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Measurement of, and psychological intervention with, partial adherence to inhaled antibiotic therapies in adults with cystic fibrosis

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2011	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N0436130480

Study information

Scientific Title

Study objectives
1. To determine factors that affect adherence to nebuliser treatment in cystic fibrosis patients
2. To evaluate a psychological intervention designed to improve adherence in those whose adherence is less than 80%

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Nutritional, Metabolic, Endocrine: Cystic fibrosis

Interventions
Database analysis; Questionnaire; Randomised controlled trial (psychological intervention versus no psychological intervention); Before-after trial.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. The difference in adherence pre and post intervention. This will be measured using the ProDose adaptive aerosol delivery system, which records patient usage data
2. The relationship between adherence and clinical outcome such as forced expiratory volume (FEV1), use of additional antibiotic treatment and patients' own psychopathology (measured using questionnaires)

Key secondary outcome(s))
Not provided at time of registration

Completion date
01/11/2006

Eligibility

Key inclusion criteria

1. Male and female patients with a diagnosis of cystic fibrosis
2. 18+ years of age
3. Taking nebulised colistin through the ProDose Adaptive Aerosol Delivery (AAD) system for cystic fibrosis
4. Able to use a nebuliser mouthpiece

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/03/2003

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Academic Unit Psychiatry & Behavioural Sciences
Leeds
United Kingdom
LS2 9LN

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

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	01/04/2009		Yes	No