Disease-related Malnutrition, Frailty and Disability:
Relations and Clinical Outcome in COPD patients

Published: 03-03-2015
Last updated: 21-04-2024

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 chronic obstructive pulmonary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42007

Source
ToetsingOnline

Brief title
DiFiDi-COPD study

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
malnutrition & frailty: undernutrition & vulnerability/fragility/weakness

Health condition

ondervoeding, kwetsbaarheid en invaliditeit

Research involving
Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen
Source(s) of monetary or material Support: Centre of Expertise Healthy Ageing

Intervention

Keyword: disability, frailty, malnutrition

Outcome measures

Primary outcome

Disease-related malnutrition, frailty and disability

Secondary outcome

Dietary intake and requirement, physical activity, body composition, physical

functioning, clinical outcome

Study description

Background summary

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.

Study objective

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 chronic obstructive pulmonary disease. The secondary objective is to explore adaptive strategies for dietary challenges in chronically ill patients, and thus predictors of dietary resilience, and dietary resiliency subsequently.

Study design

For this study (quantitative and qualitative research), an exploratory longitudinal study design is used.

Study burden and risks

Patients will be assessed during rehabilitation at the UMCG-rehabilitation center. In this longitudinal design, patients will be assessed 3 times during their rehabilitation and 4 times in follow-up setting.
The following tests and questionnaires will be used: 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. The burden of these study measurements is minimal (about 70 minutes per study measurement at the UMCG-rehabilitation center and 45 minutes in preparation). The risks of these measurements are negligible. In the qualitative study, duration of the in depth interviews is 60 min. at maximum.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Aged 40 years or older
Able to understand and speak the Dutch language
Diagnosed with COPD by a pulmonary physician

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-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-03-2015
Enrollment:	86
Type:	Actual

Ethics review

Approved WMO

Date:	03-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL49996.042.14

Study results

Date completed:	28-02-2019

Actual enrolment: 82