ISRCTN16230629 https://doi.org/10.1186/ISRCTN16230629

Building resources to improve treatment in two clinical priority areas – antibiotic prescribing for routine infections and treatment for frail elderly populations

Submission date
06/10/2021

Recruitment status
No longer recruiting

Registration date
01/11/2021

Overall study status
Completed

Last Edited
25/08/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
The Learning Healthcare System approach has been proposed to better integrate research into clinical practice. It involves routine and repeated phases including analysis of data, feedback to clinicians, and deciding on and completing quality improvement activities by the clinicians. In this project, this approach will be applied to two different clinical areas in general practice, one concerning antibiotic prescribing for common infections and the other concerning treatments for frail elderly. The aim of this study is to evaluate whether the Learning Healthcare System improves prescribing without increasing the risks of complications.

Who can participate?
All GP practices in the study area (NorthWest UK) can take part – the participants are the patients in this practice who have not opted out of data for use for secondary care purposes

What does the study involve?
General practices participating in the trial will be randomly allocated to the following interventions: a) periodic practice-level feedback using dashboards only, b) practice and individual prescriber feedback, and (in the antibiotic sub-study only) c) periodic practice, individual feedback and a knowledge support system (KSS). When a patient attends an appointment with a GP for an infection related condition, or a frail older patient attends, the GP will conduct their usual assessment and the data is inputted into the patient's electronic health record. The anonymised data for all patients in the practice will be analysed and fed back to the GP practice through a series of dashboards. The GP practice will periodically review the dashboards and the data analysis to see where they might be able to focus efforts to improve prescribing and care for the patients. All practices in the study will receive additional prompting feedback through emails or letters to direct them to areas where data suggests improvement could be made. For practices in the antibiotic prescribing group that have been randomly allocated into the knowledge support tool, as a GP inputs data into the patient's electronic health record the knowledge support tool will provide additional information to the GP such as

the patient's risk of developing infection-related complications. The conversation a GP has with a patient to prescribe an antibiotic or not can be supported by information that can be printed off the knowledge support tool. This tool will not provide treatment recommendations (such as do prescribe an antibiotic) but provide contextual educational information – it will be up to the GP what to do with this information and whether relevant to the patient consulting the GP. A patient leaflet containing individualised information could be printed out and provided to the patient if considered important and relevant by the GP.

What are the possible benefits and risks of participating?
This is a low-risk study looking at the impact of tools to support prescribing. The benefits of taking part may include increased confidence in prescribing, reduced risks for inappropriate prescribing and increased antibiotic risk awareness, therefore reducing antibiotic prescribing overall. The KSS system will provide personalised information to patients which may benefit doctor/patient discussion around prescribing.

Where is the study run from?
University of Manchester (UK)

When is the study starting and how long is it expected to run for?
November 2020 to October 2023

Who is funding the study?
1. National Institute for Health Research (NIHR) (antibiotics sub-study) (UK)
2. HDR UK (frailty sub-study)
3. Medical Research Council (UK)
4. Public Health England (UK)

Who is the main contact?
Francine Jury
francine.jury@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Tjeerd van Staa

ORCID ID
https://orcid.org/0000-0001-9363-742X

Contact details
The University of Manchester
School of Health Sciences
Division of Imaging, informatics and Data Science
Health eResearch Centre (HeRC)
Vaughan House
Portsmouth Street
Manchester
United Kingdom

M13 9GB
+44 (0)1613060662
tjeerd.vanstaa@manchester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
290050

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49395, IRAS 290050

Study information

Scientific Title
Knowledge support to general practitioners and patients: evaluation of the effectiveness of periodic feedback, decision support during consultations and peer comparisons in multi-arm cluster randomised trial (BRIT2)

Acronym
BRIT2

Study objectives
A Learning Healthcare System (LHS) approach (i.e., detailed data analysis followed by feedback to clinicians) improves prescribing without increasing the risks of complications. The specific research questions will be to evaluate the effectiveness of periodic practice-level feedback (in an observational study) and to evaluate the effectiveness of individual prescriber feedback and of a Knowledge Support System (in a randomised cluster trial).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2021, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)207 1048091; newcastlenorthtyneside2.rec@hra.nhs.uk), REC ref: 21/NE/0103

Study design
Multi-arm pragmatic cluster randomized controlled trial

Primary study design
Interventional

Study type(s)

Efficacy

Health condition(s) or problem(s) studied
Primary care

Interventions
The Learning Healthcare approach can be used in numerous clinical areas. In this project, this will be applied to two different clinical areas in general practice, one concerning antibiotic prescribing for common infections and the other concerning treatments for frail elderly.

When a patient attends an appointment with a GP for an infection related condition, or a frail older patient attends, the GP will conduct their usual assessment and the data is input into the patient's electronic health record. The anonymised data for all patients in the practice will be analysed and fed back to the GP practice through a series of dashboards. The GP practice will periodically review the dashboards and the data analysis to see where they might be able to focus efforts to improve prescribing and care for the patients.

All practices in the study will receive additional prompting feedback through emails or letters to direct them to areas where data suggests improvement could be made.

For practices involved in the antibiotic prescribing arm where they have been randomised into the knowledge support tool. As a GP inputs data into the patient's electronic health record, the knowledge support tool will provide additional information to the GP such as the patient’s risk of developing infection-related complications. The conversation a GP has with a patient to prescribe an antibiotic or not can be supported by information that can be printed off the knowledge support tool. This tool will not provide treatment recommendations (such as do prescribe an antibiotic) but provide contextual educational information – it will be up to the GP what to do with this information and whether relevant to the patient consulting the GP. A patient leaflet containing individualised information could be printed out and provided to the patient if considered important and relevant by the GP.

All practices that provide data to the data centre for integrated care and health management will be able to access the dashboards. The data processing, analysis and feedback mechanisms must be established and assured for each practice prior to randomisation. Practices will take part in the study for 12 months.

If practices agree to become study sites, they (including their patient dataset) will be randomised into the study arms.

There are two studies that the practices can take part in:
1. Antibiotic prescribing
2. Prescribing for frail elderly (with polypharmacy and comorbidities)
Practices can choose to take part in either or both studies

The researchers will recruit to the Frailty project first. Practices will be randomised into one of two arms. Randomisation will be conducted by using an approved online software application for randomising patients into clinical trials.
1. Data will be extracted and analysed and practices will receive practice level dashboards with 3 monthly feedback and behaviour modifications (nudging)
2. Data will be extracted and analysed and practices will receive practice and individual level dashboards with 3 monthly feedback and behaviour modifications (nudging)

If practices taking part in the frailty project wish to also take part in the antibiotic project, randomisation will depend on prior randomisation to the frailty project.

Those randomised into Arm 1 for the frailty project will continue in Arm 1 for the antibiotic project

Those randomised into Arm 2 will join other practices (who did not want to take part in the frailty project) into a further round of randomisation

3. Data will be extracted and analysed and practices will receive practice and individual level dashboards with 3 monthly feedback and behaviour modifications (nudging). Practices will also have a Knowledge support system integrated into their practice electronic health record to be activated in consultation.

Or they will remain in arm 2 and continue to receive practice and individual level feedback for both the frailty and the antibiotic studies.

Intervention Type
Other

Primary outcome(s)
Antibiotic sub-study:
The overall rate of antibiotic prescribing measured using electronic health records at baseline and 12 months

Frailty sub-study:
Prescribing rates in frail elderly measured using electronic health records at baseline and 12 months

Key secondary outcome(s))
Antibiotic sub-study:
1. Infection-related complications as recorded in the primary care records such as pneumonia and lower respiratory tract infections (RTIs), peritonsillar abscess, mastoiditis, intracranial abscess, empyema, scarlet fever, pyelonephritis, septic arthritis, osteomyelitis, meningitis, toxic shock syndrome and septicaemia, and Lemierre syndrome
2. Rate of hospital admission for infection-related complications

Both measured using electronic health records at baseline and 12 months

Completion date
30/10/2023

Eligibility

Key inclusion criteria
1. Any population of individuals whose data contribute to the Greater Manchester care record, Liverpool and Cheshire care record or the Yorkshire and Humber care record who have not opted out of secondary data use.
2. For the workshops/interviews/surveys any professional involved in the prescribing of antibiotics or providing guidance on such. The researchers will work with members of the public as a PPI activity with a core PPI group.

3. The intervention is applied at the practice level (this is also the legal entity for signing data sharing agreements with the data centres i.e. the data controller). Any general practice that has provided data to the data centres in the study with permission for secondary use or practice that consents to the use of data for research purposes is eligible to become a study site. When a general practice participates, this will imply that all their staff directly participate in the study and all their patients indirectly participate in the study.

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. The main exclusion criteria concern patients who have opted out of sharing their anonymised data for research. Their data will not be analysed.
2. The researchers will also not use any READ codes associated with data considered to be sensitive, such as sexually transmitted infections or infections following abortions

Date of first enrolment
01/04/2023

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

Study participating centre
All GP practices in the study area (North West UK)
United Kingdom
-

Study participating centre
South Chadderton Health Centre
Eaves Lane
Chadderton
United Kingdom
OL9 8RG

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Medical Research Council; Grant Codes: CFC0124

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR130581

Funder Name
Public Health England

Alternative Name(s)
PHE

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to Information Governance reasons and the signed Data Shared Agreements as patient-level or small-cell data cannot leave the Trusted Research Environment.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		22/08/2023	25/08/2023	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes