

# A randomized controlled trial on the effect of pre-thickened oral nutritional supplements on nutritional status of nursing home residents with dysphagia and (at risk of) malnutrition

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Suspended
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22842

### Source

NTR

### Brief title

DYNAMO

### Health condition

Dysphagia and malnutrition

## Sponsors and support

**Primary sponsor:** Maastricht University Medical Center

**Source(s) of monetary or material Support:** Nutricia Research BV.

## Intervention

## Outcome measures

### Primary outcome

Body weight

## **Secondary outcome**

- To assess differences in nutritional intake between participants in the control and intervention group
- To assess compliance to the pre-thickened oral nutritional supplement in the intervention group
- To assess differences between participants in the control - and intervention group regarding changes in quality of life (QoL), activities of daily living (ADL), micronutrient status, upper - arm and calf circumference, dysphagia severity, pre - and post hydration status, complications as part of (serious) adverse events
- To assess product appreciation of the investigational product in the intervention group

## **Study description**

### **Background summary**

#### Rationale

Malnutrition and dysphagia are commonly seen in an aging population, e.g. in nursing home residents. Up to 50% of people with dysphagia are at risk of malnutrition. Appropriate nutritional intake and safe and effective swallowing is of great importance to maintain overall health, recover from disease and improve quality of life in these residents. Treatment of malnutrition usually involves special nutritional care including dietary counselling, food fortification and / or oral nutritional supplements. Swallowing problems are addressed by modification of diet consistencies and / or thickening fluids. However, no study has ever investigated the effectiveness of pre-thickened oral nutritional supplements on nutritional status in nursing home residents with dysphagia and malnutrition (risk).

#### Primary objective

To investigate the effect of daily use of pre-thickened oral nutritional supplements for 12 weeks on body weight of older nursing home residents with dysphagia and malnutrition (risk) as compared to standard nutritional - and dysphagia management.

#### Study design

A multicentre, open label (no blinding), parallel group, two arm randomized controlled trial

#### Study population

Dutch nursing home residents from somatic - and psychogeriatric wards, age 65+, with dysphagia and malnutrition (risk)

#### Treatment

- Intervention group: standard nutritional - and dysphagia management + pre-thickened oral nutritional supplement

- Control group : standard nutritional - and dysphagia management

Main study parameter

- Change in body weight

Nature and extent of the burden and risks associated with participation, benefit and group relatedness

Because malnutrition and dysphagia are common risks in both somatic and psychogeriatric nursing home residents, this study aims to include all residents, capacitated and incapacitated, from both wards to whom the outcomes of this study are relevant. In both groups, health benefits are expected as a result of improved nutritional status and decreased risk of aspiration. The burden of participation in the current study is minimal when considering the time and degree of invasiveness of the assessments for the participants. Overall burden is also highly dependent on personal attitude of the participants towards the measurements, irrespective of cognitive abilities. The assessment methods that will be performed in the current study do not add to any health risk for the participants on top of routine care. The intake of the commercially available investigational product is considered safe based on prescribers' clinical practice and patients' feedback and results of previously conducted clinical - and non-clinical studies.

### **Study objective**

Daily use of pre-thickened oral nutritional supplements for 12 weeks will have a positive effect on body weight of older nursing home residents with dysphagia and malnutrition (risk) as compared to standard nutritional - and dysphagia management

### **Study design**

Pre-screening, screening, baseline- , midterm - and final measurements

### **Intervention**

The control group receives standard nutritional and dysphagia management and will be compared to residents in the treatment arm who will receive standard treatment plus the provision of the pre-thickened oral nutritional supplement

## **Contacts**

### **Public**

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### **Scientific**

## Eligibility criteria

### Inclusion criteria

1. male or female resident  $\geq 65$  years of age
2. diagnosis of malnutrition (risk) based on the validated short nutritional assessment questionnaire for residential care (SNAQ-RC)
3. diagnosis of dysphagia based on the 90 mL water swallow test (WST) according to Dutch guidelines and subsequent assessment by the SLT
4. admitted to - or living in a somatic - or psychogeriatric ward in one of the participating nursing homes
5. written IC from participant or legal representative

### Exclusion criteria

1. consequent daily use of protein- and energy containing ONS in the past 4 weeks
2. consequent use of enteral - or parenteral nutrition at the moment of screening or 4 weeks prior to screening
3. renal disease requiring dialysis
4. residents of which both lower legs were amputated
5. investigator's uncertainty about the willingness or ability of the subject to comply with the protocol requirements
6. known allergy or intolerance to any ingredient of the intervention product, e.g. lactose intolerance or galactosemia
7. participation in any other study involving investigational or marketed products or care improvement programs within 6 weeks prior to or after randomisation
8. known cachexia

## Study design

### Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	22-08-2019
Enrollment:	156
Type:	Anticipated

## IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	24-07-2019
Application type:	First submission

## 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
NTR-new	NL7898

**Register**

Other

**ID**

METC azM/UM : METC19-006

## Study results

**Summary results**

Huppertz, V.A.L., van Wijk, N., Baijens, L.W.J. et al. Design of the DYNAMO study: a multi-center randomized controlled trial to investigate the effect of pre-thickened oral nutritional supplements in nursing home residents with dysphagia and malnutrition (risk). *BMC Geriatr* 20, 537 (2020). <https://doi.org/10.1186/s12877-020-01947-4>