

Health illiteracy among patients with chronic lung disease entering pulmonary rehabilitation and their resident loved ones: prevalence and relationship with health outcomes: A pilot study.

No registrations found.

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

Summary

ID

NL-OMON23878

Source

Nationaal Trial Register

Health condition

Health Illiteracy, COPD, Health Literacy, Lung disease, Asthma

Sponsors and support

Primary sponsor: Performer; Maastricht University

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

Primary outcomes are subjective and objective health literacy as measured by the REALM-D and HLS-EU-Q16 questionnaire.

Secondary outcome

The following secondary outcomes were assessed as part of standard clinical routine: diagnosis, comorbidities, height, weight, body mass index (BMI), smoking behavior, sensation of dyspnea (mMRC dyspnea Scale (mMRC)), symptoms of anxiety and depression (Hospital Anxiety Depression Scale (HADS)), disease-specific health status (COPD Assessment Test (CAT)), exercise tolerance (six-minute walk distance (6MWD); cardio pulmonary exercise test (CPET); constant work rate test (CRWT)) lung function (FEV1; FVC; IC/TLC). Background characteristics included: gender, age, country of birth, social/marital status, and educational attainment level based on Verhage (1964) and the Dutch Standard Classification of Education (CBS, 2014; Hendriks et al., 2014). Moreover, previous studies suggested that a variability in health literacy can be explained by cognitive abilities. To identify patients characteristics, the Montreal Cognitive Assessment was performed among patients during the three-day baseline assessment (Levinthal et al., 2008). Finally, the degree of patients' self-managements was assessed using a 10-point Likert scale.

Study description

Background summary

A pilot observational study among patients with a chronic lung disease referred for PR to CIRO (the Netherlands) and their resident loved ones will be conducted. Patients are eligible when diagnosed with chronic lung disease (defined as chronic disease of the airways and other structures of the lungs, including but not limited to: asthma, chronic obstructive pulmonary disease (COPD), pulmonary hypertension, interstitial lung disease, and bronchiectasis, (WHO, 2007)), and are referred for a pre-rehabilitation assessment to CIRO. We aim to include 120 patients and if available and willing to participate, their resident loved ones. Patients will be asked to complete the Dutch 16-item European Health Literacy Survey Questionnaire (HLS-EU-Q), Montreal Cognitive Assessment and REALM-D during their pre-rehabilitation assessment. Relevant patient characteristics (including but not limited to demographics, disease severity, smoking status, comorbidities) and PR outcomes (including modified Medical Research Council (mMRC) dyspnea score, COPD Assessment Test (CAT), Hospital Anxiety and Depression Scale (HADS), degree of self-management, and 6-minute walking distance) are collected as part of the clinical routine. In addition, available resident loved ones will be asked to complete the HLS-EU-Q as well as a short questionnaire including demographics and self-reported morbidities. The current project results in: 1) knowledge concerning the prevalence of HI among patients with COPD entering PR and their resident loved ones; preliminary knowledge concerning the impact of HI on PR outcomes. This knowledge is needed to optimize education and self-management interventions offered as part of PR.

Study objective

We hypothesize that health illiteracy (HI) is prevalent among approximately 50% of the

patients with chronic lung diseases, referred for PR (Puente-Maestu et al., 2016; Kale et al., 2015; Lee et al., 2009). Moreover, it is expected that HI is common amongst their resident loved ones. Finally, we expect that outcomes of PR are negatively affected by the prevalence of HI.

Study design

Primary outcomes, background characteristics and the Montreal Cognitive assessment are assessed during a three-day baseline assessment.

The other secondary outcomes are assessed during a three-day baseline assessment and two-day outcome assessment.

Degree of self-management was assessed by the start and ending of pulmonary rehabilitation.

Intervention

Not applicable, observational study

Contacts

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Eligibility criteria

Inclusion criteria

Patients were considered eligible when diagnosed with chronic lung disease (defined as chronic disease of the airways and other structures of the lungs, including but not limited to: asthma, chronic obstructive pulmonary disease (COPD), pulmonary hypertension, interstitial lung disease, and bronchiectasis, (WHO, 2007)), and referred for PR. Resident loved ones are defined as persons living together with a patient with chronic lung disease (Nakken et al., 2014).

Exclusion criteria

Participants were excluded when they were younger than 18, unable to speak or understand the Dutch language or were considered incapacitated.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2018
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date: 31-10-2018
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	NL7384
NTR-old	NTR7592
Other	Maastricht University Medical Centre+ : 2018-073

Study results

Summary results

not applicable