ISRCTN84229105 https://doi.org/10.1186/ISRCTN84229105

BRonchiectasis Information and Education Feasibility study

Submission date
25/07/2014

Recruitment status
No longer recruiting

Registration date
25/07/2014

Overall study status
Completed

Last Edited
16/04/2020

Condition category
Respiratory

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is currently little patient information about bronchiectasis, a long-term lung disease. We found in a previous study that patients and their families wanted more information, which could help to improve their understanding and self-management. A new information package has been developed by healthcare professionals working with patients and their families. During this study, this information package will be evaluated and refined and the feasibility of carrying out a clinical study to find out its effect on understanding and health outcomes will be assessed.

Who can participate?
Adults who have a diagnosis of bronchiectasis and attend a specialist or general clinic at the Newcastle upon Tyne Hospitals NHS Trust, UK.

What does the study involve?
Those who consent to take part in the study will be randomly assigned to either receive the new patient information resource or to receive usual care. Those who receive the information package will receive a booklet and the login details for the website. They will be able to use this as much as they wish for the 3 months that they take part in the study. Should they have family members/a spouse who is interested we would also encourage them to use the resource. Participants will have three study visits over 3 months: the initial visit, a follow-up visit at 2-4 weeks (with this as an optional telephone visit rather than in person), and a final end of study visit at 3 months. Each visit should last less than 1 hour and will involve completion of quality of life, symptom, knowledge and evaluation questionnaires. At visits 1 and 3 lung function tests will also be performed. Each month participants will be asked to complete a short postal questionnaire about their symptoms and use of information. Some participants will also be invited to focus groups to discuss their experience at the end of the study. In addition, up to 10 additional carers will be invited to these groups if they have used the information pack and wish to give their views. Those who are allocated to the usual care group will be offered use of the information package once they have completed the study.

What are the possible benefits and risks of participating?
We cannot promise the study will help you. The information we get from this study may help improve the understanding of patients needs, and help us develop better information resources

for patients with bronchiectasis. There are no likely risks to taking part in this study. Participants will be asked to attend three study visits in total, each lasting less than 1 hour, over the 3-month period of their involvement in the study. Also, patients will be given the option of completing the 2nd (middle) visit over the telephone to reduce the burden of travel should they wish. Some participants will also be invited to take part in a focus group but this will be entirely optional.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
The study started in June 2014 and is expected to end in September 2016. Participants are involved for a 3-month period only.

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

Who is the main contact?
Dr Katy Hester
Katy.hester@ncl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Katy Hester

Contact details
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United Kingdom
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-
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
16655

Study information

Scientific Title
BRonchiectasis Information and Education: Feasibility study and evaluation of a novel resource

Acronym
BRIEF

Study objectives
This is a feasibility study to determine if it would be possible to conduct a large trial to assess whether provision of a patient-focussed information and education resource can improve patient understanding, self-management and health outcomes in bronchiectasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland REC, 27/05/2014, ref. 14/NE/0119

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Respiratory disorders; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
30 participants will be recruited to both the intervention and control groups. 10 additional carer participants will be recruited to the focus groups at the end of recruitment
Patient information package: a novel information resource in the form of a website (or PDF) and a booklet will be used as the intervention

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Feasibility of conducting a definitive RCT; Timepoint(s): End of study

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/06/2014

Completion date
30/09/2016

Eligibility

Key inclusion criteria
1. Participant has capacity to provide written informed consent
2. Aged 18 years or over
3. Clinical and radiological diagnosis of bronchiectasis
4. English speaking
5. Internet access (direct personal access or access via family/friend/local library etc)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 70; UK Sample Size: 70

Total final enrolment
62

Key exclusion criteria
1. Cognitive impairment
2. Non-English speaking
3. Complete lack of internet access
4. Aged <18 years
5. Participation in the preceding BRIE study

Date of first enrolment

02/06/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Road
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Doctoral Research Fellowship (UK); Grant Codes: NIHR-DRF-2012-05-149

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?
Protocol article	protocol	23/04/2016		Yes	No
Results article	results	15/04/2020	16/04/2020	Yes	No
HRA research summary			28/06/2023	No	No