ProIntens Intensive Dietetic Care Pathway

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The ProIntens study aims to evaluate the impact of an intensive dietetic care pathway on dietary protein intake and physical functioning in older adults during hospitalisation and after discharge. Process and economic evaluations will be performed

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

Summary

ID

NL-OMON23893

Source
NTR

Brief title
ProIntens

Condition

- Muscle disorders

Synonym
Older patient; undernutrition; transmural care; muscle mass; cost-effectiveness; hospitalization; primary care

Health condition

Malnutrition

Research involving
Human

Sponsors and support

Primary sponsor:	SiA Taskforce for applied research
Secondary sponsors:	Sorgente, Fonterra
Source(s) of monetary or material Support:	SiA Nationaal Regieorgaan Praktijkgericht Onderzoek

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

Short Physical Performance Battery (SPPB)

Secondary outcome

Physical performance, muscle strength, muscle quality, food intake, quality of life, body composition, socio-demographics, cost-effectiveness

Study description

Background summary

Disease-related malnutrition is common among hospitalised and recently discharged older adults. Consequences of malnutrition are physical limitations, negative health outcomes, decreased quality of life and increased healthcare costs. In current regular care in the Netherlands, most older adults have insufficient dietary protein intake and are physically inactive. Dietetic care can counteract the effects of malnutrition by increasing protein and energy intake.

Study objective

The ProIntens study aims to evaluate the impact of an intensive dietetic care pathway on dietary protein intake and physical functioning in older adults during hospitalisation and after discharge. Process and economic evaluations will be performed

Study design

a two-armed multicentre parallel individually randomised trial

Intervention

The intervention consists of intensive personalised care with guidance of a dietitian during hospitalisation until three months after discharge.

Study burden and risks

The risks of intensive dietetic care are minimal. Patients in the intervention groups will receive more dietary guidance from professionals.Benefits for patients are the best nutritional care based on the latest science and practice, preservation of muscle mass and strengthand therefore possibly a faster recovery during hospital stay and post-discharge. The patient will be stimulated to mobilize. This couldincrease the risk of falling. However, the patients are guided by physical therapist to reduce this risk.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)
Elderly (65 years and older)
Elderly (65 years and older)

Inclusion criteria

- Aged 55 or older
- At risk of malnutrition
- Written informed consent
- Ability to comply with the study protocol
- Willingness to comply with the study protocol
- Agrees that his/her general practitioner will be notified about study participation
- Consent of the participants' in-hospital clinical team

Exclusion criteria

- Inability to understand the Dutch language
- Cognitive impairment (MMSE <15)
- Current/admission diagnosis of cancer or active cancer treatment (systemic and/or immune therapy)
- COPD GOLD >3
- Heart failure NYHA >3
- Initially admitted to intensive care unit
- Use of total parenteral nutrition
- Palliative treatment or a life expectancy of ≤3 months

Study design

Design

Study phase:	N/A
Study type:	Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2021
Enrollment:	250
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	10-07-2020
Application type:	First submission
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 49799
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8041
Other	METC VUmc : 2019.689
CCMO	NL72069.029.19
OMON	NL-OMON49799

Study results