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Testing of a new community pharmacy service to help older patients who live in their own homes and who are prescribed several medicines

Submission date
25/11/2016

Recruitment status
No longer recruiting

Registration date
01/12/2016

Overall study status
Completed

Last Edited
09/08/2018

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
Older patients (aged 65 years or older) often have to take many medicines to treat several long-term medical conditions. This can include taking medicines in a range of different forms (e.g. tablets, inhalers, patches) and at different times throughout the day. Previous research has shown that these factors can make it difficult for older patients to take medicines as prescribed by their General Practitioner (GP). Patients who have difficulty taking their medications as recommended and agreed with their GP are described as non-adherent and older patients may be at increased risk of this. Non-adherence can lead to poorer control of medical conditions for patients, increased hospital and GP visits and increases in healthcare costs. A number of studies have previously tried to improve non-adherence in older patients but these generally showed only limited benefits. Previous approaches have often been developed based on what researchers think might work well, rather than being developed in a logical manner, taking into consideration the views and opinions of patients and trying to change behaviour. To overcome the limitations of previous research, a new approach to tackle non-adherence to medicines has been developed in line with current recommendations. This involved using the latest published evidence, asking patients about the problems they faced when taking many medicines, what helped them overcome those problems, and then considering the best ways that might help improve adherence. This approach was used to select the best solutions that might help patients. The aim of this study is to test these solutions as part of a new approach (intervention) to improve adherence to medicines.

Who can participate?
Patients aged 65 or older who take four or more regular medications

What does the study involve?
The intervention has been developed to be used in the community pharmacy by trained pharmacists over a period of 12 months. Patients are asked to attend three (30-40 minutes) appointments in the pharmacy from which they normally collect their medicines. Patients are

asked about any difficulties they experience when taking several medicines (Appointment 1) and together, the patient and pharmacist choose the best solutions to help overcome any difficulties (Appointment 2). For example, patients are offered a medication diary to record when they have taken their medicines. This diary also includes a list of the patient's regular medicines, instructions on when and how to take each medicine and the reasons why medicines have been prescribed. After four weeks, the pharmacist and patient then review whether the recommended solutions have been helpful (Appointment 3). The findings show how these solutions might work in practice and whether this type of intervention is acceptable and useful for both patients and community pharmacists. This study also aims to find out if study procedures (e.g. asking patients to take part, collecting information) work well or what would be done to improve these. The research team also review all the paperwork completed by pharmacists during the study and ask for feedback on the intervention from patients and pharmacists during telephone and face-to-face interviews, respectively. Together, this information will determine whether this new approach can be used in community pharmacies as intended.

What are the possible benefits and risks of participating?
Participation in this study may be beneficial for both pharmacists and patients, as it will help to determine whether the intervention needs to be changed before further tests can be undertaken. In the long term, it is hoped that this type of intervention will lead to improvements in medication adherence, reduce GP visits and hospitalisations and lead to improvements in older people's quality of life. Due to the nature of the study, the risk of harm to participants is considered to be low. However, it is possible that discussions between the pharmacist and patient may prompt the patient to think of upsetting or distressing aspects of their medical conditions. This risk will be minimised by having a study information sheet that clearly outlines what will happen at each appointment. The appointments will also be held in the community pharmacy that the patient normally attends and the intervention will be delivered by a pharmacist with whom the patient is likely to be familiar. There is a low risk that we may identify poor practice by healthcare professionals during the study. In the unlikely event that poor practice is identified by the researcher, then the case will be reported to the Chief Investigator who will, in the first instance, refer the case to the healthcare professional(s) involved and if necessary, the case will be reported to the appropriate regulatory authority. The procedure for disclosing cases of poor practice will be outlined in the study information sheets received by all participants.

Where is the study run from?
Queen's University Belfast (UK)

When is the study starting and how long is it expected to run for?
March 2016 to March 2017

Who is funding the study?
Harold and Marjorie Moss Charitable Trust Fund (UK)

Who is the main contact?
Prof. Carmel Hughes

Contact information

Type(s)
Scientific

Contact name
Prof Carmel Hughes

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 3.0

Study information

Scientific Title
Feasibility testing of the ID-MAP (IDentification of Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

Acronym
ID-MAP (IDentification of Medication Adherence Problems)

Study objectives
The overall aim of this project is to test the feasibility of a complex theory-based intervention delivered by community pharmacists to improve adherence to polypharmacy in older adults in the community pharmacy setting. The intervention has been developed in line with the United Kingdom (UK) Medical Research Council's (MRC's) guidance for 'developing and evaluating complex interventions'.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee (REC) A, 04/03/2016, ref: 16/NI/0028

Study design
Non-randomised feasibility study in two community pharmacy sites

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Non-adherence to polypharmacy in older adults

Interventions
The intervention will be delivered to non-adherent older adults by a trained community pharmacist over three (30-40 minute) appointments held within the community pharmacy. At Appointment 1, the pharmacist will ask the patient questions using an adherence assessment tool. This tool has been specifically designed by the research team to assist pharmacists in identifying the nature of adherence problems. Once adherence problems have been identified and discussed with the patient, the pharmacist will conclude the appointment and schedule a second appointment to take place in 1-2 weeks.

During Appointment 2, the pharmacist will recommend or provide potential adherence solutions. These adherence solutions stem from the field of psychology and are known as ‘Behaviour Change Techniques (BCTs)’. For example, patients will be asked to monitor their medication-taking behaviour for a four week period using a personalised medication diary (BCT: ‘Self-monitoring of the behaviour’). This diary will also include an accurate list of the patient’s prescribed medications. Other 'optional' adherence solutions will be delivered based on the patient’s individual needs. For example, a patient who decides not to use their preventer inhaler for asthma everyday will be informed of the potential health consequences, such as an increased risk of an asthma attack (BCT: ‘Information about health consequences’). Once all required adherence solutions have been delivered or recommended, the pharmacist will conclude the appointment and schedule a third appointment, to take place after at least four weeks.

At Appointment 3, the pharmacist will review the adherence solutions, e.g. they will review the patient’s medication diary and provide feedback on the patient’s current adherence behaviour (BCT: ‘Feedback on behaviour’). The pharmacist will find out how the patient managed with any other adherence solutions that were recommended and make further recommendations, if necessary. The patient will be informed that this is the last official appointment with the pharmacist, but that they can contact them at any time in the future for further information on their medications.

Intervention Type
Behavioural

Primary outcome measure
1. Usability and acceptability of the intervention from the viewpoint of community pharmacists using qualitative face-to-face interviews conducted following the completion of all patient appointments

2. Usability and acceptability of the intervention from the viewpoint of older patients using qualitative telephone interviews conducted after the patient has attended their final intervention appointment

Secondary outcome measures
1. Feasibility of the screening strategy (i.e. inclusion and exclusion criteria), recruitment strategy and willingness of participants to be recruited, assessed based on the numbers approached and those who are subsequently recruited
2. Feasibility of data collection procedures, assessed by collecting data on self-reported adherence and health-related quality of life via validated questionnaires, and collecting data from pharmacy-held Patient Medication Records to calculate objective measures of medication adherence such as Medication Possession Ratios
3. Fidelity to the intervention, assessed by examining materials (e.g. appointment check lists, summary notes) completed by pharmacists during the study. Pharmacists and patients are also asked about the delivery and receipt of components of the intervention, during qualitative feedback interviews

Overall study start date
05/03/2016

Completion date
07/04/2017

Eligibility

Key inclusion criteria
Community pharmacist participants:
1. Located in Northern Ireland
2. At least one pharmacist (maximum 2) willing to take part in the study and provide written informed consent
3. Access to a private consultation room/area
4. Access to printing facilities

Patient participants:
1. Aged 65 years or older
2. Prescribed four or more regular medications (excluding medications prescribed to be taken only when required or medicines purchased over-the-counter)
3. Living in their own home
4. Have at least six months of dispensing data available from the time of screening (on the pharmacy-held Patient Medication Record)
5. Only attend the study site pharmacy for regular medications
6. Have an identified adherence problem (detected using self-report adherence questionnaire)

Participant type(s)
Mixed

Age group
Senior

Sex
Both

Target number of participants
Community pharmacists: n=2-4 (max. 2 per community pharmacy site); Patients: n=10 (target= 5 per community pharmacy site)

Key exclusion criteria
Community pharmacist participants:
1. Not meeting the inclusion criteria
2. Not proving written informed consent

Patient participants:
1. Not meeting the inclusion criteria
2. Not providing written informed consent
3. Prescribed medications for the treatment or management of dementia (e.g. donepezil, galantamine, rivastigmine or memantine)
4. Unable to complete the Eligibility Screening Questionnaire
5. Has high adherence (as detected using self-report adherence questionnaire)

Date of first enrolment
18/03/2016

Date of final enrolment
07/11/2016

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Queen's University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
United Kingdom
BT9 7BL

Sponsor information

Organisation
Queen's University Belfast

Sponsor details

Research and Enterprise Office
University Road
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BT7 1NN

Sponsor type
University/education

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Charity

Funder Name
Harold and Marjorie Moss Charitable Trust Fund (Pharmacy PhD Research Award)

Results and Publications

Publication and dissemination plan
The plan is to publish the findings of the feasibility study once results become available. The findings will also be presented at appropriate conferences.

Intention to publish date
01/02/2019

Individual participant data (IPD) sharing plan
Participant level data will not be reported for this small-scale feasibility study (n=10 patient participants) as they are considered to be of little significance on their own. Results with be grouped and reported together in any research publications. Hardcopy data will be stored in a locked fire-resistant cabinet in the School of Pharmacy at Queen's University Belfast. Electronic data will be stored on a password protected laptop computer. The hardcopy and electronic data will be securely held for a period of five years before being destroyed.

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