ISRCTN18400127 https://doi.org/10.1186/ISRCTN18400127

Evaluation of Bronchiectasis Empowerment Tool (BET)

Submission date	Recruitment status	[_] Prospectively registered
24/06/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/07/2023	Respiratory	

Plain English summary of protocol

Background and study aims
Bronchiectasis is a long-term condition where the airways are abnormally widened (called bronchial dilatation), resulting in the build-up of mucus that can cause infection in the lungs. Symptoms include a persistent cough and breathlessness. The damage that is caused to the lungs by the condition is permanent. However, there are treatments available that will relieve symptoms and stop the damage from getting any worse. Healthcare providers largely control and manage the disease without documented guidance for patients on when to seek healthcare assistance. Patient self-management plans/tools have been used in other respiratory conditions similar to bronchiectasis, for many years, with improved healthcare outcomes. Although advocated by the National Guidelines, there is no data on the beneficial effects of self-management plans in bronchiectasis. In an on-going collaboration of patients with, and professionals treating, bronchiectasis we have developed the Bronchiectasis Empowerment Tool (BET). This is a one-page action plan, incorporated within a patient-held pack containing concise information about bronchiectasis and optional notepads to encourage patient note taking to gain insight and information about their condition. The tool has been developed in collaboration with patients and healthcare providers and is easy to use with pictographical instructions. It is designed work alongside, rather than to replace, existing care in order to improve the patient's ability to manage their condition. Our aim is to conduct a study to evaluate the effectiveness and cost-effectiveness of the Bronchiectasis Empowerment Tool (BET) as a support to patients throughout their healthcare journey. We will assess patients' self-efficacy, which is the confidence patients have in their ability to successfully deal with their condition, using the validated Chronic Disease Self-Efficacy Scale. We will also measure health care contacts; health related quality of life, appropriateness of antibiotic therapy and costs from questionnaires. To add a qualitative dimension pertinent to successful integration to practice we will seek the opinions of patients at the end of the study.

Who can participate?
Adults (aged at least 18) identified from clinic lists as having bronchiectasis.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 (control) receive standard care. Those in group 2 (intervention) also receive standard care but also BET. Patients

randomised to the intervention are given the plan documents and are shown how to use BET. All patients are given the British Lung Foundation bronchiectasis information leaflet and British Thoracic Society Physiotherapy Guideline. At the beginning of the study and after 12 months, participants complete the chronic disease self-efficacy scale, lung information needs questionnaire (LINQ), the St Georges Respiratory Questionnaire (a validated respiratory quality of life tool), the Euroqol-5D (EQ5D) (to determine health utility) and resource use questionnaires. In addition, participants complete chronic disease self-efficacy scale, SGRQ, resource use and health utility questionnaires (which should take 10-15 minutes to complete in total) by mail every 3 months. Exacerbation data are obtained from the resource questionnaire. Patients are asked to collect the packet inserts for all antibiotics which will be cross-referenced to antibiotic sensitivities obtained by microbiology records to determine appropriateness of prescriptions. Patients' views about BET are captured to aid integration using an exit questionnaire and focus groups.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Norfolk and Norwich University Hospital NHS Trust (UK)

When is study starting and how long is it expected to run for?
May 2013 to April 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Ms Clare Brockwell

Contact information

Type(s)
Scientific

Contact name
Ms Claire Brockwell

Contact details
Department of Respiratory Medicine, Colney Lane
Norwich
United Kingdom
NR4 7UY

Additional identifiers

Protocol serial number
14371

Study information

Scientific Title
A randomised, investigator-blind controlled trial of the effectiveness and costs of the bronchiectasis empowerment tool in patients with bronchiectasis

Acronym
BET

Study objectives
Our primary objective is to obtain evidence of the effectiveness and cost-effectiveness of the Bronchiectasis Empowerment Tool (BET).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central-Berkshire, 03/04/2013, ref: 13/SC/0140

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Primary Care, Respiratory disorders; Subtopic: Respiratory (all Subtopics), Respiratory disorders; Disease: Respiratory, All Diseases

Interventions
Participants are randomly assigned to one of two groups:
1. Bronchiectasis empowerment tool (BET):
This consists of a one-page action plan, educational support documents and optional notepads for patients to keep track of their health events. The booklet has four sections charting changes pivotal to bronchiectasis: sputum, health, medication, healthcare contacts.Patients randomised to the intervention arm of the study receive training/education to help them learn to utilise the booklet delivered by telephone (on four consecutive days where possible) each lasting between five and twenty minutes.
2. Standard Care:
Patients will attend routine appointments and be guided in their disease management according to current practice.
Follow Up Length: 12 month(s)

Intervention Type
Other

Primary outcome(s)
Self Efficacy; Timepoint(s): By questionnaire at baseline and then every 3 months for a 12 mth period, 5 time points in total.

Key secondary outcome(s))
1. Change from baseline in health related quality of life measured using the St Georges Respiratory Questionnaire
2. Changes in disease understanding assessed using the Lung Information Needs Questionnaire (LINQ) and non validated questionnaire
3. Difference in the number of exacerbations treated with appropriate antibiotic therapy targeted against sputum bacterial sensitivities during the study obtained from microbiology sensitivity data and prescription data from questionnaires and medication packet inserts returned
4. Difference in the number of unscheduled, emergency or out of hours healthcare contacts for bronchiectasis over the 12 month duration of the study
5. Difference in number and type of all routine and emergency NHS contacts over the 12 month duration of the study
6. Incremental Quality Adjusted Life Years (QALYs) accrued (estimated from EQ-5D data[16]) from baseline
7. A qualitative evaluation of BET from a patient and health care professional point of view

Completion date
30/04/2016

Eligibility

Key inclusion criteria
1. Male or female, aged more than 18 years
2. High Resolution Computed tomography (HRCT) diagnosis of bronchiectasis
3. At least one exacerbation of bronchiectasis within the previous 12 months
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
220

Key exclusion criteria
1. Cystic fibrosis related bronchiectasis or traction bronchiectasis
2. Severe or uncontrolled co-morbid disease, which is likely to affect the outcome of the study
3. Abnormalities in cognitive functioning that would limit the patient’s ability to undertake the

procedures
4. Currently using a written patient self-management plan or involved in the design of BET
5. Unable to provide written informed consent

Date of first enrolment
03/05/2013

Date of final enrolment
30/04/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Norfolk and Norwich University Hospital NHS Trust
Department of Respiratory Medicine, Colney Lane
Norwich
United Kingdom
NR4 7UY

Sponsor information

Organisation
Norfolk and Norwich University Hospital NHS Trust

ROR
https://ror.org/01wspv808

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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		02/12/2020	10/07/2023	Yes	No
Abstract results	results presented at British Thoracic Society Winter Meeting	01/12/2017		No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes