

Effects of a home-based versus hospital-based outpatient pulmonary rehabilitation program in patients with chronic obstructive pulmonary disease (COPD): a multicentre, randomised trial

Submission date 26/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/09/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/01/2019	Condition category Respiratory	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00169897

Protocol serial number

Study information

Scientific Title

Effects of a home-based versus hospital-based outpatient pulmonary rehabilitation program in patients with chronic obstructive pulmonary disease (COPD): a multicentre, randomised trial

Study objectives

To compare the effectiveness of self-monitored, home-based rehabilitation versus outpatient hospital-based rehabilitation to improve quality of life in patients with chronic obstructive pulmonary disease (COPD).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Comite d'ethique de la recherche, Hopital de Laval, QC, gave approval on the 24th November 2003

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Chronic obstructive pulmonary disease (COPD)

Interventions

Home-based exercise training for 12 weeks or hospital-based exercise training for 12 weeks.

Trial details received: 12 Sept 2005

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Dyspnoea domain of the chronic respiratory questionnaire (CRQ) at 12 months

Key secondary outcome(s)

1. Total CRQ score and other CRQ domains, exercise tolerance (6MWD and submaximal exercise test) and activity of daily living (ADL) at 12 months
2. CRQ total score and specific domains, exercise tolerance (6MWD and submaximal exercise

test) and ADL at 4 months

3. Health service utilisation (physician and emergency department visits, hospitalisations) over the 1-year study period

4. Intervention cost

Completion date

31/03/2006

Eligibility

Key inclusion criteria

1. Subject is able to ambulate. Defined as a six-minute walking distance (6MWD) greater than 110 metres.
2. Subject is diagnosed with COPD
3. 40 years old and older, either sex
4. Currently or previously smoking with a smoking history of at least 10 pack-years
5. Forced expiratory volume in one second (FEV1) after the use of a bronchodilator between 25 and 70% of the predicted normal value, and FEV1 to forced vital capacity (FVC) ratio less than 70%
6. Subject has a stable COPD condition defined as no COPD exacerbation or no changes in dyspnoea, volume or colour of sputum in the previous 4 weeks
7. No previous diagnosis of:
 - 7.1. Asthma
 - 7.2. Left heart congestive heart failure (either radiographic evidence of pulmonary congestion, echocardiographic or ventriculographic evidence of a reduced ventricular ejection fraction)
 - 7.3. Terminal disease, dementia or uncontrolled psychiatric illness
8. No participation to a respiratory rehabilitation program in the past year and not staying or planning to stay in a long-term care facility
9. Subject understands and is able to read, write French or English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

The need for supplemental oxygen at rest or during exercise will not be an exclusion criterion

Date of first enrolment

01/04/2003

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

Canada

Study participating centre

Hôpital Laval

Québec

Canada

G1V 4G5

Sponsor information

Organisation

University Laval (Canada)

ROR

<https://ror.org/04sjchr03>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-63162)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/12/2008	28/01/2019	Yes	No

