

# Healthy through the night. Minimize harmful health effects among caregivers on emergency care caused by night shifts

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Sleep disorders and disturbances
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON48015

### Source

ToetsingOnline

### Brief title

Healthy through the night

### Condition

- Sleep disorders and disturbances
- Lifestyle issues

### Synonym

sleep quality and health

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Jeroen Bosch Ziekenhuis

**Source(s) of monetary or material Support:** Wetenschapsbureau>Stipendium

## Intervention

**Keyword:** food, Night shift, powernap, sleep quality

## Outcome measures

### Primary outcome

Subjective sleepiness during the night shift measured with the Karolinska Sleepiness Scale (KSS).

### Secondary outcome

General physical and psychological well-being around the night shift measured by means of General Health Questionnaire.

Sleep quality after performing the night shift measured by the Shift Work Disorders questionnaire.

Serum values of fasting glucose, insulin, glucagon, HbA1C, cortisol, lipid spectrum, triglycerides and leptin.

## Study description

### Background summary

Working at night during hours disturbs the day-night rhythm of the body. The normal pattern is broken and the day- night cycle changes, with exposure to light, nutrition and activity taking place at a different time than normal. The biological clock indicates in the night shift that it is time to sleep and the caregivers are usually long awake before the start of the service, they become sleepy and less alert during the night. By working in shifts, due to the disruption of the biological clock, many problems arise. Sleep disorders but also serious health risks such as heart disease and diabetes.

### Study objective

The aim of the study is to test whether the implementation of a package of specific measures during the night shifts at the emergency room, improved subjective sleepiness during the night shift.

In addition, we investigate whether the package of measures has an affect after 6 months implementation the long- term health effects (testing markers of diabetes mellitus and cardiovascular disease)

## **Study design**

This is a single center intervention study with a before and after design at the care providers who do night shift at the emergency room in the Jeroen Bosch Hospital.

## **Intervention**

The intervention consists of a number of measures, namely light therapy in the night and in the morning, food and powernap during the nightshifts. These measures are applied for a period of 6 months.

## **Study burden and risks**

The burden for the participants consists of completing a short questionnaire regarding subjective sleepiness (1 minute) in each night shift and before intervention and after 6 months a questionnaire regarding sleep quality, general physical and psychological well-being (2 x 60 minutes). Likewise, blood is taken before and after 6 months to mark health complaints.

Possible risks: Participants may have a nut and / or fruit allergy that has not previously been revealed. There are possible pain complaints and / or bruising after blood tests.

Damage caused by the use of the Energypod / Loungescape power nap is considered minimal.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

All caregivers who work in a night shift and who, after inclusion, will be working for more than 6 months at the Emergency Department.

### Exclusion criteria

Lack of informed consent from the participants.

Woman who are pregnant and do not have night shifts during the study

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 18-06-2019

Enrollment:	179
Type:	Actual

## Ethics review

Approved WMO	
Date:	07-06-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	19-08-2019
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## 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	NL69590.028.19