Nutrition and night shift work

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1) To investigate the effect of either the consumption of 1 or 3 small meals compared to no meal during the night shift on alertness levels, gastrointestinal complaints and glucose levels.
2) To investigate the effect of low glycaemic loaded meal(s...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON25574

Source
Nationaal Trial Register

Brief title
Time to Eat

Condition

- Gastrointestinal signs and symptoms

Health condition
Healthy

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen University and Research
Source(s) of monetary or material Support: NWO, TiFN

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

Objective alertness levels (reaction time, number of lapses)

Secondary outcome

Glucose metabolism (glucose levels, iAUC), gastrointestinal complaints, subjective alertness levels (Samn Perelli Scale), hunger feelings, and chronotype.

Study description

Background summary

Rationale: Night shift workers have a 30 percent higher risk of making (medical) errors or having accidents than day shift workers. This is mainly the result of shift work-related fatigue which is related to lower alertness levels. Alertness levels are at lowest between 2:00h and 6:00h in the early morning, and eating a large meal may impair alertness levels even further. Not eating, or eating one or more small meals during the night shift could improve alertness levels. Objectives: 1) To investigate the effect of either the consumption of 1 or 3 small meals compared to no meal during the night shift on alertness levels, gastrointestinal complaints and glucose levels. 2) To investigate the effect of low glycaemic loaded meal(s) compared to high glycaemic loaded meal(s) during the night shift on alertness levels, gastrointestinal complaints and glucose levels. Study design: 2-armed randomized cross-over intervention study, where each study arm consist of three intervention periods. In one study arm participants will receive 3 small meals during the night shift and in the other study arm participants will receive 1 small meal during the night shift. Study population: 60 healthy female nurses who work the night shift at Hospital Gelderse Vallei (ZGV), aged 18 to 67 years old. Intervention: During two of the three intervention periods, nurses will receive either 1 small meal or 3 small meals during the night shift. During one of these two intervention periods the meals consist of carbohydrates high in glycaemic load and during the other intervention period the meals consist of carbohydrates low in glycaemic load. During a third intervention period participants in both study arms will receive no meal during the night shift as a control. Main study parameters/endpoints: The main study parameters will be objective alertness measured as total number of lapses and reciprocal reaction time. Secondary study parameters will be subjective alertness levels, gastrointestinal complaints and glucose levels.

Study objective

1) To investigate the effect of either the consumption of 1 or 3 small meals compared to no

meal during the night shift on alertness levels, gastrointestinal complaints and glucose levels.
2) To investigate the effect of low glycaemic loaded meal(s) compared to high glycaemic loaded meal(s) during the night shift on alertness levels, gastrointestinal complaints and glucose levels.

Study design

"A 2-armed randomized cross-over intervention study.
"

Intervention

"In one study arm participants will receive 3 small meals during the night shift and in the other study arm participants will receive 1 small meal during the night shift. Each study arm consist of three intervention periods.
During one of these intervention periods the meals consist of carbohydrates high in glycaemic load and during the other intervention period the meals consist of carbohydrates low in glycaemic load. During a third intervention period participants in both study arms will receive no meal during the night shift."

Study burden and risks

Participation in the study will not bring any risks. Also patient safety will not be jeopardized. The burden for participants will be kept as low as possible. The placement of the CGM, though quite non-obtrusive, can be considered as a burden for the participants. The calibration of the CGM may be considered a burden due to the finger prick that is required four times a day by a glucose meter. Participants will have to invest approximately 5 hours in the study, therefore time investment could be a potential burden. Also following the dietary regimen can be considered as a burden. As a personal benefit, participants get more insight in their eating patterns, alertness levels and glucose metabolism.

Contacts

Public
Wageningen University & Research
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Scientific
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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

Female Working the night shifts for at least 3 months At least 18 years old and not older than 67 years at time of recruitment Willingness to reduce or substitute caffeine containing beverages.

Exclusion criteria

Diagnosed with Diabetes Mellitus type 1 or 2 Diagnosed with hypoglycaemia Do follow a specific diet (e.g. Atkins, ketogenic diet) Current participation in other medical research Reported unexplained weight loss or weight gain of > 5 kg in the month prior to pre-study screening Smoking during the night shift Being lactose-intolerant. Being fructose-intolerant.

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Dose comparison
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	29-09-2020
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO Date:	15-06-2020
Application type:	First submission
Review commission:	METC Oost-Nederland

Study registrations

Followed up by the following (possibly more current) registration

ID: 49414
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8715
Other	METC-WU : ABR: NL72634.081.20
CCMO	NL72634.081.20
OMON	NL-OMON49414

Study results