Pre-Obesity Markers In Shift workers and non-shift workers

Published: 15-07-2024
Last updated: 27-12-2024

The primary objective of this study is to compare lifestyle factors, dietary behaviours, environmental factors and pre-obesity risk markers between shift workers and non-shift workers from the industrial sector and the health care sector.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56886

Source
ToetsingOnline

Brief title
PROMIS

Condition

- Other condition

Synonym
circadian disruption

Health condition

circadiane verstoring

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Biomarkers, Lifestyle, Obesity, Shiftwork

Outcome measures

Primary outcome

The main study parameters are lifestyle factors (sociodemographic background & environment, shift schedules & work activities, sleeping behaviour, diet, quality of life, lifestyle and physical activity, health, literacy, and interests in ways to change lifestyle), body composition, biomarkers (urine, faeces, blood, hair), smell and taste ability, food preferences and perceptions and dietary behaviour. The biomarker hs-CRP is taken is primary outcome for the sample size estimation.

Secondary outcome

Not applicable

Study description

Background summary

Multiple studies have recently shown that working rotating night shifts is associated with an increased BMI and a higher risk for developing overweight and obesity. In addition, there is growing evidence that chrono-disruption and mis-timed eating have deleterious effects on metabolic health and consequently, shift work is linked to the risk of chronic diseases such as cardiovascular disease, type 2 diabetes and several types of cancer. Disruption of the internal circadian timing system and concomitant sleep disturbances is thought to play a critical role in the development of these health problems, but also other factors may play a role. To further address how night shift work impacts

metabolic health population-based mechanistic study data is needed. The European Shift2Health project will focus on providing population-based mechanistic data on a wide range of biomarkers of metabolic disease risk that will advance our knowledge on the short- and long-term health effects related to night shift and eventually will help in designing and applying efficient prevention policies.

Study objective

The primary objective of this study is to compare lifestyle factors, dietary behaviours, environmental factors and pre-obesity risk markers between shift workers and non-shift workers from the industrial sector and the health care sector.

Study design

The PROMIS study is a cross-sectional study comparing lifestyle factors and pre-obesity marker between shift workers and non-shift workers. In addition, the shift workers are nested in an additional mechanistic component of the study investigating differences in pre-obesity marker between different shifts.

Study burden and risks

All participants will have a study day at the location of employment before a day shift (shift workers) or at the start of a regular working day (non-shift workers). This study day will take approximately 1 hour and 30 minutes. Prior to the study day participants will complete a baseline questionnaire (±45 minutes), collect morning spot urine and faeces samples, which will be handed in on the study day. During the study day, participants* body composition will be measured, a fasting blood sample, and hair sample will be collected. Hair sampling is painless but venapunctures can occasionally cause a local hematoma or bruise and some participants may report pain or discomfort. All participants will perform a food preference and perception task as well as an identification test for smell and taste. After having breakfast, participants will complete one final questionnaire (±5 minutes). At the end of the study day, participants will be invited to report their food intake via Traqq®; shift workers will complete a total of six 2hR-days and non-shift workers a total of three 2hR-days, within a two-week period. Responding to the 2hR prompts will take on average 5 minutes.

The shift workers will have some additional measurements, i.e., collection of two 24-hour urine samples; once the day before the study day, and once during the night shift measurement day. During the study day (before the day shift), they will collect a dried blood spot and tongue swap, which will be repeated after the day shift. Within the following two weeks there will be another measurement day, during a night shift, where the night shift workers repeat the

dried blood spot collection and tongue swap. In addition, they will once more complete the short questionnaire from the study day (±5 minutes). Between the study day and the night shift day, the shift workers wear a MotionWatch to assess physical activity and sleep.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria for shift workers:
• Health care sector or industrial shift worker
• Employed or self-employed
• 21 years or older
• Working hours: >= 28 h/ week
• Shift work duration > 3 years and currently doing night shifts
• 4 or more rotating night shifts/month (night shift defined as a work schedule

that involves working at least 3 hours between 00:00 and 5:00), at least 2 consecutive nights/month

Inclusion criteria non-shift workers:
• Health care sector or industrial work
• Employed or self-employed
• 21 years or older
• Working hours: >= 28 h/ week
• No night shift or rotating shift work in the last 10 years
• No history of night shift or rotating shift work for more than 5 years

Exclusion criteria

Exclusion criteria for shift workers and non-shift workers
• Pregnancy
• Lactation period
• BMI of 40 or above
• Present treatment of a disease e.g. cancer radio- or chemotherapy
• Chronic diseases if in an ongoing therapy but not after a remission (renal failure, active hepatitis, cirrhosis, myocardial infarction, chronic obstructive pulmonary disease and cancer)
• Immunodeficiency syndrome, any acute episode of auto-immune or auto-inflammatory diseases (e.g., type-1 diabetes, multiple sclerosis, lupus, rheumatoid arthritis) and acute episodes of atopic diseases (atopic dermatitis, asthma, type 1 allergies such as hay fever)
• Bariatric surgery
• Antibiotics in the last month
• Participation in another human trial
• No literacy in Dutch (not able to speak and read Dutch)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2024
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO Date:	15-07-2024
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-11-2024
Application type:	Amendment
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
CCMO	NL86146.091.24