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Evaluating the effectiveness of a pharmacist-led IT-based intervention when widely implemented

Submission date
21/12/2020

Recruitment status
No longer recruiting

Registration date
11/03/2021

Overall study status
Completed

Last Edited
13/04/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
This study will evaluate the effectiveness and cost-effectiveness of a pharmacist-led IT-based intervention (PINCER) to reduce hazardous prescribing when widely implemented in general practices. The hypothesis is PINCER reduces exposure to hazardous prescribing, reduces the incidence of serious avoidable harm, and represents value for money for the NHS.

Who can participate?
Practices in the East Midlands who implemented PINCER as part of the Health Foundation Scaling Up PINCER project, between September 2015 and April 2017.

What does the study involve?
This study involves a single remote extraction of de-identified medical record data by PRIMIS, a health informatics service within the University of Nottingham who are specialists in the extraction of primary care data. The researchers plan to extract general practice data covering a period of up to 72 months from 28 February 2013 to 31 August 2019.

What are the possible benefits and risks of participating?
The GP practice involvement is to facilitate a single secure remote data extraction, for this the practices will be paid £120 to cover the costs of participating in the study. Any risks of data extraction have been minimised by only extracting deidentified patient data. Additionally, PRIMIS, a health informatics service within the University of Nottingham who are specialists in the extraction of primary care data, will use the 'Away From My Desk' software to 'dial into' the practice clinical system and run the queries on the practice clinical system MIQUEST interpreter and transfer the data output to a server hosted by the University of Nottingham.

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

When is the study starting and how long is it expected to run for?
July 2016 to April 2021

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

Who is the main contact?
Dr Amy Taylor
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
243026

Central Portfolio Management System (CPMS)
43153

Protocol serial number
sponsor ref: 19057

Study information

Scientific Title
Evaluating the effectiveness, and cost-effectiveness, of a pharmacist-led IT-based intervention (PINCER) when widely implemented in general practices to reduce the prevalence of patient exposure to hazardous prescribing, and the incidence of serious harm

Acronym
PRoTeCT

Study objectives

The PINCER intervention will reduce exposure to hazardous prescribing, reduce the incidence of serious harm, and represent value for money to the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/12/2019, East Midlands - Leicester Central Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8070, +44 (0)207 104 8107, +44 (0)207 104 8388; leicestercentral.rec@hra.nhs.uk, nrescommittee.eastmidlands-leicestercentral@nhs.net), REC ref: 19/EM/0283

Primary study design
Observational

Study design
Observational; Design type: Cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hazardous prescribing

Interventions
This is a multi-centre, primary care observational study utilising routinely recorded primary care data linked to other national datasets.
Up to 350 general practices known to the study team as previously participating in the Health Foundation Scaling Up PINCER project will be contacted by email and/or by post directly by a member of the research team. Practices will be provided with a covering email/letter about the study, a practice information sheet, organisation information document and a Remote Access Agreement, supplied by PRIMIS. Up to three follow-up telephone calls and/or emails will be sent.

Practices wishing to take part will complete the organisation information document and return the completed form to the research team.
The research team will confirm with PRIMIS that the practice has agreed to participate and will provide a copy of the organisation information document. The study team (or PRIMIS) will contact the practice to conduct the remote data extraction as per their data extraction protocol. This process includes digitally signing the Remote Access Agreement for the extraction. De-identified routinely recorded data will be collected from general practice clinical systems (TPP SystmOne and EMIS) by Primary Care Information Systems (PRIMIS) using Morbidity Information and Query Export Syntax (MIQUEST) software. The data searches have been designed to ensure that 1) no patient-identifiable data are extracted, and 2) no data are extracted on patients with a computer code in their clinical records indicating that they do not wish for their medical records to be used for research or secondary purposes. The de-identified data will be transferred by Secure File Transfer Protocol to secure computer servers at the University of Nottingham. Named staff in the PRIMIS team will undertake initial processing of the data. It will then be further processed by named staff within the Advanced Data Analysis Centre (ADAC) at the University of Nottingham so that it is in a format suitable for statistical analysis. The de-identified datasets, held on secure servers at the University of Nottingham, will then be made

available to named members of the research teams at the University of Nottingham and University of Manchester for statistical analysis. If any data are transferred to the University of Manchester, they will be transferred securely and will continue to be stored on secure local University servers. The Universities will not hold any personal identifiable data of patients at any time, but will hold contact details for participating general practices.

Intervention Type
Other

Primary outcome(s)
The number and proportion of patients in each general practice exposed to at least one type of hazardous prescribing; the deidentified data for all outcome measures will be extracted from routinely recorded primary care data for a maximum of 27 audit dates over a 78-month period (28/02/2013 to 31/08/2019) and analysed quarterly.

Key secondary outcome(s)
The number and proportion of patients within each general practice:
1. With 11 specific types of hazardous prescribing
2. With serious harm (composite measure), and the following types of serious harm (associated with particular types of hazardous prescribing):
2.1. Gastrointestinal bleeding
2.2. Exacerbation of asthma
2.3. Heart failure
2.4. Stroke
2.5. Acute kidney injury
3. With a hospital admission
4. With death
5. Exposed to specific types of hazardous prescribing
The deidentified data for all outcome measures will be extracted from routinely recorded primary care data extracted for a maximum of 27 audit dates over a 78-month period (28/02 /2013 to 31/08/2019) and analysed quarterly.

Completion date
30/04/2021

Eligibility

Key inclusion criteria
Inclusion criteria for general practices:
1. Agree to take part and sign the organisation information document
2. Practices within the East Midlands who have taken part in the Health Foundation Scaling Up PINCER project

Inclusion criteria for patients:
1. All patients in the general practices taking part in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
115

Key exclusion criteria
Exclusion criteria for general practices:
1. Practices who have not taken part in the Health Foundation Scaling Up PINCER project

Exclusion criteria for patients:
2. Patients with a computer code in their clinical records indicating that they do not wish for their medical records to be used for research or secondary purposes

Date of first enrolment
08/09/2020

Date of final enrolment
18/03/2021

Locations

Countries of recruitment
United Kingdom

Study participating centre
Invitation only to 331 practices across East Midlands – Nottinghamshire, Leicestershire and Derbyshire. Practices identified for invite were originally one of c350 practices in the East Midlands that participated in the Health Foundation Scaling Up PINCER project, a pharmacist-led IT-based intervention to reduce hazardous prescribing.
United Kingdom
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Sponsor information

Organisation
University of Nottingham

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-1214-20012

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 confidentiality for the GP practices involved. They are stored at the secure data storage facility at the University of Nottingham. Only data with anonymised patient IDs will be stored.

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes