Healthy through the night.

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To test whether implementing a bundle of specific measures during the night shifts at the A&E department improves sleep quality and general physical and psychological well-being Investigate whether this bundle of measures 6 months after...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21237

Bron
NTR

Verkorte titel
GDDN

Aandoening

no diseases

Ondersteuning

Primaire sponsor: none
Overige ondersteuning: none

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

RATIONAL
Performing work during the night hours disrupts the day-night rhythm of the human body. The normal pattern is broken and the day-night cycle changes, with exposure to light, food and activity occurring at a different time than normal. During the night shift, the biological clock indicates that it is time to sleep and caregivers are usually awake long before the start of the shift, making them sleepy and less alert at night. Many health problems arise from working in services and the disruption of the biological clock. Thus, a disruption of the biological clock not only causes sleep disorders, but also serious health risks such as cardiovascular disease and diabetes.

Goals:
To test whether the implementation of a bundle of specific measures during the night shifts in the A&E department improves sleep quality and general physical and psychological well-being.
Investigate whether this bundle of measures 6 months after implementation has an effect on the health effects in the longer term (tests predictive markers of diabetes mellitus and cardiovascular disease
Research design:
This was first a single center intervention study with a "before and after" design among care providers who perform night work at the Emergency Department in the Jeroen Bosch Hospital (JBZ).Later an addendum was added. The study has expanded to the SEH and IC at the Maxima Medical Center in Veldhoven.

Research population:
Emergency care providers who work night shifts. There are 53 emergency room nurses and 14 emergency room doctors. In the Maxima Medical Center 70 care providers.
The research team does not work in the department of the research population. The principal investigator and research nurses work in the Intensive Care Unit and are not affiliated and / or employed in the Emergency Department.

Intervention:
The intervention consists of a bundle of specific measures:
- light therapy at night and in the morning;
- nutrition;
- power nap.
This bundle of measures is applied for a period of 6 months.

Research parameters / endpoints:
Primary Study Parameter / Endpoint
• Subjective sleepiness during the night shift measured with the Karolinska Sleepiness Scale (KSS).

Secondary research parameters / endpoints
• General physical and psychological well-being around the night shift measured by means of the General health questionnaire.
• Sleep quality after performing the night shift measured by means of the Shift Work Disorders questionnaire.
• Fasting serum levels of glucose, insulin, glucagon, HbA1C, cortisol, lipid spectrum, triglycerides and leptin.

Load of subjects:
The burden on the subjects consists of completing a short questionnaire on subjective sleepiness (1 minute) in each night shift. Before the start of the intervention and after 6 months, a questionnaire on sleep quality, general physical and psychological well-being (2 x 60 minutes) will have to be completed. There is a pre- and post-measurement in which blood is taken to determine predictive markers of health complaints.
The research involves moderate risks. Test subjects may have a nut and / or fruit allergy that has not manifested itself before (Lucassen PLBJ 2010). The chance of this is very small, but possible with serious damage (anaphylactic shock).
The GP is only informed in case of unexpected side effects / findings.
Damage due to the use of the Energypod / Loungescape power nap is considered minimal.

Doel van het onderzoek

To test whether implementing a bundle of specific measures during the night shifts at the A&E department improves sleep quality and general physical and psychological well-being Investigate whether this bundle of measures 6 months after implementation has an effect on the health effects in the longer term (tests predictive markers of diabetes mellitus and cardiovascular disease).

Onderzoeksopzet

measurements at time 0 and after 6 months.

Onderzoeksproduct en/of interventie

The intervention consists of a bundle of specific measures:
- light therapy at night and in the morning;
- nutrition;
- power nap. (20 min)

Contactpersonen

Publiek

JBZ
GAM Salet

0614555155

Wetenschappelijk

JBZ
GAM Salet

0614555155

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All care providers who work the night shift and who, after inclusion, will work at the Emergency Department for longer than 6 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Lack of informed consent from the subjects.
Women who are pregnant.
All care providers who do not perform a night shift during the study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	18-06-2019
Aantal proefpersonen:	37
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Processing and storage of data and documents
The personal data will be stored in accordance with the General Data Protection Regulation (GDPR). All data is encrypted. The subjects are given a code consisting of an ascending number (00001-00067). There is a 1 file with name code in which the test subject is linked to the code. These are kept on paper in a lockable research cabinet by the principal investigator Drs. G.A.M. Salet and the IC research coordinators as well as the PIF. This key is kept in a locked key cabinet, which is only accessible to the research team. The raw data becomes

stored using the subject code. Only the researchers directly involved in this research have access to the raw data.
The Emergency Department does not have access to the raw data. The coded data is collected in the ECRF; The research manager using the Data Management module. Reporting to fellow scientists, research subjects and scientific publications will be free of traceable personal data. The individual data cannot be traced back to persons, this data is anonymous and not encrypted. The personal data and body materials will be kept for a maximum of 15 years and will be stored in the archive of the Jeroen Bosch Hospital after the end of the research.

11.2 Monitoring and quality
Monitoring is carried out by the JHA science office. A monitoring plan is available (V3.0 05 Feb2018). The risk classification is by the principal investigator Drs. G.A.M. Salet determined at moderate risk. Subjects may have a nut and / or fruit allergy that has not manifested itself before. The chance of this is very small, but possible with serious damage (anaphylactic shock).

Ethische beoordeling

Positief advies

Datum:	28-09-2020

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8980
CCMO	NL. Nummer: NL69590.028.19 METC nr. : P1917

Resultaten

Samenvatting resultaten
Upon completion of the study, the results will be prepared in a manuscript within 1 year of the end of the study. This manuscript will be submitted to a peer-reviewed medical journal and the results will be presented at meetings and conferences. Until the data has been thoroughly analyzed, the results will not be made public.