Clockwork+: An observational study to the effects of shift work on body weight and infection susceptibility and the mechanisms underlying these health effects

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

Summary

ID

NL-OMON46251

Source
ToetsingOnline

Brief title
Clockwork+

Condition

- Other condition
- Hepatobiliary neoplasms malignant and unspecified

Synonym
acute respiratory infection; overweight, flu, Influenza-like-illness, obesity

Health condition

overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Eerste geldstroom RIVM

Intervention

Keyword: Body weight, Infection susceptibility, Shift work

Outcome measures

Primary outcome

The primary study parameters are shift work exposure, body weight and infection susceptibility. Shift work exposure will be measured with an extensive questionnaire covering the different domains of shift work, i.e. shift system, cumulative exposure and shift intensity. Furthermore, anthropometric measurements (i.e. height, weight and waist circumference) will be performed during the study to assess changes in body weight. Infection susceptibility will be defined as the development of influenza-like illness (ILI). The occurrence of ILI cases during the study period will be measured with a log (app).

Secondary outcome

The secondary study parameters are the potential mechanisms that link shift work to health effects on which we will focus in this study; these are sleep factors, physical activity, diet behaviors, light, vitamin D level and immunological factors. Furthermore, other parameters that may play a role in the relation between shift work and health will be measured; these are smoking, alcohol use, job satisfaction, work-life balance, general health, absenteeism

and presenteeism. In addition, factors that may modify the relation between

shift work and health will be measured; these are socio-demographic factors,

chronotype and quality of life.

Study description

Background summary

Shift work may cause severe disruptions in the worker*s circadian rhythm, which can lead to the onset of health problems and diseases. As a large part of the workforce is exposed to shift work, harmful aspects of shift work should not be overlooked. Therefore, clear evidence for, as well as mechanistic insight into, the relation between shift work and health problems such as overweight and infectious diseases is needed. This knowledge can be the starting point for the development of scientific-based interventions that prevent and reduce negative health effects caused by shift work. In addition, the identification of biomarkers that are indicative of loss of homeostasis due to circadian disruption may be an important asset in monitoring the effects of such interventions.

Study objective

The aim of this project is to study the effects of shift work on body weight and infection susceptibility and the mechanisms underlying these health effects. First, we will study the relation between shift work exposure and body weight and between shift work exposure and infection susceptibility. Second, we will examine the mechanisms linking shift work exposure to body weight and infection susceptibility, with a specific focus on sleep, physical activity, diet, light, vitamin D level and immunological factors. Lastly, we will focus on the identification of biomarkers for shift work associated circadian disruption.

Study design

The design of this study will be a prospective observational cohort study consisting of 1,960 health care workers. The study population will consist of both shift working and non-shift working health care workers. There will be two measurement periods: one at the beginning of the flu season in October/November (baseline measurement) and one at the end of the flu season in April (after 6 months). The measurements will consist of questionnaires, anthropometric measurements, a log (app) to determine infection susceptibility, food diaries,

actigraphy, light sensors, and blood sample analyses.

Study burden and risks

Participants are asked to fill in a questionnaire at baseline and after 6 months, keep a log (app) about infection susceptibility during 6 months, and keep a food diary for 3 days at baseline. These activities may be fairly time-consuming for participants. Furthermore, a subsample of the participants (n=260) will be asked to wear an actigraphy device and a light sensor for 7 days at baseline and at 6 months to measure activity levels and light exposure. These wearing devices may also cause slight inconvenience. Lastly, the collection of blood samples at 6 months (one blood sample per participant) may also cause short-term discomfort for the participant and may cause a hematoma or bruising at the puncture site.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Participant is between 18 and 65 years old at time of recruitment.
Participant has a job as a nurse or an (allied) health professional in the participating hospital.
Participant is expected to be employed as a health care worker during the complete follow-up period (until the summer of 2017).

Exclusion criteria

Participant is on long-term sick leave (* 4 weeks) at time of recruitment.
Participant is pregnant or on maternity leave during the study period.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2016
Enrollment:	1960
Type:	Actual

Ethics review

Approved WMO

Date:	15-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	08-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL56022.041.16