Compliance of dairy products versus oral nutrition supplements in patients with a risk for malnutrition.

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

Summary

ID

NL-OMON41996

Source
ToetsingOnline

Brief title
Dairy.Com

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
malnutrition; undernutrition

Health condition

ondervoeding

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina Nederland BV
Source(s) of monetary or material Support: financiering door sponsor (FrieslandCampina)

Intervention

Keyword: Dairy products, Malnutrition, Oral nutrition supplements, Protein

Outcome measures

Primary outcome

The main study parameter is compliance, specified as adherence to prescription of daily protein goals (daily protein intake). A compliance questionnaire will be assessed to list the experiences of the participant about associated factors of compliance.

Secondary outcome

Secondary study parameters are (1) patient experiences (2) urine nitrogen secretion, (13) nutritional status, (24) body composition (BMI, bio-electrical impedance analysis), and (35) hand grip strength.

Study description

Background summary

Malnutrition is a considerable problem within the health care setting. Prevalence of malnutrition is estimated at about 12 percent in the acute hospital setting (Halfens et al., 2014). To prevent malnutrition, a high-protein diet is essential to build muscle mass and improve muscle function. However, little is known aboutIn this respect, the compliance of extra intake of protein-rich products is key to maintain and improve nutritional status. Therefore, protein-rich dietary interventions with a high compliance may be more beneficial for patients with risk of malnutrition in order to prevent malnutrition on long term. and effectiveness of dairy food and oral nutrition supplements in relation to maintain or improve nutritional

status in patients with a risk for malnutrition. We hypothesize that for both protein rich dairy products and oral nutrition supplements the nutritional requirements of patients with risk of malnutrition can be met adequately, but the compliance of these interventions may differ. without the use of oral nutrition supplements, and that changes in patient*s nutritional status, body composition and muscle strength will be similar when a dairy based diet or an oral nutrition supplement based diet is prescribed. Besides, we hypothesize thatThe patient satisfaction on dairy products maywill be higher because dairy products are easier to incorporate in the daily eating habits than oral nutrition supplements.

Study objective

The main objective is to gain insights inassess the compliance (i.e. adherence to prescription) of a dairy based diet compared to a diet including oral nutrition supplement in (out)patients with a risk of malnutrition. dairy products and oral nutrition supplements in clinical outpatients with risk of malnutrition. Secondary objective is to gain insights into the potential improvements in the nutritional status and body composition over time resulting from the dairy-based diet vs. diet with oral nutritional supplements.

Study design

A randomized controlled intervention study.

Intervention

Participants receive a high-protein diet: the experimental group receives extra (protein-rich) dairy products, and the control group receives extra oral nutrition supplements for in between use in order to supplement protein to their diet. The dietary advice consists of at least 12 gram of protein per day in addition to the normal protein intake, aiming at a total intake of 1.0 - 1.2 gram protein per kg body weight per day. Both groups will be counselled by a dietician for 8 weeks, and will receive two consultations in the hospital (week 0, and week 4) and two telephone consultations (week 2 and 6).

Study burden and risks

As part of the usual care, (out)patients of the UMCG are screened on malnutrition with the Malnutrition Universal Screening Tool (MUST). In current UMCG policy,As part of usual care, malnourished outpatients, with a MUST=2 score, are referred to a dietician. Outpatients with a medium risk of malnutrition (MUST = 0 or 1 point and PG-SGA SF score >= 4 and <9) are not referred to a dietician. Still, these patients need also dietary advice to prevent further progress of malnutrition. We will include this group of patients and offer these patients a high protein diet to prevent malnutrition.

There will be no costs for the participants. All dairy products as well as the oral nutrition supplements will be provided by the sponsor and distributed by UMCG dieticians or, if necessary, will be delivered at home.
The participants need to visit the hospital four times, of which at least one usual care hospital visit. The screening is part of the usual care for outpatients. We planned three assessment moments in the hospital (week 0, week 4, and week 8), and one assessment moment at home consisting of questionnaires (week 1). Besides, participants will be asked to keep a simple diary to check if daily protein goals are achieved and to list the product choice. The measurement moments in the hospital will last about 60 minutes and consist of questionnaires to fill in and measurements of body composition and hand grip strength. To assess urine nitrogen excretion, participants will be asked to collect 24 hours urine samples at baseline and week 8. This may be a slight burden for participants.
The benefit of participation in this study, is that participants will receive individual dietician advice with accompanying products without extra costs. We expect positive effects of participation on nutritional status, body composition, and possibly muscle strength. There are no risks associated with participation. Overall, we think the benefits for the participants will outweigh the possible burden.

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

* Risk for malnutrition (MUST = 0 or 1 point and PG-SGA SF score >= 4 and <9)
* Aged 18 years and older
* Able to eat orally and without the help of others
* Able to understand, speak, and write in the Dutch language

Exclusion criteria

* Use of oral nutrition supplements in the past six months at time of inclusion.
* Receiving treatment of a dietician at time of inclusion.
* High current daily protein intake (less than 12 gram difference between current intake and protein requirement).
* Protein requirements >18 gram protein per day.
* Prescription of oral nutrition supplements by the dietician.
* Contra-indication for dairy products (e.g. lactose-intolerance, cow milk allergy).
* Protein restriction (<=0.8 gram protein / kg actual body weight)
* Diseases associated with a reduced protein intake advice: Congenital disorders of amino acid metabolism; Chronic kidney disease; Kidney transplantation (> 2 months ago); Duchenne muscular dystrophy; Gout.
* Fluid restriction (<=1500 ml).
* Pacemaker.
* Bound to wheel chair, longterm (>6 months).
* Eating disorder.
* Dementia.
* Distance from home to the UMCG is greater than 70 km. (due to practical reasons concerning distribution of the products).

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2015
Enrollment:	131
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL51827.042.15

Study results

Date completed:	15-02-2016
Actual enrolment:	4