

# Transmural Nutritional Support.

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21262

### Source

NTR

### Brief title

N/A

## Sponsors and support

**Source(s) of monetary or material Support:** ZonMw

## Intervention

## Outcome measures

### Primary outcome

1. Changes in ADL, functional limitations, muscle strength, quality of life;
2. Length of hospital stay, number of re-admissions to hospital, complication rate, number of medical prescriptions and number of doctor contacts within the first 3 months after discharge;
3. Economic evaluation.

### Secondary outcome

Changes in body weight, body composition.

# Study description

## Background summary

Objective(s) / research question(s):

To study the cost-effectiveness of transmural nutritional support (from admission to hospital until 3 months after discharge) in malnourished elderly patients, compared to usual care.

Study design:

Randomised Clinical Trial

Study population:

Hospitalised patients of 60 years and over admitted to the wards of mixed internal medicine with a BMI < 20 and/or involuntary weight loss > 10% (= malnourished).

Intervention:

Standardised Oral Nutritional Support (600 kcal/day) from admission until three months after discharge versus usual care

Outcome measures:

Primary:

- Changes in ADL, functional limitations, muscle strength and quality of life between admission and at 3 months after discharge.

- Length of hospital stay, number of re-admissions to hospital, complication rate, number of medical prescriptions and number of doctor contacts within the first 3 months after discharge.

Secondary:

- Changes in body-weight and composition between admission and at 3 months after discharge.

Power/data analysis:

100 Control and 100 intervention patients are needed in order to detect a clinically relevant difference of 20% in functional and nutritional status or a difference in complication rates of 40% (control) vs. 20% (intervention). Intention-to-treat analysis. Multivariate techniques to test differences between intervention and control group. Regression analysis to test the relative contribution of the intervention on the outcome parameters.

Economic evaluation:

Cost-effectiveness ratios and cost-utility ratios will be calculated with bootstrapping according to the bias corrected percentile method.

Keywords:

malnutrition, transmural, elderly, nutritional support

## **Study objective**

To study the cost-effectiveness of transmural nutritional support (from admission to hospital until 3 months after discharge) in malnourished elderly patients, compared to usual care.

## **Intervention**

Usual nutritional care vs. oral nutritional supplements from admission to hospital under 3 months after discharge.

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Malnourished older patients (>60y);
2. Admitted to the departments of internal medicine;

3. Gastroenterology;
4. Nephrology;
5. Rheumatology;
6. Dermatology.

## Exclusion criteria

1. Well-nourished;
2. Decreased consciousness;
3. Inability to speak the Dutch language;
4. Expected Length of Hospital Stay <2 days.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2006
Enrollment:	164
Type:	Anticipated

## Ethics review

Not applicable	
Application type:	Not applicable

## 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	NL436
NTR-old	NTR476
Other	: N/A
ISRCTN	ISRCTN29617677

## Study results

### Summary results

N/A