

# Triage of Reduced Exercise Tolerance in Frail Elderly (TREE).

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON21050

### Source

NTR

### Brief title

TREE

### Health condition

Heart failure  
Chronic obstructive pulmonary disease  
COPD  
Hartfalen  
Chronisch obstructive longziekte

## Sponsors and support

**Primary sponsor:** UMC Utrecht

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

## Intervention

## Outcome measures

### Primary outcome

1. Prevalence of latent heart failure and COPD;

2. Difference in prevalence of latent heart failure and COPD between both groups.

### **Secondary outcome**

(Cost-)effectiveness of the diagnostic triage strategy.

## **Study description**

### **Background summary**

Background of the study:

Many elderly suffer from reduced exercise tolerance or exercise induced shortness of breath (dyspnoea) which causes decreased mobility and restrictions in physical, psychological and social functioning. Patients commonly attribute this symptom to their age, and simply adjust their life style to it. Reduced exercise tolerance/dyspnoea is very common with prevalence rate of 20-60% of those aged 65 years and over. The main causes in the elderly are heart failure and chronic obstructive pulmonary disease (COPD). Both diseases have a high negative impact on the quality of life and are associated with frequent hospital admissions. Over-diagnosis, but more often under-diagnosis of heart failure and COPD is rather common in primary care. Establishing a diagnosis early in the course of the disease is useful because both diseases can be adequately and evidence-based treated. Therefore, an easy diagnostic triage-strategy followed by direct treatment would be of great importance to assess and treat heart failure and COPD in elderly patients with shortness of breath.

Objective of the study:

Quantify how many frail elderly aged over 65 years with reduced exercise tolerance and/or exercise induced dyspnoea have previously unrecognised COPD and heart failure. Quantify the difference in prevalence of unrecognised COPD and heart failure between those who underwent the diagnostic triage compared to those who received care as usual. Quantify the effect of the diagnostic triage plus the additional treatment changes on functionality and quality of life after 6 months compared to those who received care as usual. Quantify the cost-effectiveness of the diagnostic triage strategy compared to care as usual.

Study design:

A clustered randomized diagnostic (follow-up) study.

## Study population:

First, pre-selection of patients aged over 65 years from 50 general practices is based on frailty. Frailty is based on the next criteria: use 5 or more different types of medical drugs chronically in the last year and/or have 3 or more chronic or vitality threatening diseases (such as diabetes mellitus, COPD, heart failure, impaired vision, hard hearingness). This will be done from the electronic medical files of the general practices. These elderly will receive the MRC questionnaire of dyspnoea and three additional questions related tot exercise intolerance. Those with any dyspnoea and/or reduced exercise tolerance will be invited to participate, except those with established heart failure and COPD.

## Study parameters/outcome of the study:

Prevalence of latent heart failure and COPD. Difference in prevalence of latent heart failure and COPD between both groups. Differences in functionality and quality of life after 6 months between both groups. Cost-effectiveness and experienced patient burden of the diagnostic triage strategy.

## Study objective

The diagnostic triage will be a simple and feasible way to improve the diagnosis and treatment of frail elderly with exercise induced dyspnoea and/or reduced excersie tolerance.

## Study design

Primary outcomes will be measured at one time point. Secudary outcomes will be measured in two time points (in the beginning of the study and after six months).

## Intervention

1. Diagnostic triage strategy (index group) including; electrocardiography, echocardiography, spirmetry and blood testing;
2. Care-as-usual (control group).

## Contacts

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## Eligibility criteria

### Inclusion criteria

1. Patients aged 65 years and older;
2. Must have a minimum of three chronic or vitality threatening diseases and/or use five or more medical drugs chronically in the last year;
3. Must have dyspnea and/or reduced exercise tolerance (scored by two short questionnaires).

### Exclusion criteria

1. Patients with both confirmed COPD and heart failure (lungfunction test performed < 1 year ago and heart failure confirmed by echocardiography);
2. Patients unable or unwilling to sign informed consent.

## Study design

### Design

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

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 01-06-2010  
Enrollment: 800  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 25-05-2010  
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	NL2212
NTR-old	NTR2336
Other	ZonMW : 311040302
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A