Patient Information Leaflet

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Study title: SPPiRE study – Supporting medicines management in older adults with multiple medical conditions.

Principal investigator's name:	**_Prof. Susan Smith_____**
Principal investigator's title:	**_Professor of General Practice_____**
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Co-investigator's name:	**__Dr. Caroline McCarthy____**
Co-investigator's title:	**__ Clinical Research Fellow_____**

You are being invited to take part in a research study carried out at your doctor's general practice by The Health Research Board (HRB) Centre for Primary Care Research, Royal College of Surgeons in Ireland (RCSI).

Before you decide whether or not you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends or GP (doctor). Take time to ask questions – do not feel rushed or under pressure to make a quick decision.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. This process is known as 'Informed Consent'.

You do not have to take part in this study and a decision not to take part will not effect on your future medical care.

You can change your mind about taking part in the study any time you like. Even if the study has started, you can still opt out. You do not have to give us a reason. If you do opt out, it will not affect the quality of treatment you get in the future.

Why is this study being done?

As people get older, they often develop health conditions that require a lot of medications and treatment. Also, the ageing process changes the way the body uses and breaks down medications. Choosing the right medications can be difficult in older patients with many illnesses and it is important to find practical ways to help GPs and patients choose the right medication.

The aim of this research study is to help and support GPs when making prescribing decisions for older patients (aged 65 years and over). It will involve testing specially developed information material about medicines for

GPs and will encourage patient involvement in the decision making process. There will also be an analysis of the direct costs associated with implementing this prescribing support.

Who is organising and funding this study?

This study is organised by a team of researchers from the HRB Centre for Primary Care Research based in the Royal College of Surgeons in Ireland (RCSI). This study is funded by the HRB Clinical Trials Network and is building on previous research conducted by the HRB Centre for Primary Care Research.

The research group includes:

- Prof. Susan Smith, Associate Professor of General Practice, Department of General Practice and the HRB Centre for Primary Care Research, RCSI
- Dr. Caroline McCarthy, Clinical Research Fellow, Department of General Practice, RCSI and the HRB Centre for Primary Care Research, RCSI
- Dr. Emma Wallace, Clinical Research Fellow and lecturer, Department of General Practice, RCSI and the HRB Centre for Primary Care Research, RCSI
- Prof. Tom Fahey, Head of Department of General Practice, RCSI and the HRB Centre for Primary Care Research, RCSI
- Dr. Barbara Clyne, Postdoctoral Researcher, the HRB Centre for Primary Care Research, RCSI.

Why am I being asked to take part?

You are being asked to take part because you are aged 65 years or older and you are taking a number of repeat medications.

How will the study be carried out?

This study is a randomised controlled trial - a study in which people are assigned by a computer at random (by chance) to one of two possible methods of treatment or interventions.

For this study we would like to recruit 30 GP practices and 440 patients (15 from each practice) to take part. 15 GP practices and 220 patients will be randomly assigned to an intervention group (meaning they will take part in a medicines review and fill in a questionnaire) and 15 GP practices and 220 patients will be randomly assigned to the control group (meaning they will fill in a questionnaire and will receive care as usual). Direct costs of providing the intervention will be calculated from the information collected also.

The study is due to commence 2016 and will last 36 months.

What will happen to me if I agree to take part?

By giving your consent to participate, you are agreeing to being randomly assigned by a computer to either the intervention or the control group.

If you agree to participate and are assigned to the intervention group, you will be asked to:

1. Fill in a questionnaire, either by post or over the telephone, about you (e.g. age, marital status), your general health and well-being. The questionnaire will be filled in at the start of the study and 12 months later and will take approximately 15-20 minutes to complete.

2. Allow the above named members of the research team to view, and analyse your medical records (your name and contact details will be removed and a study ID will be used instead to ensure confidentiality) to find out the effects of the intervention.

3. To take part in a medicines review (discussion about your medications) with your GP at a scheduled GP appointment.

4. Once the medicines review has taken place during your visit with your GP, you may be contacted again to participate in a short interview (approx 30 minutes). The interview will be about your opinions on medications in general, the medicines review process and

    - Will be with the study researcher
    - You can do it either in person or by phone
    - It will be audio-recorded and typed up into a transcript after the interview for analysis by the researcher
    - Should you participate in an interview, you have the right to review to edit, or to indicate that part or all of the transcript should not be used. If you wish to avail of this option, please inform the interviewer at the end of the interview.

If you agree to participate and are assigned to the control group, you will be asked to:

1. Fill in a questionnaire, either by post or over the telephone, about you (e.g. age, marital status), your general health and well-being. The questionnaire will be filled in at the start of the study, and again 12 months later and will take approximately 15-20 minutes to complete.

2. Allow the above named members of the research team to view, and analyse your medical records (your name and contact details will be removed and a study ID will be used instead to ensure confidentiality) to assess the effects of the intervention.

What are the benefits?

As a patient, if you are are in the intervention group, you will be invited to a medication review visit with your GP and will have an opportunity to discuss any concerns you have about your medications. The control group will be invited for a medication review once the study is complete.

Overall we hope to find a way to support GPs in making decisions about medications for older people and to engage older patients in that decision making.

What are the risks?

The potential for risks from taking part in this study are minimal. Any changes to your medication regime that arise from this study will be made in consultation between you and your GP.

Is the study confidential?

If you consent to participate in this study, all the information you provide (i.e. medical records questionnaires, interview transcripts) will be pseudo-anonymised. This means any identifying information (e.g. name, address) will be removed and a unique study ID will be assigned to you. Your pseudo-anonymised medical record will be reviewed by the above named members of the research team. Only members of the research team will be able to find out your identity, however, they will only do so when they need to contact you, otherwise all documentation relating to you will carry a study ID. All information about you will be stored electronically on a secure RCSI server and be password protected. All information will be stored for 7 years after completion of the study and then destroyed, in accordance with research best practice guidelines.

At the end of the study, the results will be published in a number of journal articles arising from this study. All the data used for these purposes will be anonymised i.e. it will not be possible to connect the data with the individual.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect the quality of treatment you get in the future.

If you need any further information now or at any time in the future, please contact:

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