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Phased In: delivering antimicrobial stewardship in primary care

Submission date
07/06/2024

Recruitment status
No longer recruiting

Registration date
20/06/2024

Overall study status
Completed

Last Edited
27/01/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
One in three people contact their GP surgery each year with minor infections, such as sore throat, cough, cold, ear, urinary and skin infections. Half of the people contacting their GP with infections receive antibiotics, but antibiotics mostly don't help. Overuse of antibiotics harms people and causes antibiotic resistance to develop, where antibiotics no longer work well. More infections are now being managed by trained pharmacists. This service is already offered in many areas, helping patients as well as helping to use our NHS services more efficiently. The researchers have developed decision-making tools to help pharmacists improve the quality of care that patients receive. This study aims to evaluate the feasibility of a pharmacy package using decision-making tools and point-of-care tests to share the management of acute infections in primary care.

Who can participate?
The study will involve GP practices and local, linked independent prescribing pharmacists. Patients presenting to participating GP practice/pharmacy clusters will be invited to take part if they have the following:
• Urinary tract infections (women (16-65 years),
• Upper respiratory tract infections (adults 18-79 yrs and children 1-17 yrs with sore throat/otitis-media/sinusitis/influenza).
• Lower respiratory tract infections (adults 18-79 yrs and children 3-17 yrs)
• Skin infections (adults 18-79 yrs and children 1–17 yrs with impetigo and insect bites)

What does the study involve?
GP practice/pharmacy clusters will be randomly assigned to the intervention or control arm for 6 months. In the intervention arm, patients presenting to their GP practice with a minor illness will be offered an appointment with their local, trained pharmacist. Pharmacists will use decision aids and point-of-care tests to assess, diagnose, and provide advice and treatment (both over-the-counter and prescription) if necessary. In the control arm, patients presenting to their GP practice with minor illnesses will be managed as usual.

What are the possible benefits and risks of participating?
The main benefit of taking part is that patients will be offered a 'fast-track' appointment with

their local pharmacist and will receive the same care as they would get from the GP surgery. This research will test if it is possible to refer patients with common infections to linked pharmacies where their infections will be managed with decision aids. If this is feasible, it could lead to a further large trial to find out if this can reduce the overuse of antibiotics.

Where is the study run from?
The Primary Care Research Centre, University of Southampton (UK)

When is the study starting and how long is it expected to run for?
September 2023 to August 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
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Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
334489

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
82452, CPMS 59964, IRAS 334489, NIHR158312

Study information

Scientific Title
PHarmacy-first partnership delivering Antimicrobial Stewardship for EveryDay practice IN primary care (PHASED IN): a feasibility study

Acronym
PHASED IN

Study objectives
To finish development and feasibility test a pharmacy package using decision-making tools and point of care tests to share the management of acute infections in primary care.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 24/05/2024, Cambridge Central REC (2 Redman Place, London , E20 1JQ, United Kingdom; +44 (0)2071048285; cambridgecentral.rec@hra.nhs.uk), ref: 24/EE/0050

Study design
Mixed-methods cluster randomized controlled feasibility trial with process evaluation

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Common illnesses including respiratory infections (upper respiratory tract infections [URTIs] and lower respiratory tract infections [LRTIs]), urinary tract infections (UTIs), skin infections and insect bites.

Interventions
Triage and referral of patients with common illnesses from GP practices to linked pharmacies, who will use diagnostic aids and point-of-care tests where indicated.

The intervention will include evidence-based decision-making tools to standardise care and help identify people who do not need antibiotics and those who might need them or need further assessment, as well as diagnostic tests that can be carried out on the spot if needed (such as C-reactive protein) and patient leaflets to support self-care. There will be a training package to help health professionals to use all these tools in inpatient consultations.

10 general practices will continue with management as usual, and 10 will be trained to refer patients presenting with common infections to linked community pharmacies that will use the intervention. The study will include practices in a wide range of settings (including high- and low-income areas, urban and rural, and practices with high ethnic minority populations) and will look at how well the service works, what the implications are for providing the service, and patient and healthcare professional views with a view to any revisions needed before a fuller trial of the new service.

Computer-generated 1:1 randomisation of GP/Pharmacy clusters will be used, stratified by whether pharmacies are participating in the Pharmacy First national scheme.

Intervention Type
Mixed

Primary outcome(s)
The primary feasibility outcome measures include:
1. To establish recruitment methods for a future definitive trial by evaluating recruitment and retention of pharmacies and GP practices in a range of UK geographical and sociodemographic regions. Data collected will include numbers invited, responded, initiated, completed /withdrawn, and reasons for not taking part at each stage, at the end of the study.
2. To establish the feasibility of cluster randomisation by evaluating recruitment of pharmacies /GP practices clusters and acceptability of randomisation to intervention and control arms through qualitative interviews with pharmacy and practice staff after randomisation, during and at the end of the study
3. To determine the feasibility of the triage/referral pathway from GP practices to their linked cluster pharmacy, by establishing: i) time taken, staff requirements, and resources used to triage and manage infections in both the general practices and pharmacies; ii) staffing requirements including time and resource required for training, monitoring and supporting pharmacy staff iii) referral rates to and from pharmacies, referrals to pharmacies not made, and referrals from pharmacies to hospitals. Data will be recorded directly by GP practice and pharmacy staff,

qualitative interviews, and through the digital intervention, during and at the end of the study.
4. To establish patient recruitment and consent to i) the main study period and ii) the more intensive audit period, through numbers approached, referred, and consented to the trial collected by GP practice staff and pharmacists, by the digital intervention, and through qualitative interviews during and at the end of the study
5. To finalise data collection methods for primary and secondary outcomes by evaluating i) rates of completion of CRFs by pharmacists and GP practices through data from the digital intervention ii) rates of routine practice level antibiotic prescribing data through data from the RCGP Research and Surveillance Centre (RSC) iii) rates of patient-level data (baseline and audit patients) through medical notes review at the end of the study

Key secondary outcome(s))
The following outcomes will be collected in preparation for a future definitive trial:
1. Experience of the intervention (decision-making tools and point-of-care tests), acceptability of the intervention, and trial materials, through qualitative process interviews conducted during and at the end of the study
2. Engagement with key behaviours – the use of online training; the use of decision support; and engagement with the in-practice audit through qualitative interviews and digital intervention usage data during and at the end of the study
3. Effects on antibiotic prescribing: i) Antibiotic prescribing rates at practice level for the key bundle of antibiotics; ii) Overall antibiotic prescribing at individual level, controlling for illness spectrum, iii) Antibiotic prescribing at individual level for each condition (e.g. LRTI, sore throat), iv) Appropriateness of antibiotic prescribing. Data will be collected through practice level and individual patient data (audit patients) at the end of the study.
4. Consultation rates and complication rates at practice level, through collection of practice level and individual patient data (audit patients) at the end of the study
5. Clinical safety (complications recorded; adverse events) of the triage/referral pathway, and use of the intervention/POCTs through collecting individual patient data (medical notes review and GP/pharmacy report) during and at the end of the study
6. Characteristics of participants in intervention and control practices through the collection of individual patient data at baseline and audit periods recorded by the digital intervention and through medical notes review at the end of the study

Completion date
31/08/2025

Eligibility

Key inclusion criteria
Patients presenting to ‘index’ general practices with the commonest acute uncomplicated infections including:
1. UTI (women aged 16-65 years)
2. URTI: (adults aged 18-79 years and children aged 1-17 years): sore throat/otitis-media/sinusitis /influenza
3. LRTI: (adults aged 18-79 years and children aged 3-17 years)
4. Skin infections (adults aged 18-79 years and children aged 1–17 years with impetigo and insect bites)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
1 years

Upper age limit
79 years

Sex
All

Key exclusion criteria
1. Infection not suspected
2. Pregnancy
3. Known immunological deficiencies
4. Symptoms of serious illness such as rapid deterioration in consciousness level; too unwell to walk
5. Aged under 1 year old or aged under 3 years with suspected UTI
6. Over age 75 years old with 2 or more major co-morbidities
7. Aged > 80 years old
8. Those who do not accept referrals to the partner pharmacies
9. Recurrent/chronic infection defined as:
9.1. LRTI: 2 or more infections in the last year
9.2. UTI: 2 or more episodes in the last 6 months or 3 or more in the last 12
9.3. Impetigo: 2 or more episodes in the last year
9.4. Chronic sinusitis (symptoms for >= 12 weeks)
9.5. Otitis: more than one infection in the last year in adults (aged > 16) and 3 or more/6 months or 4 or more in 12 months in children

Date of first enrolment
03/02/2025

Date of final enrolment
17/08/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Wessex CRN
Unit 7, Berrywood Business Village

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Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
The current data-sharing plans for this study are currently unknown but will be made available at later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes