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Pilot testing of a new service designed to improve the use of multiple medications by older people who are living at home in the community setting

Submission date
12/01/2018

Recruitment status
No longer recruiting

Registration date
05/02/2018

Overall study status
Completed

Last Edited
12/01/2021

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study tests a new service that aims to help older patients (aged 65 or older) living in Northern Ireland and London (England) who are prescribed several medicines. This service will be delivered in community pharmacies, by trained pharmacists. To develop this service focus group discussions were held with older patients and testing was done on how the service could work in a small study at two pharmacies and with ten patients in total. This helped identify how to improve the service for both older patients and pharmacists and some changes were made to refine the service. There are still some aspects that the researchers are not certain about (for example, how best to identify older people who could benefit from this new service) and so the aim of this study is to test the refined service in a larger group of pharmacies and patients.

Who can participate?
Patients aged 65 or older who are prescribed four or more regular medications and who have a medication adherence problem

What does the study involve?
The study involves pharmacists delivering the refined service to older patients. The previous study found that recommending a set number of sessions with a pharmacist was not ideal for this group of patients. Therefore, the number of sessions with a pharmacist that each patient attends is matched to each patient's own needs (maximum of four sessions in the pharmacy). During these sessions patients are asked about any difficulties they experience when taking several medicines. In a new approach, the pharmacist uses a handheld electronic device (an iPad) to guide these sessions and record recommendations made. Together, the patient and pharmacist choose the best solutions to help overcome any difficulties.

What are the possible benefits and risks of participating?
This study will show whether the refined service works in a larger group of people and a larger number of pharmacies. This study will also help the researchers to decide whether they should

proceed to a larger study to explore if this service is better than usual care in community pharmacies. In the long-term, it is hoped that this type of service will lead to improvements in how patients take (or use) their medication and ultimately reduce the number of unplanned visits to hospital and lead to improvements in older people's quality of life. Due to the type 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 lead the patient to think of upsetting or distressing aspects of their medical conditions. This risk will be lessened by having a study information sheet that clearly outlines what will happen during the service. The sessions will also be held in the community pharmacy that the patient normally attends and the service 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 (e.g. pharmacists, general practitioners) during the study. In the unlikely event that poor practice is identified by the researcher, then the case will be reported to the Principal Investigator who will, in the first instance, contact the healthcare professional(s) involved and if necessary, the case will be reported to the appropriate regulatory body. 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?
1. Queen's University Belfast (UK)
2. City University of London (UK)

When is the study starting and how long is it expected to run for?
December 2017 to May 2020

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
Prof. Carmel Hughes

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

N/A

Protocol serial number
Version 2.0

Study information

Scientific Title
A pilot study of the S-MAP (Solutions for Medication Adherence Problems) intervention in older adults prescribed polypharmacy in primary care

Acronym
S-MAP (Solutions Medication Adherence Problems)

Study objectives
The overall aim of this study is to pilot test a complex theory-based medication adherence intervention for older patients that has been developed in line with the United Kingdom (UK) Medical Research Council's (MRC's) guidance for 'Developing and evaluating complex interventions'. The intervention (previously known as the ID-MAP intervention) has undergone initial feasibility testing in two community pharmacies in Northern Ireland (10 patients in total) (https://www.isrctn.com/ISRCTN17966504). Modifications have been made to the intervention, pharmacist training and study procedures based on the feasibility study findings. The intervention name has also been amended from 'ID-MAP (Identification of Medication Adherence Problems) intervention' to 'S-MAP (Solutions for Medication Adherence Problems) intervention' based on feedback received. It was agreed that the name change better reflects that the intervention goes beyond simply identifying adherence problems and instead, has a major focus on providing tailored (i.e. personalised) solutions for each individual patient. The findings from this study will establish whether to proceed to a definitive cluster-randomised controlled trial (c-RCT) to explore the effectiveness of the S-MAP intervention in comparison with usual care in community pharmacies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Health and Social Care Research Ethics Committee (REC) B, 30/10/2017, REC ref: 17/NI/0193

Study design
Non-randomised multi-centre pilot study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Non-adherence to multiple medications (i.e. polypharmacy) in older adults

Interventions

The S-MAP intervention will be targeted at older patients aged 65 years or older who are prescribed multiple medications (polypharmacy) to improve their adherence to agreed recommendations. In the current pilot study the intervention will be delivered to older patients by trained pharmacists. Pharmacists will be recruited from 12 community pharmacies in the United Kingdom (UK); 6 community pharmacies in England (greater London area) and 6 community pharmacies in Northern Ireland. Pharmacist training, developed in conjunction with experts in health psychology, will consist of an interactive workshop (including role play elements and demonstrations) to equip pharmacists with the skills and knowledge required to deliver the S-MAP intervention in practice. Each pharmacy will be instructed to recruit 10 patient participants (120 patients in total).

The S-MAP intervention is a 'personalised' intervention whereby the content will be tailored to the individual needs of each patient. The intervention has been developed in line with the MRC Framework for complex interventions using the latest available evidence, psychological theory and feedback from both patients and pharmacists. The intervention will be targeted at patients who are identified as non-adherent (identified via a short validated self-report questionnaire). All non-adherent patients will be invited to attend an initial face-to-face adherence assessment in their usual community pharmacy. The assessment will be completed by pharmacists and guided by a novel computer-based decision support tool (application that will be available on provided iPads). Based on the findings from the adherence assessment, the pharmacist and patient will collaboratively select strategies to try and address any challenges faced by the patient with the aim of improving their adherence and health outcomes.

The S-MAP intervention package consists of a range of strategies which stem from the field of health psychology incorporating behaviour change techniques. These techniques were selected based on previous qualitative research that was carried out with older patients. This research identified a wide range of factors that older patients deemed to be important influences on their medication adherence behaviours (e.g. forgetfulness, support from others, routine, beliefs about medications). Using established methods, these important influences were then linked to techniques that could be included in the intervention to improve adherence. Techniques include self-monitoring of medication use behaviour via a daily medication diary, feedback on the behaviour, social support from others, prompts/cues (such as setting medications in a highly visible location), action planning and goal setting exercises, physical/practical changes (e.g. alternative packaging, reducing the complexity of the regimen) and providing information on the health consequences of non-adherence. In the SMAP intervention these techniques will be tailored to the needs of each patient based on the adherence assessment carried out at the first session in the pharmacy.

The prior feasibility study also identified that as well as tailoring the types of adherence support required by each patient, the number of sessions also requires individual-level tailoring. The intervention will therefore be delivered over a minimum of two face-to-face sessions in the pharmacy along with a follow-up telephone call and a maximum of four face-to-face sessions. Support sessions will take place over a period of three to four months. At each session the patient's adherence and any previously identified barriers/challenges will be re-assessed by the pharmacist to identify if the patient could benefit from further support sessions. Decisions regarding tailoring of the number of sessions (as well as the intervention content) will be guided by the computer-based decision support tool (iPad application) to ensure consistency and replicability.

Analysis in relation to the outcome measures in this study (medication adherence, health-related quality of life and unplanned hospital admissions) will be largely descriptive as the trialists are not seeking to assess effectiveness of the intervention at this pilot phase of testing. The current

study will also test the practicality of involving pharmacy support staff who will be trained in key research procedures such as patient eligibility screening and data collection procedures. A process evaluation will be embedded in the study to (a) assess if the intervention was delivered by pharmacists and received by patients as intended (i.e. intervention fidelity) and b) identify the most likely potent components of this complex intervention (i.e. the potential mechanism of action of the intervention).

Intervention Type
Behavioural

Primary outcome(s)
Medication adherence, measured using the following two approaches:
1. Refill/dispensing data (objective): patient records held in the community pharmacy will provide details of medications dispensed in the 12 months pre-baseline and 12 months post-baseline (i.e. pre-session 1). These data will be used to calculate the Medication Possession Ratio (MPR) and Daily Polypharmacy Possession Ratio (DPPR).
2. Self-report (subjective): adherence will be measured using two validated measures (Medication Adherence Rating Scale- 5 item (MARS-5) and a 1-item self-rating of ability scale developed by Lu et al.) at baseline (eligibility screening stage), 6 months post-baseline and 12 months post-baseline.

Key secondary outcome(s))
1. Health-related quality of life (HRQOL) measured via self-report using the EQ-5D-5L at baseline (pre-session 1) and 6 and 12 months from baseline
2. Unplanned hospitalisations (resulting in an overnight stay in hospital) in the previous six months measured via self-report at baseline (pre-session 1) and 6 and 12 months from baseline. The feasibility of collecting data from GP surgeries on unplanned hospitalisations to verify self-report data

Completion date
31/05/2020

Eligibility

Key inclusion criteria
Community pharmacist participants:
1. Must be registered as a pharmacist with the Pharmaceutical Society of Northern Ireland or The General Pharmaceutical Council
2. The pharmacist must be employed and regularly work at the study pharmacy site (i.e. not a locum pharmacist)
3. The pharmacy in which they work must a registered pharmacy located in Northern Ireland or greater London area (England)
4. The pharmacy in which they work must have a private consultation room/area, access to WiFi internet and printing facilities

Pharmacy support staff participants:
1. Pharmacy support staff involved in the study must have completed an accredited Medicines Counter Assistant course or equivalent (as a minimum)

Patient participants:
1. Aged 65 years or older

2. Prescribed four or more regular medications (excluding medications prescribed to be taken only when required)
3. Living in their own home
4. Have at least 12 months of dispensing data available from the time of eligibility 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 a validated self-report adherence questionnaire)

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
75

Key exclusion criteria
Community pharmacists:
1. Not meeting the eligibility criteria
2. Not providing written informed consent
3. Previous participation in the feasibility study (conducted only in Northern Ireland; ISRCTN17966504)

Pharmacy support staff:
1. Not meeting the eligibility criteria
2. Not providing written informed consent

Patient participants:
1. Not meeting the eligibility 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 self-report adherence screening questionnaire

Date of first enrolment
01/06/2018

Date of final enrolment
31/07/2019

Locations

Countries of recruitment
United Kingdom

England

Northern Ireland

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

Study participating centre
City University of London
School of Health Sciences
Northampton Square
London
United Kingdom
EC1V 0HB

Sponsor information

Organisation
Queen's University Belfast

ROR
https://ror.org/00hswnk62

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Participant level data will not be reported for this non-randomised pilot study which focuses on exploring the practical aspects of the intervention and does not seek to assess effectiveness. Results with be grouped and reported together in any research publications solely to provide a descriptive overview of the findings. The sharing of individual participant level data for this type of study would provide limited additional information. Hardcopy data will be stored in a locked fire-resistant cabinet in the School of Pharmacy at Queen's University Belfast and/or in the School of Health Sciences, City University of London. Electronic data will be securely stored on password protected computers/laptop computers (to which only the research team will have access) and backed up onto the University's encrypted server. All 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?
Results article	results	07/01/2021	12/01/2021	Yes	No
Protocol article	protocol	22/10/2019	12/01/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes