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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

Registration date
26/09/2005

Overall study status
Completed

Last Edited
28/01/2019

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00169897

Secondary identifying numbers
MCT-63162

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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

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

Secondary outcome measures
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

Overall study start date
01/04/2003

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

Age group
Adult

Sex
Both

Target number of participants
240

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)

Sponsor details
Cité Universitaire, C.P. 2208
Québec
Canada
G1K 7P4

Sponsor type
University/education

Website
http://www.ulaval.ca/

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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