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The PRINCE Trial: Pulmonary Rehabilitation In Nurse-led Community Environments

Submission date	Recruitment status	[_] Prospectively registered
24/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/10/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2014	Respiratory	

Plain English summary of protocol
Not provided at time of registration

Study website
http:\\princestudy.com

Contact information

Type(s)
Scientific

Contact name
Prof Kathy Murphy

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-
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title
A cluster randomised controlled trial evaluating the effectiveness of a structured pulmonary rehabilitation programme (SPRP) for improving the health status of people with chronic obstructive pulmonary disease (COPD) delivered at the level of general practice compared with usual care

Acronym
PRINCE

Study objectives
The aim of this study is to evaluate the effectiveness of a structured pulmonary rehabilitation programme on the health status of people with chronic obstructive pulmonary disease (COPD) delivered at the level of the general practice compared with usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Irish College of General Practitioners (ICGP), National University of Ireland, Galway Research Ethics Committee, approved on the 30th September 2008
2. Health Research Board (HRB) approved initially on the 6th March 2008 and gave secondary approval post-submitted amendments on the 26th September 2008

Study design
Two armed single blind clustered randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease (COPD)

Interventions

Randomisation to control and intervention is at the level of the General Practice.

The experimental group will receive a structured pulmonary rehabilitation programme (SPRP), which consists of an eight week programme with one 2-hour session each week (16 hours total duration). The SRPR will be facilitated by Practice Nurses and Physiotherapists who have received a Practice Nurse preparation programme (PNPP) (a three day programme focused on preparing practice nurses to deliver the structured education programme) or a Physiotherapist preparation programme (PNPP) (a one day programme focused on preparing physiotherapists to deliver the structured education programme). Practice Nurses and Physiotherapists will be supported in the delivery of the programme by having recourse to members of the research team for purposes of clarification on training materials, identification of sources of information in response to specific patient queries.

A standardised curriculum and programme materials will be developed by the research team for use in the intervention. The SPRP curriculum will be developed in accordance with the key criteria for structured education programmes and will include the development of a course philosophy, a detailed curriculum, development of common course materials and training for all educators.

Secondary sponsor details:
Mr David Gallagher MD
Pfizer Health Care Ireland
9 River Walk
National Digital Park
Citywest Business Campus
Dublin 24
Ireland

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Health status as measured by the Chronic Respiratory Questionnaire (CRQ)

Secondary outcome measures
1. Incremental Shuttle Walking Test
2. Self-Efficacy for Managing Chronic Disease 6-Item Scale
3. Economic analysis specific:
3.1. EuroQol EQ-5D
3.2. Utilisation of health care service:
3.2.1. Hospital admissions/length of stay
3.2.2. Attendance at the emergency department
3.2.3. Attendance at/by GP
3.2.4. Attendance at/by Practice Nurse
3.2.5. Attendance at/by Public Health Nurse
3.2.6. Attendance at/by Physiotherapy
3.2.7. Attendance at/by Social Worker
3.2.8. Attendance at/by Dietician

3.2.9. Outpatient attendances
3.2.10. Attendance at/by consultant
3.2.11. Utilisation of home help

Overall study start date
01/01/2008

Completion date
31/12/2012

Eligibility

Key inclusion criteria
Practice eligibility criteria:
1. Supported by a practice nurse
2. Practice supported by a computerised patient (medication recording) system
3. Commitment on the part of the practice team to participate in the proposed work
4. Have a client population with greater than 2500 clients
5. Participation by a minimum of 10 consenting patients meeting eligibility criteria

Participant eligibility criteria:
1. Patient with an existing diagnosis or suspected of having COPD. Patient eligibility algorithm provided to each practice to support identification of participants.
2. COPD confirmed at baseline assessment by spirometer results of:
2.1. Post-bronchial dilator forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) ratio of less than 70%* unless body mass index (BMI) greater than 30 in which case FEV1 /FVC ratio greater than 70% are acceptable provided other criteria fully met
2.2. Post-bronchial dilator predicted value of FEV1 greater than or equal to 30% and less than or equal to 80%**
3. Must be able to converse in and read English as initial delivery of programme will be only available in English
4. Ability to understand the study and a willingness to give informed consent

*This value is reported in the spirometry result under the column heading 'Base'
**This value is reported in the spirometry result under the column heading '%Pr'

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
32 practices with 10 participants per practice are required

Key exclusion criteria

Any significant underlying co-morbidities or mental health problems (based on the recorded judgement of practice staff) which are likely to impair their capacity to successful participate in or assimilate new information as part of the rehabilitation programme or which may pose a risk to their health.

Date of first enrolment
01/01/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Ireland

Study participating centre
School of Nursing and Midwifery
Galway
Ireland
-

Sponsor information

Organisation
Health Research Board (HRB) (Ireland)

Sponsor details
73 Lower Baggot Street
Dublin
Ireland
2
hrb@hrb.ie

Sponsor type
Government

Website
http://www.hrb.ie

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Government

Funder Name
Health Research Board (HRB) (Ireland)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Funder Name
Pfizer (Ireland) - unconditional educational grant providing nursing, and support services and the temporary loan of two spirometers for the study

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	18/01/2011		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	25/11/2013		Yes	No