

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

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| Submission date 18/06/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 07/08/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| Last Edited 07/08/2018 | Condition category Nervous System Diseases | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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?
Professor Carmel Hughes
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Study website

<https://thecomparestudy.weebly.com/>

Contact information

Type(s)

Scientific

Contact name

Prof Carmel Hughes

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design

Single-centre feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Other

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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

Overall study start date

01/11/2017

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

Age group

Mixed

Sex

Both

Target number of participants

10 patient/carer dyads (five from each participating community pharmacy)

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

Northern Ireland

United Kingdom

Study participating centre

Queen's University Belfast

School of Pharmacy

97 Lisburn Road

Belfast

BT9 7BL

United Kingdom

United Kingdom

BT9 7BL

Sponsor information

Organisation

Queen's University Belfast

Sponsor details

Research and Enterprise Office

University Road

Belfast
Northern Ireland
United Kingdom
BT9 1NF

Sponsor type

University/education

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

Publication and dissemination plan

A final report will be prepared for the funder and the Office for Research Ethics Committees Northern Ireland. A manuscript will be written outlining the findings from this feasibility study, which will be submitted to a peer-reviewed journal for publication.

Intention to publish date

31/10/2019

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 |