

Effectiveness of Cater with Care products in reaching recommendations for protein intake during and after hospital stay and in improving functional status after hospital stay in elderly patients.

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To study the effectiveness of supplementing a standard hospital and 12-week home menu with protein-enriched Cater with Care products in reaching a protein intake of 1,2-1,5 g/kg/day and in improving functional status after hospital stay in elderly...

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

Summary

ID

NL-OMON40880

Source

ToetsingOnline

Brief title

Cater with Care effect study

Condition

- Other condition

Synonym

protein requirements elderly patients

Health condition

geen specifieke aandoeningen (voedingsstatus en veroudering)

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: GO-EFRO (Gelderland Overijssel - Europees Fonds voor Regionale Ontwikkeling), Het Cater with Care consortium

Intervention

Keyword: elderly patients, hospital and home setting, physical performance, protein intake

Outcome measures

Primary outcome

The main study parameters are:

- Protein intake in grams of protein per kilogram bodyweight on the 4th day of hospitalization.
- Change of physical performance assessed by the Short Physical Performance Battery (SPPB) after 12 weeks following hospital discharge.

Secondary outcome

Phase 1 (hospital):

- All foods and drinks served to the patient through the hospital service system *At Your Request® (AYR). This will be collected daily.
- Protein intake in g/kg/d at the day before discharge.
- Percentage of patients who meet recommended protein intake at Day 4 of hospitalization.
- Length of hospital stay: in days.
- SPPB at the day before discharge.
- Knee extensor strength at the day before discharge

- Hand grip strength at the day before discharge:

Phase 2 (home):

- Nutritional Status assessed with the Mini Nutritional Assessment (MNA):
- Hand grip strength (hand dynamometer).
- Knee extensor strength (hand-held dynamometer).
- Dietary intake at 2, 6, 12, and 24 weeks after discharge
- Physical Activity will be measured using the LASA Physical Activity

Questionnaire (LAPAQ).

- Activities of Daily Living (ADL) using the Barthel Index
- Quality of life will be measured using the EuroQol-5D-5L questionnaire
- Amount of unplanned readmissions: this will be asked to the participant during home visits.

Study description

Background summary

About 25% of hospitalized elderly patients are at risk of undernutrition at admission. Many hospitals provide an energy and protein enriched diet, extra snacks, and oral nutritional supplements if needed. Still, a considerable part of these patients are unable to meet protein requirements and are still at risk of undernutrition at hospital discharge. This may impair recovery of illness, partly due to loss of muscle mass and physical performance. To improve protein intake, Cater with Care products have been developed: a selection of foods and drinks that are consumed often by elderly persons, but now enriched with protein up to 10 grams per portion. We hypothesize that these products help to reach protein requirements in elderly patients during and after hospital stay and thereby improve their health outcomes.

Study objective

To study the effectiveness of supplementing a standard hospital and 12-week home menu with protein-enriched Cater with Care products in reaching a protein intake of 1,2-1,5 g/kg/day and in improving functional status after hospital stay in elderly patients.

Study design

Randomised Controlled Trial (RCT) with 2 intervention groups and two phases: a hospital phase including all admitted patients and a home phase with a selection of patients.

Intervention

The control group receives the standard hospital menu for elderly at risk of undernutrition (energy and protein rich) and a variety of foods and drinks to be used as part of their home diet for 12 weeks after hospitalization. Foods and drinks for home use are non-enriched variants of Cater with Care products (e.g. normal fruit juice).

The intervention group receives Cater with Care protein-enriched foods and drinks during hospital stay (in addition to the standard hospital menu) and at home as part of their home diet for 12 weeks.

Study burden and risks

The burden of this study is minimal. All patients will receive menus that are designed to prevent and treat undernutrition taking individual dietary restrictions into account. The SPPB and other measurements are not invasive. Blood collection is done in the hospital as part of the routine blood assessment that is done for every patient admitted to the hospital. If the CwC menu is more effective in reaching protein requirements than standard menus to prevent undernutrition, these products could be used in other hospitals, care homes and at home.

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

Hospital phase (only observational):

- admitted to the wards of Geriatric medicine, Pulmonary Medicine or Internal Medicine in ZGV;

- aged 65 years or over;

- being eligible for receiving a standard protein enriched menu based on hospital protocol;;Home phase:

- included in the hospital phase of this study

- consent to continue treatment and study participation after hospital discharge

Exclusion criteria

- unwilling to give consent for gathering data from the medical record or meal service system;

- unable to understand Dutch;

- food allergies, food intolerances, or other dietary restrictions that prevents the patient from receiving the standard protein enriched menu or Cater with Care products based on the judgment of a dietician and/or medical staff;

- expected length of hospital stay < 4 days;

- renal insufficiency (eGFR <30);

- starting with tube feeding or total parenteral nutrition within 2 days of admission;

- refeeding syndrome score > 0 based on ZGV screening tool for refeeding risk;

- delirium at admission;

- receiving palliative care;For continuation in the home phase, the following exclusion criteria

are formulated:

- going to a nursing home, rehabilitation centre or hospice after hospital discharge;
- cognitive impairment or diagnosed with dementia;
- legally incapacitated

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO	
Date:	07-07-2014
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL48893.081.14