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Developing a way of improving how medicines are managed by community pharmacists for people with memory problems who live in their own home

Submission date
18/06/2018

Recruitment status
No longer recruiting

Registration date
07/08/2018

Overall study status
Completed

Last Edited
07/08/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
People with memory problems often have to take many different medicines at various times during the day. Research has shown that people may find it difficult to manage the medicines that have been prescribed by their General Practitioner (GP). Carers or family members are known to help people with their medicines. However, without the support of healthcare professionals, carers may find it hard to maintain the complicated medicine routines that are typical of many people with memory problems. There has been limited research on approaches that can be taken to help people to manage their medicines better, particularly people who are living at home. It is important that more studies are conducted in this area as successful medicines management for people with memory problems could have a number of benefits, including improvements in quality of life. As part of this study, a new approach (intervention) has been developed to help people with memory problems to manage their medicines better.

Who can participate?
People with memory problems who are living in their own homes and are taking four or more medicines every day. They must also have a carer or family member who they have contact with at least three times a week and who helps them with their medicines.

What does the study involve?
The intervention will be delivered in two community pharmacies by trained pharmacists. Patients with memory problems who collect their medicines from one of the participating pharmacies will be asked to attend a medicine review appointment with the pharmacist. Their carer or family member will go with them. At the start of the appointment, the patient and their carer will both complete some surveys. The carer will complete surveys that will ask them about their experiences of looking after the person they care for as well as symptoms that the person may experience and their quality of life. The patient will complete surveys that ask them about taking their medicines, their quality of life, and looking after their health. Once the surveys are complete, there will be discussion around the patient's medicines and whether they are getting

the best from them. For example, the pharmacist might check that the patient still needs all the medicines they are taking and may ask the patient if they are having problems with any of their medicines. After the appointment, the pharmacist will send a letter to the patient's GP along with a form that will summarise what was discussed. Pharmacists cannot make changes to a patient's prescription but they might suggest some changes that the GP could make to the patient's medicines if they feel it is appropriate.

This study is being conducted to find out if this new approach works in practice. In order to do this, face-to-face interviews will be conducted with patients, their carers and pharmacists to find out about their experiences of taking part and to see if they have any suggestions on how the intervention (new approach) could be improved. The results of these interviews will be reviewed to find out if this type of intervention is acceptable and useful for patients, their carers and pharmacists. In order to find out if there has been any change to patients' medicines following the appointment at the pharmacy, pharmacists will be asked to provide information from patients' pharmacy medication records (e.g. details of their regular medicines) to the researchers. This information will be provided with patients' consent. Information about medicines will be taken from patients' medication records at baseline (date of medication review) and at one month after the review. Finally, this study also aims to find out if study procedures work well (e.g. approaching patients to take part, completing the surveys).

What are the possible benefits and risks of participating?
Participation in this study could be beneficial for pharmacists, patients and their carers. First, taking part will help to show if this new approach needs to be adjusted before further testing can be done to assess if it is effective in improving medicines management for people with memory problems. In the longer term, it is hoped that this type of approach will lead to reductions in inappropriate medicines, better medication adherence, and improvements in quality of life for people with memory problems and the people who help them with their medicines. In addition, this study will also contribute to the development of the evidence base regarding the role of pharmacists in the care of people with memory problems.

Due to the nature of the study, there is little risk associated with taking part. However, there is a potential risk that patients or their carers may become upset or distressed when talking about the patient's medicines and the condition(s) for which they take them. This risk will be minimised by providing participants with a study information sheet that clearly outlines what will happen during the medication review appointment and during the follow-up interview with the researcher. In addition, the medication review will be conducted by the patient's local pharmacist at the community pharmacy they normally attend, so they will be in a familiar environment. A further potential risk is that participants may reveal information that may suggest poor practice by healthcare professionals. A procedure has been outlined within the study protocol that any such cases will be referred to the Chief Investigator, who may refer to the appropriate regulatory authority if necessary. The procedure for disclosing cases of poor practice has been 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?
November 2017 to October 2018

Who is funding the study?
The HSC Public Health Agency R&D Office (Dementia Care Research Call) and The Atlantic Philanthropies

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A feasibility study of an intervention to improve medicines management for persons with dementia in primary care in Northern Ireland

Study objectives
It is hypothesised that a model of medicines management for patients with dementia will be produced following feasibility testing in two community pharmacies. The results from the feasibility study will enable us to judge if we should progress to further pilot testing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Office for Research Ethics Committees Northern Ireland, 08/06/2018, 18/NI/0100

Study design
Single-centre feasibility study

Primary study design
Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied
Mild-to-moderate dementia

Interventions
This intervention is for community-dwelling patients with memory problems in Northern Ireland and will be held within a community pharmacy. The intervention consists of two parts, which are completed sequentially:
1. The community pharmacist will watch a video demonstrating how to conduct a medication review and check adherence with a person with memory problems and their carer or family member. There is also a complementary quick reference guide for pharmacists to refer to. This guide contains information on combinations of drugs that may not be safe together and examples of issues that can be resolved quickly. There is also a list of resources should the pharmacist wish to obtain further information.
2. Once the pharmacist has watched the video and read the quick reference guide, they will recruit five patients with memory problems and their carers (patient/carer dyads) and schedule a medication review and adherence check with them. Following the review, the pharmacist will complete a clinical record form and communicate any recommended medication changes to the patient's GP.
The acceptability of the intervention to community pharmacists, patients and their carers will be assessed through semi-structured interviews. In addition, data will be collected on medication appropriateness, psychotropic drug use, clinically significant drug interactions, adherence, anticholinergic burden, quality of life, behavioural and psychological symptoms of dementia and treatment burden. These data will be collected on the day of the review appointment (baseline) and at 4 weeks after the review.

Intervention Type
Behavioural

Primary outcome(s)
1. The usability and acceptability of the intervention will be assessed through qualitative face-to-face interviews with pharmacists, patients and their carers. These interviews will enable us to find out about their experiences of taking part as well as identifying any ways in which the intervention could be improved. Interviews with pharmacists will take place 2 weeks after all medication reviews are completed with recruited patients and carers. Interviews with patients and their carers will be conducted 2 weeks after they have attended the medication review and adherence check.
2. The feasibility of recruitment procedures will be assessed by collecting the following data throughout the course of study, and final calculations which will be conducted at the end of the study:
2.1.The number of pharmacists approached, recruited and consented
2.2.The number of patients/carers screened, approached, recruited and consented
2.3. Patient retention rates.

Key secondary outcome(s))
1. Feasibility of data collection procedures will be assessed by collecting data via questionnaires on the patient's ability to take their prescribed medications, quality of life, behavioural and psychological symptoms of dementia and treatment burden. This data will be collected on the day that the patient and
carer attend the review appointment and again, 4 weeks after the review has taken place.

2. The appropriateness of the medicines that the patient is prescribed will be assessed using data from pharmacy-held Patient Medication Records

Completion date
31/10/2018

Eligibility

Key inclusion criteria
Community pharmacist participants:
1. Located in Northern Ireland
2. Access to a private consultation room

Patient participants:
1. A formal diagnosis of mild-to-moderate dementia (confirmed by their GP)
2. Prescribed four or more regular medications (excluding medications prescribed to be taken or used only when required)
3. Have at least 12 months' dispensing data available on the pharmacy patient medication record from the time of screening
4. Live in their own home
5. Have a carer

Carer participants:
1. Have contact with the patient at least three times a week
2. Assist the patient with their medicines

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Those who cannot provide written informed consent

Date of first enrolment
12/06/2018

Date of final enrolment
10/08/2018

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Study participating centre
Queen’s University Belfast
School of Pharmacy
97 Lisburn Road
Belfast
BY9 7BL
United Kingdom
United Kingdom
BT9 7BL

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Not defined

Funder Name
HSC Public Health Agency Dementia Care Research Call

Funder Name
The Atlantic Philanthropies

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available as this study is a small-scale feasibility study and participant level data (10 patients in

total) are considered to be of little significance on their own. Results will 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. Only members of the research team will have access to this data. The hardcopy and electronic data will be stored securely for a period of 5 years before being destroyed. This is in line with the General Data Protection Regulation.

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
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