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An evaluation of a new approach to reduce antimicrobial prescribing in care home residents

Submission date
10/03/2016

Recruitment status
No longer recruiting

Registration date
25/04/2016

Overall study status
Completed

Last Edited
24/01/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
There have been concerns about the level of prescribing of antimicrobials (antibiotic, antifungal and antiviral medicines) in care homes for older people. The Chief Medical Officer (CMO) of England has highlighted that high use of antimicrobials can lead to resistance, meaning that these drugs may no longer be effective. The CMO's report also suggested that older people, especially those living in care homes, may be at higher risk of infection. The report noted that education and training of doctors and nurses about infections and antimicrobials was very important to ensure that antimicrobials are used properly. A Canadian study found that education and training was useful in reducing the use of antimicrobials in Canadian care homes. We have based our study on this work.

Who can participate?
We will recruit 6 care homes to the study: 3 in Northern Ireland and 3 in the West Midlands.

What does the study involve?
Using the most up-to-date scientific research on how to manage infections in care home residents, we are developing training material and a training programme for care home staff and general practitioners (GPs). The Canadian approach is discussed with staff, GPs and family members of residents, and adapted for use in the UK. Care home staff and GPs are trained in using this new approach. The new approach is then tested in the 6 care homes to ensure that it is practical and feasible. Members of the research team interview the staff and GPs to explore how they found the new approach, if they had any particular difficulties, and if they have any suggestions for improvements. We also test how we will collect information about residents from care homes, community pharmacies and large databases.

What are the possible benefits and risks of participating?
For care home staff and GPs who take part in this study, the possible benefits are greater knowledge of infections in care home residents and contributing to a possible new way of improving prescribing of antimicrobials. The possible risk is the time spent undertaking training and recording activities during the study. However, we would hope that this will be out-weighed by the possible benefits.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
April 2016 to January 2018

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

Who is the main contact?
Prof. Carmel Hughes

Contact information

Type(s)
Scientific

Contact name
Prof Carmel Hughes

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2

Study information

Scientific Title
An evaluation of a multifaceted intervention to reduce antimicrobial prescribing in care home residents [REducing Antimicrobials in Care Homes (REACH)]: a non-randomised feasibility study and process evaluation

Acronym
REACH (REducing Antimicrobials in Care Homes)

Study objectives

The aim is to evaluate the feasibility and acceptability of a multifaceted intervention on rational prescribing for infections in a non-randomised feasibility study in care homes for older people. The intervention will consist of an educational and management approach, supported by discussion on resident cases.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee B, 28/01/2016, ref: 16/NI/0003

Study design
Multicentre non-randomised feasibility study with an embedded process evaluation

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Care home, GP practice, Workplace

Study type(s)
Other

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
Infections in care home residents and antimicrobial prescribing

Interventions
A feasibility study will be conducted in six care homes for older people (three care homes in Northern Ireland and three care homes in the Warwick/Coventry area). At this stage, the exact content of the intervention has not yet been confirmed as it requires further adaptation and development. This will be done by undertaking interviews and focus groups with care home staff, general practitioners and family members of those resident in a care home. The intervention will be based on one that was tested in Canadian care homes, but it would not be appropriate to simply apply the same intervention in the United Kingdom setting. Furthermore, the Canadian intervention only focused on urinary tract infections. This current study will examine prescribing in other conditions such as respiratory and soft tissue infections. The proposed intervention will consist of education and training of care home staff and the GPs caring for the residents, on appropriate management of common infections and appropriate use of antimicrobials. This will be achieved via visits by research staff to the participating care homes and general practices which serve these care homes. During these visits, the research staff will deliver training on common infections in care homes and how they should be best treated. The research staff will introduce the care home staff and general practitioners to algorithms (flow charts) which will help guide decision-making about prescribing of antimicrobials. Care home staff will be asked to use these algorithms over the duration of the feasibility study (6 months)

when caring for residents who may have infections. This training approach will be undertaken in all 6 homes with separate sessions being provided for qualified nursing staff and care assistants who are not formally qualified. We will also offer training to general practices associated with the participating care homes. Training will be delivered on one occasion only in each setting, but we will produce a DVD of the care home training which can be viewed by staff who are unable to attend designated session.

Intervention Type
Mixed

Primary outcome measure
Because this is a feasibility study, we are unable to judge effectiveness. The outcomes that we are interested in for this feasibility study are predominantly process-related and outlined as follows:
1. Acceptability of the intervention in terms of recruitment and delivery of training as assessed by collecting data on recruitment of care homes (3 months from the start of the project, based on the number of homes approached and the number recruited) and attendance at training events (after the training events have taken place during months 9-12)
2. The feasibility of measuring appropriateness of prescribing and collecting dispensing data from community pharmacies (12 months pre-baseline and 6 months from baseline)
3. Comprehensive overview of the implementation of the intervention as measured through process evaluation (observation, interviews and focus groups) over the course of the study (over 6 months).

Secondary outcome measures
There will be two main secondary outcomes for this feasibility study:
1. The costs of implementing the intervention which will be recording resource used associated with labour, training, intervention materials, equipment and space. These data will be collected over the course of the study through the use of documentation that will be prepared for the study.
2. The likelihood of being able to recruit to a larger definitive study will be assessed by distributing a short questionnaire (providing details about a proposed definitive study) to care homes in selected geographic areas (month 21)

Overall study start date
01/04/2016

Completion date
30/04/2018

Eligibility

Key inclusion criteria
Care homes:
1. Care homes (some with/without nursing care), principally providing 24 hour care for older residents
2. A minimum of 20 (permanent) residents
3. Associated with a small number of general practices (up to four per home providing care for a minimum of 80% of residents within a home)
4. An exclusive arrangement with one pharmacy for dispensing medications

Care home staff:
1. Working in the participating care homes
2. Willing to participate in focus group discussions

General Practitioners:
1. Working with the participating care homes
2. Willing to participate in interviews

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
Six care homes; up to 50 participants for the qualitative aspects of the process evaluation (care home staff and GPs)

Key exclusion criteria
1. Not meeting the inclusion criteria
2. Not providing written informed consent

Date of first enrolment
01/05/2016

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
England

Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL

Study participating centre
Warwick Clinical Trials Unit, The University of Warwick
Gibbet Hill Road
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
Queen's University Belfast (UK)

Sponsor details
Research and Enterprise Office
University Road
Belfast
Northern Ireland
United Kingdom
BT7 iNN

Sponsor type
University/education

ROR
https://ror.org/00hswnk62

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

Publication and dissemination plan
We plan to publish the protocol for the study by April 2017. Further papers will be produced once results become available after April 2018. We will also present the findings at appropriate conferences.

Intention to publish date
30/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository at the School of Pharmacy, Queen's University Belfast. , this is a feasibility study to test acceptability and implementation of an intervention in six care homes. Data will not be at the resident level. Participant level data will not be reported for this feasibility study as they are considered to be of little significance on their own given that the study will not seek to assess the effectiveness of the intervention

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2020	27/02/2020	Yes	No
HRA research summary			28/06/2023	No	No