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

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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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22842

Bron
Nationaal Trial Register

Verkorte titel
DYNAMO

Aandoening

Dysphagia and malnutrition

Ondersteuning

Primaire sponsor: Maastricht University Medical Center
Overige ondersteuning: Nutricia Research BV.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Body weight

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. male or female resident ≥ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	22-08-2019
Aantal proefpersonen:	156
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-07-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7898
Ander register	METC azM/UM : METC19-006

Resultaten

Samenvatting resultaten

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