The effect of either the consumption of 1 or 3 small meals, with a high or low glycaemic load, compared to no meal during the night shift on alertness levels, gastrointestinal complaints and glucose levels.

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The primary objective of this study is 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. Secondary objectives of this study are to investigate the effect of...

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

Summary

ID

NL-OMON49414

Source
ToetsingOnline

Brief title
Time to Eat

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Alertness, gastrointestinal complaints

Health condition

cognitief functioneren

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: NWO;TiFN,Danone Vitapole,DSM Food Specialties,Friesland Nutrition,Universiteit Maastricht

Intervention

Keyword: alertness, glycemic load, meal frequency, Night shift

Outcome measures

Primary outcome

The main study parameters will be objective alertness measured as total number

of lapses and reciprocal reaction time.

Secondary outcome

Secondary study parameters will be subjective alertness levels,

gastrointestinal complaints and glucose levels.

Study description

Background summary

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 impairs alertness levels even further. Not eating, or eating one or more small meals during the night shift could improve alertness levels.

Study objective

The primary objective of this study is 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.
Secondary objectives of this study are to investigate the effect of either the consumption of 1 or 3 small meals compared to no meal during the night shift on gastrointestinal complaints and glucose levels and 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.

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 both study arms will receive no meal during the night shift as a control.

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 continuous glucose monitor (CGM), though quite non-obtrusive, can be considered as a burden for the participants. The placing of each piece of equipment will be done by experienced researchers and will be secured by well-practiced measures to minimize issues the participant may encounter. 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. The results of this study will provide information about the effects of meal frequency on the nurses* alertness levels, gastrointestinal complaints and glucose metabolism. With the results of this study we want to optimize dietary guidelines for shift workers in order to improve the fitness and wellbeing of shift workers and to reduce the risk of making (medical) errors or having accidents.

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

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 adhere to a nutrition protocol

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 type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2020
Enrollment:	66
Type:	Actual

Ethics review

Approved WMO

Date:	20-07-2020
Application type:	First submission
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

ID: 25574
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
Other	Nederlands Trial Register
CCMO	NL72634.081.20
OMON	NL-OMON25574