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Testing a new approach to supporting people with bronchiectasis to take prescribed inhaled antibiotics

Submission date
12/12/2016

Recruitment status
No longer recruiting

Registration date
05/01/2017

Overall study status
Completed

Last Edited
14/12/2016

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bronchiectasis is a lung condition in which the airways become permanently damaged. People who have bronchiectasis can have many different chest symptoms, commonly produce a large amount of phlegm and experience many chest infections. Pseudomonas aeruginosa is a bacterium (bug) that is found in the phlegm of almost a third of bronchiectasis patients. These patients require more antibiotics, are admitted to hospital more and attend more clinic appointments than patients without this bug. Colistimethate sodium and tobramycin are antibiotics that are breathed directly into the lungs using a nebuliser. They are known as inhaled antibiotics. They are effective at treating P. aeruginosa infection, yet patients continue to have repeated infections requiring further antibiotics. This may be because patients do not take their inhaled antibiotics as they have been prescribed. This is described as non-adherence. Research conducted at Queen's University Belfast found that among patients who were prescribed inhaled antibiotics for P. aeruginosa infection, 53% took their antibiotics as prescribed (adherent). Adherence to inhaled antibiotics was also linked with having fewer infections (adherent patients had 2.6 exacerbations [chest infections] per year whereas non-adherent patients had 4). A new approach to support people with bronchiectasis to take their inhaled antibiotics has been developed. This approach has been developed using a recommended process for developing ways to change people's behaviour to improve their health. This study aims to test if the intervention can be delivered as intended to patients with bronchiectasis, and whether or not patients consider it to be an acceptable and useful form of support.

Who can participate?
People aged over 18 who have been diagnosed with bronchiectasis and who have been prescribed the medicine Colistimethate Sodium (also known as Colomycin®)

What does the study involve?
The study involves testing the new approach with five participants recruited from the Regional Respiratory Centre at the Belfast Health and Social Care Trust. The participants meet with a researcher three times (Visits 1-3) at a dedicated Clinical Research Facility at the Belfast City Hospital. At Visit 1, the researcher confirms that the participant is happy to take part in the

study. The researcher then asks the participant a number of questions about their treatment plan. The researcher uses the answers to these questions to find out what form of support the participant needs in order to improve their adherence to their inhaled antibiotic. Using this information, the researcher plans what is going to happen in Visit 2. At Visit 2, the researcher uses a manual and supporting materials to provide adherence support that is tailored to the participant. During the visit, an action plan is drawn up for the participant to follow at home. They are also given a diary to help them monitor their treatment. At Visit 3, the participant's progress is reviewed and the researcher provides further support for adherence if needed. When all three visits have been attended, the researcher telephones each participant and asks them for feedback about their experience. Participants are asked what they liked and disliked about the three visits and if they thought the information and advice they received was a useful form of support. Information is collected from the participant at Visit 1 and around three months later.

What are the possible risks and benefits of participating?
The main benefit of participating in the study is that participants' adherence may improve. Studies show that people who are adherent to inhaled antibiotics have fewer chest infections than those who are not. Therefore participation in the study could lead to fewer chest infections, a reduced need for antibiotics, fewer admissions to hospital and a better quality of life. By taking part in the study, participants will also be contributing to the body of evidence relating to bronchiectasis. There is a low risk of harm associated with this study. The main risk is the potential for distress when answering questionnaires that cause participants to reflect on their condition. Any potential for harm will be minimised by reviewing the information sheets with the participant before they provide informed consent. Should a participant become distressed at any point in the study, they will be given time to take a break and to decide if they want to proceed. If they do not want to proceed they can withdraw. Their medical team will be notified that they are no longer participating but this will not affect their medical care.

Where is the study run from?
Belfast Health and Social Care Trust (Belfast City Hospital site) (UK)

When is the study starting and how long is it expected to run for?
July 2016 to April 2017

Who is funding the study?
Queen's University Belfast (UK)

Who is the main contact?
Prof. Carmel Hughes

Contact information

Type(s)
Scientific

Contact name
Prof Carmel Hughes

Contact details
School of Pharmacy
97 Lisburn Road

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BT9 7BL

Additional identifiers

Protocol serial number
Version 3.0

Study information

Scientific Title
A feasibility study to test an intervention to change adherence to inhaled antibiotics in patients with bronchiectasis

Acronym
CAN-BE (Change AdhereNce in BronchiEctasis)

Study objectives
The aim of this study is to test the feasibility of delivering and evaluating an intervention to improve adherence to inhaled antibiotics by patients with bronchiectasis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee (REC) A, 04/03/2016, ref: 16/NI/0031 (Amendment 1, 20/09/2016)

Study design
Non-randomised feasibility study in one NHS site

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Suboptimal adherence to inhaled antibiotics in bronchiectasis

Interventions
The CAN-BE intervention is a set of 12 behaviour change techniques that are delivered to patients with bronchiectasis in an attempt to change their adherence to inhaled antibiotics. Behaviour change techniques represent the ‘active ingredients’ of interventions to change behaviour. The CAN-BE intervention is delivered by a healthcare professional (for the purposes of the feasibility study this will be a PhD researcher) to participants face-to-face over three consultations (Visits 1-3). An Intervention manual is used to guide each consultation and progress is documented in a Participant Intervention Record.

At Visit 1, the researcher asks the participant a number of questions about their treatment and attempts to identify to what extent and why the participant is not adhering to their inhaled antibiotic treatment. The researcher then uses the responses to these questions to choose the behaviour change techniques that are most appropriate for the participant.

At Visit 2, the researcher delivers the tailored set of behaviour change techniques to the participant. A set of intervention materials has been developed to facilitate the delivery of behaviour change techniques. All participants are given an action plan to follow and an adherence diary to help them monitor their treatment at home.

At Visit 3, the participant's progress is reviewed and the researcher provides further support for adherence if needed.

When all three visits have been attended, the researcher will telephone each participant and ask them for feedback about their experience. Participants will be asked what they liked and disliked about the three visits and if they thought the information and advice they received was a useful form of support. Information to measure the study outcomes will be collected from the participant at Visit 1 and around three months after the intervention.

Intervention Type
Behavioural

Primary outcome(s)
Determination of the extent to which the intervention has been delivered as intended, measured by review of completed Participant Intervention Records. For each completed record, the project team will determine the proportion of instructions completed as described in the manual. Errors of omission and deviations to the planned delivery of the intervention will be identified by researcher recall and crosschecked with audio recordings of visits with patients. Reasons for deviations will be discussed with the study team and reported. Measured within one month of intervention delivery.

Key secondary outcome(s))
1. Percentage fidelity to the planned delivery of behaviour change techniques. A coding frame will be used to describe when and how each technique should be delivered. A health psychologist, independent of the research team, will review anonymised transcripts of audio recordings of consultations and will use the coding frame to record whether the component has been delivered. Percentage fidelity will be determined by dividing the number of techniques recorded as delivered by the reviewer by the number of techniques the researcher recorded as delivered in the Participant Intervention Record, multiplied by 100. Measured within three months of intervention delivery.
2. Participant feedback about the intervention. The researcher will interview participants after they have received the full intervention to gather feedback about the intervention and usability of the intervention materials. Measured at two weeks after intervention delivery.
3. Feasibility of recruitment strategy in target population. Information about the recruitment process will be recorded on a pre-screening log (to assess eligibility) and a recruitment log, and will include the number of individuals retained at each stage of the recruitment process. Measured at three months after intervention delivery.
4. Suitability of methods used to measure participants' adherence to colistimethate sodium before and after receiving the intervention. The 8-item Morisky's Medication Adherence Scale (MMAS-8) questionnaire will be used to measure adherence to colistimethate sodium at baseline and three months after Visit 3. Medication possession ratio (MPR) will be used as a second

measure of adherence to colistimethate sodium at baseline and three months after Visit 3. Measured at baseline and 3 months after intervention delivery.
5. Suitability of methods used to measure quality-of-life before and after receiving the intervention. The Quality of Life-Bronchiectasis questionnaire Version 3.1 will be self-completed by participants at Visit 1 before receiving the intervention and will be self-completed by the participant at home three months after Visit 3. Measured at baseline and 3 months after intervention delivery.
6. Suitability of data collection and recording procedures used during the feasibility study. A "Participant checklist and study implementation log" will be kept by the researcher to document any problems encountered during the collection or recording of data. Measured by continuous log throughout the study and analysed within three months of intervention delivery.

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Aged over 18 years
2. Diagnosed with non-cystic fibrosis bronchiectasis through computed tomography (CT) or high-resolution CT (HRCT)
3. Prescribed inhaled antibiotics (specifically colistimethate sodium) for chronic suppression of P. aeruginosa
4. Have suboptimal adherence

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Those who cannot consent to take part or do not have the ability to complete study questionnaires
2. People who self-report full adherence, as measured using a validated self-reported adherence questionnaire

Date of first enrolment
01/07/2016

Date of final enrolment

28/02/2017

Locations

Countries of recruitment
United Kingdom

Northern Ireland

Study participating centre
Belfast Health and Social Care Trust (Belfast City Hospital site)
Lisburn Road
Belfast
United Kingdom
BT9 7AB

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
University/education

Funder Name
Queen's University Belfast

Alternative Name(s)
QUB

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Participant level data will not be reported for this small-scale feasibility study (n=5 participants) because they are considered to be of little significance on their own. Results with be grouped and reported together in any research publications. Identifiable participant information will be kept in a locked cabinet in the Belfast City Hospital and will not leave hospital premises. Anonymised hardcopy data will be stored in a locked fire-resistant cabinet in the School of Pharmacy at Queen's University Belfast. Anonymised electronic data will be stored on a password protected laptop computer. The hardcopy and electronic data will be securely held for a period of five years before being destroyed.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No