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Testing a support system designed to improve antibiotic use in care homes

Submission date	**Recruitment status**	[_] Prospectively registered
23/08/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/08/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/05/2023	Other	

Plain English summary of protocol

Background and study aims
Antibiotics are essential medications but they also have side effects, both for the individuals who take them and for the wider society, including increasing the risk of antibiotic-resistant infections, which are much harder to treat. This problem is relatively common among older people who live in care homes but there is less research in this area compared to hospitals or general practice. The aim of this study is to test a set of training and tools, designed to safely improve antibiotic use among care home residents, with staff in a small number of care homes, to see whether a full-scale trial is worthwhile.

Who can participate?
Staff in care homes for older people in Tayside and Fife NHS regions

What does the study involve?
All staff in participating care homes will be asked to participate in training sessions and use tools to help support assessment and monitoring of residents with suspected infection, and communication about infections and antibiotics within the care home and with healthcare professionals. Two individuals within each care home will be recruited as Antibiotic Champions to encourage others to use the training and tools and to help collect data and feedback on how they are used and whether or not they are working in practice. Staff members will also be invited to take part in interviews (and observations if COVID-19 restrictions allow) to assess how the intervention works in practice and any changes that should be made.

What are the possible benefits and risks of participating?
Participation could be used as evidence of continued professional development by some staff, and Antibiotic Champions and interview participants will receive a thank-you payment. There are no anticipated risks to participants.

Where is the study run from?
University of Dundee, in collaboration with University College London, the University of Edinburgh and Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
March 2021 to March 2022

Who is funding the study?
This work is funded by the Economic and Social Research Council (ESRC), working in partnership with the Department of Health and the Arts and Humanities Research Council (AHRC), under theme 4 of the Antimicrobial Resistance Cross Council Initiative supported by the seven research councils in partnership with other funders (https://www.mrc.ac.uk/amr).

Who is the main contact?
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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
288751

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49606, Protocol number 2.021.20

Study information

Scientific Title
Antibiotic Research in Care Homes (ARCH) Work Package 4: intervention feasibility testing (ARCHeS)

Acronym
ARCHeS

Study objectives
An antibiotic stewardship intervention for staff in care homes for older people can be remotely delivered with feasibility testing, process evaluation, and selection of future trial outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/06/2021, East of Scotland Research Ethics Committee (Tayside Medical Science Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 (0)1382 383878; tay.eosres@nhs.scot), REC ref: 21/ES/0058

Study design
Non-randomized interventional feasibility study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Improving antibiotic use among residents of care homes for older people

Interventions

In this non-randomised feasibility study, staff in all four care homes receive the intervention which comprises:

1. Training in antibiotic stewardship and the ARCHeS intervention for all staff:
1.1. Training video (25 min) recorded by the Project Lead for the Scottish Antimicrobial Prescribing Group. Focus on antibiotic stewardship and tailored to care home staff.
1.2. ARCHeS training video (25 min) featuring social care staff using the ARCHeS intervention tools (2.1-2.4. below) in simulated clinical scenarios. Demonstrating practical use of the tools and including discussion points that illustrate how using the tools promotes good use of antibiotics.
1.3. Two live online (MS Teams) Q&A sessions (up to 1 hour) with a topic/sector expert (Advanced Nurse Practitioner in Antimicrobial Stewardship) and a member of the ARCHeS study team to answer any questions or concerns about antibiotic use, stewardship and the ARCHeS intervention/tools. One session (per care home) to be delivered in the first/second month, and one session (per care home) to be delivered around month four.
Within the feasibility study, these sessions will be recorded as part of the process evaluation.

2. Tools to support resident assessment and monitoring, and to support communication about infections and antibiotics:
2.1. Algorithm (flowchart) to be used in the initial assessment and management of a resident with suspected infection. Key features: advice against the use of urine dip tests in suspected UTI; cues to consider other causes of altered status; safety-netting advice to escalate at any time for assessment if there are concerns about a resident's condition.
2.2. Monitoring Tool to be used in active watching and waiting of resident with suspected infection but who does not need urgent review. Includes specification of parameters (including temperature) and frequency (e.g. two-hourly) of recording and triggers for review to be requested.
2.3. SBAR (Situation, Background, Assessment, Recommendation) structured communication form to use when requesting input (advice or review) from a GP or ANP.
2.4. Stickers (two different paper visual prompts) to highlight current antibiotic prescriptions and trigger discussion amongst care home staff, including during handovers. One sticker to be used in individual residents' care plans and one in handover documents that cover the whole home/unit.

3. Identification of staff Antibiotic Champions: Two members of each care home staff (e.g. one nurse/senior carer and one carer per care home, or two senior carers working in different units /on opposite shift patterns) to assume Antibiotic Champion role to promote and support the ARCHeS intervention (and process evaluation, below) in their care home. Specific training (one-hour MS Teams session) for Antibiotic Champions clarifying the role, responsibilities and practicalities (e.g. data collection methods) will be provided by the study team and support will be available (via the PI) throughout the feasibility study.

4. Supporting information for prescribers (general practitioners and advanced nurse practitioners) associated with study care homes, also provided to the study care home managers, Antibiotic Champions, and all staff. Prescribers are not participants in the study but the information is to enable them to support the care homes' participation.

The mixed-methods process evaluation will use quantitative and qualitative data collection and analysis to inform on the implementation outcomes of fidelity (and any adaptation), adoption, reach/penetration, acceptability, and feasibility.
Data for the process evaluation will be collected by:
1. Interviews (face to face or remote) and observations (if possible in the evolving COVID-19 situation) with care home staff.

2. Quantitative and qualitative reporting on the use of, and views on, the training and tools by Antibiotic Champions.
3. Recording the Q&A sessions.
4. Documentary analysis of (anonymised) completed Monitoring Tools and SBAR forms.

Intervention Type
Other

Primary outcome(s)
1. Recruitment of care homes recorded as the number (and proportion of those approached) of care homes recruited at 2 months after the recruitment start date
2. Retention recorded as the number of care homes that complete the 6-month feasibility study
3. Implementation outcomes are informed by implementation science theories and frameworks, including normalisation process theory (NPT) and the Theoretical Domains Framework (TDF):
3.1. Fidelity and adaptation are measures of the extent to which the intervention is delivered as intended, assessed using: training logs recording sessions delivered and the number (and proportion) of staff participating; interviews (and observations if possible) collecting qualitative data on the use of the intervention tools; weekly activity logs submitted by Antibiotic Champions recording quantitative data on the use of the tools and any feedback; and document analysis of completed tools. Measured at 6 months.
3.2. Adoption (or uptake) measures the extent to which intervention components are used in routine practice, assessed using weekly logs submitted by Antibiotic Champions; interviews (and observations if possible), and documentary analysis at 6 months
3.3. Reach (or penetration) measures how well the intervention has reached the target population, assessed using training logs and interviews (and observations if possible) at 6 months
3.4. Acceptability measures how well the staff like the intervention and find it suitable for use, assessed using interviews with topic guide structured around the Theoretical Framework of Acceptability, and feedback within weekly activity logs submitted by Antibiotic Champions at 6 months
3.5. Feasibility measures actual fit or utility/suitability for everyday use, assessed using interviews (and observations if possible) exploring barriers and enablers to intervention use at 6 months
4. Recruitment of individuals for interviews (and observations if possible) recorded as the number (and proportion of planned) participants completing the activity measured at 4 and 6 months
5. Feasibility of measuring potential trial outcomes (for example antibiotic prescriptions dispensed to care home residents) using different data sources, assessed by comparison of data collected by care home staff and data collated at the Health Informatics Centre, University of Dundee, measured at 8 months (after study end)
6. Selection of outcome measures for a future definitive trial using interviews with care home managers, weekly activity logs submitted by Antibiotic Champions, literature review and outcome of feasibility assessment (above), measured at 9 months (after study end)

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/03/2022

Eligibility

Key inclusion criteria
All care homes for older people in NHS Tayside and NHS Fife regions with >10 beds are potentially eligible, with care homes being invited a small number at a time until four recruited. All staff members (nurses and carers) working in the study care homes are eligible to participate in individual activities for intervention delivery and process evaluation.

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
16

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
19/07/2021

Date of final enrolment
31/03/2022

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Tayside NHS Board
NHS Tayside Headquarters
Ninewells Hospital & Medical School
Dundee
United Kingdom
DD1 9SY

Study participating centre
Fife NHS Board
Hayfield House
Hayfield Road
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United Kingdom
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Sponsor information

Organisation
University of Dundee

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Research council

Funder Name
Economic and Social Research Council

Alternative Name(s)
Economic and Social Research Council (ESRC), ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
In line with the ESRC's Research Data Policy, anonymised participant-level project data will be made available to future researchers for secondary analysis. Interview and observation data generated will be deposited at the UK Data Archive. Permission for the archiving of data will form part of the consent process, and all data will be anonymised prior to archiving.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	Basic Results		04/05/2023	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2	08/06/2021	24/08/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes