Principal Investigator:
Professor Kamlesh Khunti, Professor of Primary Care Diabetes & Vascular Medicine

Study Title: MAP study (Movement through Active Personalised engagement)

Full Study Title: Promoting physical activity through group self-management support for those with multimorbidity: a randomised controlled trial

PARTICIPANT INFORMATION SHEET

You are being invited to take part in a research study. Before you decide whether to take part you should fully understand why the research is being done and what taking part involves. Please take some time to read the following information carefully. You may wish to discuss it with your family and friends. If there is anything that is not clear, or if you would like more information, please contact us using the address at the end of this leaflet.

What is the purpose of this study?

Having two or more long-term conditions can negatively impact on people's lives. Multiple chronic conditions affect more than half the elderly population. The main consequences are disability, poor quality of life and frailty. Effective strategies are needed to support people to better manage their conditions. For this reason a team of clinicians and researchers at the University Hospitals of Leicester have developed a group education programme which aims to help people self-manage chronic conditions. This will help us to assess the effectiveness of the programme. We aim to see if the delivering the MAP Programme is beneficial for patients and healthcare providers.

Why have I been invited to take part?

You have been identified as someone with two or more long term conditions who may benefit from taking part in the programme. For this reason you have been invited to take part in the study.

Do I have to take part?

It is up to you to decide whether or not you would like to take part in this study. Your usual care will not be compromised in any way if you decide not to take part or withdraw at a later stage.

What does taking part in the study involve?

Your participation in this study will last for 12 months. You will be asked to attend two clinic sessions: the first at the beginning of the study and the second 12 months later. Details of what will happen at each of these visits are listed in further detail below.

After the first visit you will be allocated to one of the two groups. Depending on the group you are allocated to, you may be asked to participate in a MAP Self-Management Education Programme.

Clinics

Clinic visits will last approximately 1.5 hours. We will send you the reminders of your clinic appointments with us.

First clinic
A member of the research team will initially discuss the study with you and answer any questions you may have. You will then be asked whether you wish to take part. If you wish to take part in the study the research staff will ask you to sign a form to show your consent.

Once you have given consent, a trained research nurse or a member of the research team will do the following:

- Take a blood sample to test your long term sugar levels (HbA1c), kidney function and lipids. You will not need to be fasting for these tests. The size of the blood will be equivalent to one tablespoon.
- Measure your height, weight, waist and hip circumference, muscle strength and blood pressure.
- Ask you some questions about your health, lifestyle, daily activities, what medications you take and your overall well-being.
- We will provide you with an activity monitor and we will ask you to attach it to your wrist. The activity monitor will be used to monitor and record your activity levels, which will then be used in the study analysis. We will ask you to wear the monitor for 8 days. After the 8 days we will ask you to return the monitor to us in the pre-paid envelope which will be provided. You will also be provided with detailed instructions on how to use the device and a short log book to make notes of any times that you have taken the monitor on and off.

Second clinic
The second visit will take place after 12 months and it will repeat all the procedures which took place at the first clinic.

Follow up at 6 months

Six Months after your first clinic visit, we will send you an activity and health related questionnaire, an activity monitor to wear again for 8 days and the log book. The

guidance of wearing the device, completing the log book and how to return everything will be the same as that what you were given at your first visit. These will be sent out to you via the post. We will provide a pre-paid envelope for you to return the questionnaire, the monitor and the log book back to us.

Will I need to attend the MAP Programme?

Half of the participants will be required to attend the MAP programme. Participants will be randomly assigned to one of two groups:

Group 1 (control group) will continue receiving usual care from their general practice (GP)

Group 2 (intervention group) will be invited to attend the MAP programme

The allocation to the groups will be done by a researcher who is independent to the study; therefore, you or a member of the research team cannot chose which group you are allocated to. At the end of the study, the two groups will be compared to look for any differences between them.

What does the MAP Programme involve?

The programme is delivered to groups of approximately eight to ten people by a trained facilitator. The programme is made up of four separate sessions, each lasting about 1.5 hours. There will be approximately a two weeks' gap between each of the sessions. The sessions will be held in your general practice or a local venue.

The sessions will be interactive and engaging. Trained facilitators will lead the sessions and discuss four topics: being active, managing emotions, treatments and communications. You do not have to actively join in the discussion but you will get more benefit if you do.

At the first session we will provide you with an exercise resistance band and a pedometer, a device which counts your steps. The pedometer will enable you to monitor your daily step count and will be yours to keep after the study finishes. After the first education session we will send you a series of automated motivating text messages. It is important to make sure you have access to a mobile phone and are willing to receive the text messages. You will not be able to respond the text messages. There will be a process in place for you to stop the text messages if you no longer wish to receive them. No charge is incurred for receiving the messages, but there may be a small charge for using the STOP service and the cost will vary depending on the network provider.

Will I be told the results of my tests?

Yes, you will be sent a copy of the results and a copy will also be available to your GP.
Your blood samples will be analysed in a hospital laboratory, and destroyed once the tests have been carried out.

What are the potential disadvantages and risks of taking part?

The study involves having blood tests and other measurements done. These procedures are very similar to those carried out in your surgery, and there is very little risk that you will be harmed in any way. You may feel slight discomfort giving the blood sample and some people may experience bruising. Only trained staff will take the blood samples and they are experienced at doing this.

Half of people taking part in the study will attend the MAP programme. Some people may feel uncomfortable discussing issues of a personal nature during the sessions. We do not expect anyone to discuss personal information unless they are willing to do so. The facilitators leading the session have experience and skills to ensure the group discussions are managed sensitively.

What are the possible benefits of taking part?

Whilst we cannot guarantee benefits from taking part in the study we still hope that it will be a positive experience for those who attended. Half of the participants will attend the MAP programme, and, in addition, both groups will receive a health check during their clinic visits.

Will the information collected about me be confidential?

All of the information about you will be treated as confidential. All electronic data will be kept on secure computer systems. Paper records will be kept in locked filing cabinets at the premises of the University of Leicester or University Hospitals of Leicester NHS Trust or at the Sponsor's secure off-site storage provider. We will use a unique reference number so you will not be identified by name during the analysis of your results. Only specific members of the research team will have access to the information that links patient names and reference numbers. In addition, for monitoring and auditing purposes, relevant sections of your medical notes and/or study data may be looked at by authorised individuals from the study team, the sponsor (University of Leicester), host NHS Trust or regulatory authorities where it is relevant to you taking part in this research. At the end of the study your contact details will be deleted unless you agree to keeping your name and address for future studies.

Can I withdraw from the study?

You are free to withdraw your participation in this study at any time without giving a reason, by telling a member of the MAP team. You should also be aware that if you

lose the ability to make decisions for yourself on matters relating to the study during the study, you will be withdrawn from any further study involvement. Any information already provided or results from tests already performed will continue to be used in the study.

Will I get any payment and/or expenses reimbursed?

We will reimburse parking charges and public transport travel expenses up to £10 for each visit per study session. Please ensure that you keep a valid receipt to claim the expenses.

What will happen to the results of the study?

We will publish the results in medical journals as well as present at research meetings and conferences. We will present all results as averages, and will not disclose and present an individual person's data. We will send you a summary of the study findings when they become available.

Will my GP be informed of my participation in the study?

Yes, we will inform your family doctor of all the results of the tests taken during your clinic visits. In addition, sometimes we might find out something that you were previously unaware of, for example an abnormal blood pressure reading. It is important that your GP knows about this and so we would send a letter to the practice.

Who is responsible for this research?

This research is being sponsored by the University of Leicester. The Chief Investigator, who will take responsibility for the study, is Professor Kamlesh Khunti.

Who has reviewed this study?

To protect your safety, rights, well-being and dignity, all research involving patients is looked at by an independent group of people, called a Research Ethics Committee. This study has been reviewed by the <insert name> Research Ethics Committee in accordance with regulations.

What if I am harmed by the study?

It is very unlikely that you would be harmed by taking part in this type of research study. However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to a member of the study team on telephone number 0116 258 xxxx. They will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, contact Patient Information and Liaison Service (PILS) at University Hospitals of Leicester NHS Trust:

Patient Information and Liaison Service (PILS)
Free phone line: 08081 788337
Patient Information and Liaison Service
The Firs C/O Glenfield Hospital
Groby Road
Leicester LE3 9QP
Email: pils@uhl-tr.nhs.uk

In the event that something does go wrong and you are harmed during the study and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the University of Leicester but you may have to pay your legal costs.

How do I get further information about the study?

If you need more information about the study please contact a member of the study team on 0116 xxx xxxx, or Mapstudy@uhl-tr.nhs.uk. If you would like to find out about research in general and what it may involve for you, please contact PILS at the University Hospitals of Leicester NHS Trust (contact details as above). They will be able to answer your general questions about research carried out in the Trust.

Thank you for taking the time to read this leaflet. If you have any questions about the study please contact the MAP Study Team at:

MAP Study Team
Leicester Diabetes Centre
Leicester General Hospital
LE5 4PW
Telephone: 0116 xxx xxxx
Email: Mapstudy@uhl-tr.nhs.uk