Pre-sleep feeding to increase daily protein intake in patients during hospitalisation

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To assess the efficacy of pre-sleep protein feeding strategies to effectively increase daily protein and energy intake during hospitalization

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

Summary

ID

NL-OMON55166

Source
ToetsingOnline

Brief title
Pre-sleep feeding to increase daily protein intake during hospitalization

Condition

- Other condition

Synonym
energy- and protein intake

Health condition

to assess the efficacy of pre-sleep protein feeding strategies to effectively increase daily protein and energy intake during hospitalization

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Friesland Campina,TKI/Health~Holland

Intervention

Keyword: hospitalization, pre-sleep snack, protein

Outcome measures

Primary outcome

total protein intake (g, g·kg body mass-1·day-1) during hospitalization

Secondary outcome

(total) energy intake (kJ), protein distribution, hunger, habitual food intake,

physical activity, grip strength.

Study description

Background summary

Hospitalization is generally accompanied by substantial changes in food intake. Low levels of energy and protein intake results in accelerated loss of lean body mass and muscle strength. Various strategies can be applied to increase protein intake during hospitalization, such as providing more protein-rich foods, fortifying meals and/or food products, supplementation with oral nutritional supplements (ONS), and/or providing well-timed snacks. The pre-sleep moment has emerged as a novel window of opportunity to increase daily protein intake. However, it remains to be established whether pre-sleep protein feeding represents an effective strategy to increase overall daily protein intake during hospitalization.

Study objective

To assess the efficacy of pre-sleep protein feeding strategies to effectively increase daily protein and energy intake during hospitalization

Study design

randomized intervention trial

Intervention

Participants will be randomized to the cheese intervention group (CHEESE, n=50), or the standard care group (CON, n=50). Patients in the CHEESE will receive 30 g protein prior to sleep. The CON group will receive standard care and do not receive a pre-sleep snack. Patients in the CHEESE group will receive the snack every evening during their hospital stay. Total protein intake, protein distribution, hunger, handgrip strength, habitual food intake, and physical activity, will be assessed during the hospital stay.

Study burden and risks

The burden and risks involved in participating in this trial are small. A benefit is that when patients are randomized to one of the intervention groups, they will receive a pre-sleep snack. A potential burden can be that a research will provide them with a hunger questionnaire every morning before breakfast. Patients will not be restricted to consume snacks and drinks during their hospital stay

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

1) Admitted to MUMC+
2) 18-90 y
3) Expected hospital stay at least 2 days

Exclusion criteria

1) Receiving enteral nutrition
2) Receiving parenteral nutrition
3) Dislike cheese
4) Use of MAO-inhibitors
5) Low sodium diet
6) *NPO* (nil per os) policy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-07-2021
Enrollment:	100

Type:	Actual

Ethics review

Approved WMO Date:	03-04-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-01-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-07-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL71830.068.19
Other	Protocol will be registered at NTR after approval by METC