Nutritional status, vulnerability and disability in COPD patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29331

Source
NTR

Health condition

malnutrition
ondervoeding
frailty
kwetsbaarheid
disability
invaliditeit

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Living Lab (Innovatiewerkplaats) Clinical Malnutrition, part of Centre of Expertise Healthy Ageing (www.healthyageing.net)

Intervention

Outcome measures

Primary outcome

disease-related malnutrition

frailty

disability

Secondary outcome

dietary intake

physical activity

body composition

physical functioning

clinical outcome

Study description

Background summary

This study will take place in the Netherlands.

Frailty is a strong predictor for the adverse clinical outcome of disability. The complex interactions between factors of the multidimensional and dynamic concept of frailty remain to be clarified (de Vries, Staal et al. 2011). Since malnutrition has such an impact on physical performance, frailty and malnutrition are suspected to correlate firmly. Knowing in what way these conditions influence each other is extremely important in achieving to revolve the process of becoming frail and disable.

The main objective of this study is to investigate whether changes in nutritional status correlate to changes in frailty status, and whether these changes impact on disability as a clinical outcome in patients with a chronic obstructive pulmonary disease. The secondary objective is to explore adaptive strategies for dietary challenges in patients with chronic obstructive pulmonary disease, and thus identify predictors of dietary resilience, and dietary resiliency subsequently.

Study objective

Frailty is considered to be a clinical state in which there is an increase in an individual’s vulnerability for developing increased dependency and/or mortality when exposed to a stressor (Morley, Vellas et al. 2013). Frailty is a strong predictor for the adverse clinical outcome of disability. This is an individual problem, but also very relevant to society; people are getting older but not necessarily in an independent and healthy way. The complex interactions between factors of the multidimensional and dynamic concept of frailty remain

to be clarified (de Vries, Staal et al. 2011).
Since malnutrition has such an impact on physical performance, frailty and malnutrition are suspected to correlate firmly. Knowing in what way these conditions influence each other is extremely important in achieving to revolve the process of becoming frail and disable.
The main objective of this study is to investigate whether changes in nutritional status correlate to changes in frailty status, and whether these changes impact on disability as a clinical outcome in patients with a chronic obstructive pulmonary disease. The secondary objective is to explore adaptive strategies for dietary challenges in patients with chronic obstructive pulmonary disease, and thus identify predictors of dietary resilience, and dietary resiliency subsequently.

Study design

Patients will be assessed 3 times during their 9 weeks of rehabilitation (begin, middle and end) and 4 times in follow-up setting (3 months, 6 months, one year and two years after finishing the rehabilitation program)

The following measures (tests and questionnaires) will be performed on every occasion: body weight, length, accelerometer, mid upper arm circumference and triceps skinfold, bio-electrical impedance analysis (including vector analysis), muscle ultrasound scan, handgrip strength, gait speed, Short Physical Performance Battery, muscle tone, PG-SGA©, MNA®, EFIP, GFI, Fried's criteria, WHODAS 2.0, food diary.

Intervention

This study will be conducted in adult patients with chronic obstructive pulmonary disease following a rehabilitation program of 9 weeks. The sample will be stratified according to nutritional status classified by PG-SGA category A, B or C (classification A (well nourished), B (moderately malnourished or risk for malnutrition) or C (severely malnourished) to assure an adequate level of distribution in the domain of malnutrition in the study population.

Contacts

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Eligibility criteria

Inclusion criteria

Aged 40 years or older

Able to understand and speak the Dutch language

Diagnosed with COPD by a pulmonary physician

Attending the full rehabilitation program

Exclusion criteria

Wheel chair dependency

Any contra-indication for physical exercise

Severe cognitive disabilities

Skin allergy or highly sensitive skin

Palliative treatment

Pacemaker

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-03-2015
Enrollment:	86
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-03-2015
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	NL4862
NTR-old	NTR5107
Other	Medisch Ethische Toetsingscommissie UMC Groningen : 2014/432

Study results