Kairos-study: Sleep interventions in night shift workers

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

Summary

ID

NL-OMON53238

Source
ToetsingOnline

Brief title
Kairos-study

Condition

- Other condition
- Sleep disorders and disturbances

Synonym
Metabolic health, Sleep

Health condition

risicofactoren voor metabole aandoeningen, alertheid

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Intervention, Shift work, Sleep

Outcome measures

Primary outcome

The primary outcomes are the quantity of sleep and alertness during night shifts.

Secondary outcome

Secondary outcomes include quality of sleep, and a set of relevant clinical biomarkers (of metabolic health and anthropometrics). The outcomes will be compared between intervention and control group, pre- and post-intervention.

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), cardiometabolic disease and infection susceptibility. 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 sleep interventions in night shift workers: a split sleep intervention strategy and a short sleep episode (powernap, max. 20 min) during a night shift. It will assess the effects of the

two interventions on sleep, alertness and anthropometric, physiological and clinical blood markers for metabolic health.

Study design

A non-blinded randomized controlled intervention study, consisting of a run-in period with baseline levels, an intervention period of ~11 months, including measurements at the start and end of the intervention with two additional interspersed measurements, and a potential follow up 12 months after the intervention period*.

Intervention

All participants, including those in the control arm, receive advice on general sleep hygiene. In addition, participants in the split sleep intervention receive advice on how to split their daytime sleep into two blocks of sleep, before and in between consecutive night shifts. Participants in the powernap intervention will receive advice on when and how to take a powernap. Participants are asked to take 1 powernap of max 20 min. during each night shift. Powernap facilities are provided by the employer.

Study burden and risks

The total burden during the study for the sleep intervention and control groups consists of: 2-3 visits to a location of choice of a national diagnostics laboratory for fasting blood draws (10 mL total blood per visit), and, at a central location near the worksite, blood pressure and anthropometric measurements. All participants will wear an actigraphy watch and fill out an activity-diary for a duration of 7 days per period for 5-6* periods over the course of the study. All participants will be requested 5-6* times to fill in questionnaires. In addition, participants will complete two 5-min alertness tests (at beginning and end of the night shift) during 10-12* night shifts, being the first two night shifts of a set. Venipuncture for blood samples might be experienced as uncomfortable. We expect no discomfort from wearing the activity trackers or responding to questionnaires. These activities are a minimal burden to the participants and with low risks. Participants will receive general sleep hygiene advice, powernap advice and/or split sleep advice. 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 3 night shifts a month on average. Night shift defined as work at least 3 hours between 0:00- and 6:00.
• Work generally at least 2 night shifts in a row
• Work >= 20 hours per week.
• History of >= 0.5 year of working night shifts prior to the study.
• Expected to remain working night shifts for >= 1 year from inclusion in the study.

Exclusion criteria

• Taking medication that the investigator believes would interfere with the objectives of the study. For example, sleep medication or supplements like melatonin.
• Pregnant or having a wish to become pregnant during the study period.
• • Using powernaps during, or split-sleep strategies during or prior to, >=50%

of the night shifts (prior to the study start).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	90
Type:	Anticipated

Ethics review

Approved WMO Date:	26-04-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-07-2023
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	NL84059.078.23