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The PINCER trial: a cluster randomised trial comparing the effectiveness of a pharmacist led IT intervention with simple feedback in reducing rates of clinically important errors in medicines management in general practices

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Registration date 04/01/2007	**Overall study status** Completed	
Last Edited 11/01/2018	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pincertrial.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PS 024

Study information

Scientific Title
The PINCER trial: a cluster randomised trial comparing the effectiveness of a pharmacist led IT intervention with simple feedback in reducing rates of clinically important errors in medicines management in general practices

Acronym
PINCER Trial

Study objectives
Principal research questions:
1. Is a pharmacist-led Information Technology (IT)-based intervention using educational outreach and practical support more effective than simple feedback in reducing rates of clinically important errors in medicines management in general practice?
2. What are the costs and benefits of the pharmacist-led intervention compared with simple feedback?
3. What are the views and experiences of health care professionals and NHS managers concerning the intervention, and what are the possible reasons why the interventions might be more effective in some practices than others?

Study hypotheses:
1. Pharmacist-led interventions will result in more than a 50% reduction in error rates for our primary outcome measures.
2. Simple feedback will result in no more than an 11% reduction in error rates (this is the 75% centile for change as a result of simple feedback in a Cochrane systematic review).
3. Benefits in error reduction in the pharmacist treatment arm will be sustained at 12 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was given a favourable ethical opinion by Nottingham Research Ethics Committee 2 at the meeting held on 28 February 2005 (REC reference number: 05/Q2404/26).

Study design
Cluster randomised controlled trial.

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Instances of potentially hazardous prescribing in general practice

Interventions
Practices will be stratified by centre (Manchester or Nottingham) and size of practice. They will then be randomly allocated within strata to either the pharmacist intervention arm of the study or simple feedback.
All practices, irrespective of study arm, will be provided with computer-generated feedback (using Quest Browser software) on specific patients who are exposed to potentially hazardous prescribing and therefore at risk of morbidity.

In the "simple feedback" arm of the trial, practices will receive the computerised feedback along with brief written educational materials explaining the potential importance of the "problems" detected. They will be asked to try to make any changes to patients' medications within 12 weeks.

In the "pharmacist intervention" arm of the trial, an NHS-employed pharmacist will work part-time with each practice over a 12 week period. The pharmacist will arrange an initial meeting with members of the practice team to discuss the computer-generated feedback. They will take an "educational outreach" approach to explain the importance of the "problems" detected. Where appropriate they will employ the principles of root cause analysis to identify the underlying reasons for hazardous prescribing. The pharmacist will then work with the practice team to agree on the best way forward for addressing the problems identified and preventing their recurrence. The pharmacist will keep an anonymised record of the actions taken to correct hazardous prescribing or reasons given for not taking actions.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The proportion of patients in each practice:
1. Aged 18 years and older with a computer-recorded history of peptic ulcer being prescribed non-selective Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) in the previous six months without receiving drugs to protect against further peptic ulcer
2. Aged 18 years and older with a computer-recorded diagnosis of asthma being prescribed beta-blockers in the previous six months

3, Aged 75 years and older receiving long-term prescriptions for Angiotensin Converting Enzyme (ACE) inhibitors or loop diuretics without a recorded assessment of renal function and electrolytes in the previous 15 months

The proportions of "at risk" patients in each treatment arm with the errors of interest will be compared between treatment arms at six and 12 months after the end of the intervention period in each practice (the primary analysis will be undertaken using the six-month follow-up data).

Secondary outcome measures
Secondary outcome measures relate to a range of potential problems in the prescribing and monitoring of the following drugs:
1. Combined hormonal contraceptives
2. Warfarin
3. Lithium
4. Methotrexate
5. Amiodarone

The proportions of "at risk" patients in each treatment arm with the errors of interest will be compared between treatment arms at six and 12 months after the end of the intervention period in each practice (the primary analysis will be undertaken using the six-month follow-up data).

Overall study start date
01/04/2006

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. NHS general practices within a 50 mile radius of Manchester and Nottingham in England
2. Practices within Primary Care Trusts (PCTs) that agree to be involved in the study
3. Practices that have been laboratory-linked (or have other reliable systems for recording blood test results on the practice computer system) for at least 15 months prior to the time of baseline data collection
4. Practices that agree to participate in the study

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
68 general practices

Key exclusion criteria
1. Practices that state they do not routinely record morbidity such as asthma or peptic ulcer on the computer
2. Practices that do not use their computers to record prescriptions
3. Practices intending to change their General Practice (GP) computer systems to that of a different supplier which is not Quest Browser compatible during the course of the study
4. Practices in PCTs that are undertaking interventions that might overlap with our intervention
5. Practices that were involved in our pilot study
6. Practices that do not agree to the installation of Quest Browser software on their practice computers (this software is essential for generating patient-specific data on patients with medication errors)
7. Practices that expect major changes in list size during the course of the study, either because of the splitting up of the practice, merger with other practices or any other reason for a large influx or loss of patients

Date of first enrolment
01/04/2006

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Division of Primary Care
Nottingham
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NG7 2UH

Sponsor information

Organisation
Patient Safety Research Programme of the Department of Health (UK)

Sponsor details
c/o Mrs Jo Foster
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Sponsor type
Government

Website
http://www.pcpoh.bham.ac.uk/publichealth/psrp/

ROR
https://ror.org/03n0qh685

Funder(s)

Funder type
Government

Funder Name
Department of Health (Leeds), part of Patient Safety Research Programme (funding reference number: PS/024).

Funder Name
Nottingham Primary Care Research Partnership NHS R&D Support Funding (funding reference number: 2006/07).

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/05/2009		Yes	No

Results article	results	07/04/2012	Yes	No