep intervention, and personalised nutritional intervention. The total participation during the study for the sleep intervention and control group consists of: 3 visits to the Erasmus MC with 3 fasting blood draws (3x 30 mL). The total burden during the study for participants in the nutritional intervention group consist of: 3 visits to the Erasmus MC, where a fasting blood draw will be taken during each visit (3x 30 mL blood) and a PhenFlex test will be done in addition during 2 out of 3 visits (2x 60 mL additional sampling of blood, resulting in a total of 90 mL of blood drawn). Furthermore, all participants will log their food intake during 3 consecutive days, during 3 periods. All participants will wear the CGM and an actigraphy watch for a duration of 14 days during 3 periods. All participants will wear a wearable activity tracker during the whole study period, will be requested 4 times to fil in multiple questionnaires, and will complete a 5-min alertness test during 6 night shifts.

Intervention

Participants in the sleep intervention receive advice on: sleep hygiene/environment, sleep timing, naps, and exposure to light. These advices will be tailored to the personal situation of the participant, as measured during the run-in period. Participants in the nutritional intervention receive personalised advice on the distribution of calories and nutrients over 24 hrs, and on specific food products based on the outcomes of the continuous glucose measurements (CGM) during the run-in period. The guidelines will include room for personal dietary preferences. The control group is asked to carry on with their normal sleep and nutritional habits.

Study burden and risks

Venipuncture for blood samples might be experienced as painful. We expect no discomfort from wearing the activity trackers, glucose monitor or responding to questionnaires. These activities are a minimal burden to the participants and with low risks. For the PhenFlex test, participants will drink a high caloric and sweet drink, which may be experienced as unpleasant or nauseating. For people with (undiagnosed) type 2 diabetes there is a small risk of

hyperglycemia. Experienced medical professionals are present during these PhenFlex tests and will closely monitor the participants. Participants will receive a personalised sleep or nutritional advice (based on their own personal situation) or no advice (control). Based on previous findings we expect that these advices may have a beneficial effect on the participants* health and provide valuable insight into the effectiveness of the interventions.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr.Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age 18 to 60 years.
• Work at least 4 night shifts a month on average.
• Shift workers, working rotating shifts (morning, evening and night shifts) or working predominantly night shifts. Night shift defined as work at least 1 hours between 0:00- and 6:00.

• Work at least 2 night shifts in a row
• Work >= 20 work hours per week.
• Having a shift duration of 6 h-12 h.
• History of >= 1 year of working rotating shift work or night shifts prior to the study.

Exclusion criteria

• Taking medication that the investigator believes would interfere with the objectives of the study. For example, sleep medication, medication that interferes with glucose homeostasis, and/or anti-inflammatory drugs.
• Pregnant or have a wish to become pregnant during the study period.
• Planned surgery during the entire study period
• Alcohol consumption > 21 units/week
• Severe psychiatric disease and/or any mental or physical disability that will hinder participation in the interventions
• Severe cardiovascular disease, to the discretion of the study doctor
• Having a chronic inflammatory disease, including asthma, rheumatic fever, IBD, COPD
• Other bowel diseases, including Chron*s disease and Colitis Ulcerosa.
• A disease or condition with higher bleeding risk (/risk of hemorrhage), under which a blood sample may lead to complications.
• Participation in any clinical trial including blood sampling and/or administration of substances up to 90 days before Day 01 of this study
• Recent blood donation (<1 month prior to the start of the study)

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	15-01-2023
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO Date:	17-01-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-07-2023
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
CCMO	NL82649.078.22