**Title of the Study:** Evaluating the impact of increasing uptake of self-management education programmes for Type 2 Diabetes in primary care: A wait-list cluster randomised controlled trial

**Principal Investigator:** Professor Melanie Davies

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**Participant Information Sheet (Stakeholder)**

**Version 2.0 (22.01.2018)**

**Title of the Study:** Evaluating the impact ofincreasing uptake of self-management education programmes for Type 2 Diabetes in primary care: A wait-list cluster randomised controlled trial

We would like to invite you to take part in our research project. Before you decide we want to tell you why we are doing the project and what we would like you to do as someone taking part in it. Please read this leaflet for more information. If you have any questions, please do contact the research team member whose details are at the end of this leaflet, they will be happy to answer them.

Thank you for taking the time to read this leaflet.

**What is the study about?**

The aim of this study is to trial an ‘embedding education package’ (a kind of tool kit of resources and support for Clinical Commissioning Groups, diabetes education providers and practices to use) to increase the number of people with type 2 diabetes accessing Structured Education programmes (SE). Over the past 2 years we have designed and trialled this embedding package with input from people with type 2 diabetes, staff and commissioners. We are now ready to roll it out more widely in England in a planned randomised control trial.

**What does the study involve?**

**Interview:** We would like to talk to you about your views of the embedding package as it is used in your organisation. This would involve you taking part in one interview that would last up to 30 minutes and would be audio recorded. Just you and the interviewer will be present. Interviews can be done at a time and place that is convenient to you (such as your workplace, or at an alternative venue such as your home) or via telephone. You will be asked to complete a demographic data form during the interview.

**Observations:** We would like to carry out observations of the embedding package being used in practice, (these could include at commissioning meetings, staff training or briefing sessions) and in specific healthcare consultations, (these can include appointments about diabetes with patients, or at SE sessions about how to manage diabetes). A researcher would be present at these activities and would take structured notes.

**Cost Effectiveness:** Practice managers, Education providers and some CCG staff members will be asked to complete a practice activity tracker and take part in an additional interview at the end of the study. This is to help us understand they type of activity undertaken in each practice/provider/CCG and any costs that may be attributed to the activities. Prior to the interview participants will be forwarded a pro-forma to complete. Participants may be contacted by email up to 3 times following the interview to confirm the information discussed and resolve any outstanding queries.

You may be invited to take part in interviews or observations. You do not have to take part in either of them; you can choose to take part in any one without the obligation to take part in the other.

**Why have I been invited?**

You have been invited to take part in this study because you work at a practice which has agreed to use the embedding package, or your work is relevant to a practice which has agreed to use the embedding package (you may be a PPI representative, an educator or a commissioner).

**I am interested in taking part, what do I do next?**

**Interview:** A member of the research team will be visiting the practice to talk about the study and to arrange the different research activities. If you are willing to be interviewed you will be given this information sheet and asked to provide consent. A copy of the signed consent form will be given or posted (telephone interviews) to you to keep and a copy will be kept by the research team.

**Observations of meetings/sessions:** If you decide to take part in observations of meetings/sessions, you will be given this information sheet to keep, and all meeting/session attendees will be asked to provide verbal informed consent by the research team. If anyone at the meeting/session does not wish to give consent, the researcher will withdraw. Attendees will also be free to request that the researcher withdraws temporarily, for example if part of the meeting/session relates to issues that are confidential, or are not pertinent to the focus of the study. The researcher will respect all such requests.

**Observations of healthcare consultations:** If you decide to take part in the observations of healthcare consultations you will be given this information sheet to keep, and asked to provide verbal consent. The researcher will also obtain verbal consent from the people with type 2 diabetes taking part in these consultations; if either of you do not consent, the researcher will withdraw.

**Cost effectiveness tracker and interview:** If you are willing to take part in these activities you will be given this information sheet to keep and asked to complete a consent form prior to interview. The study team will send the practice activity tracker and pro-forma to you and arrange a suitable date for interview.

**Expenses:**

There is no payment for taking part in this research.

**What are the possible benefits and risks of taking part?**

There may not be any direct benefits to yourself however, through taking part in this study you will be contributing to new knowledge on the topic and in the refining of the embedding package. There are no anticipated risks involved in taking part in this study.

**What if something goes wrong? / Who can I complain to?**

If you have a concern about any aspect of this study you can speak to the lead researcher, (contact details below) who will do their best to answer your questions. If you would like to speak to someone outside of the research team, you can contact the research sponsor (University of Leicester Research Governance Office on xxxx xxx xxxx during normal office hours).

**Will my taking part in this study be kept confidential?**

If you consent to take part in this study, the records obtained through observations (written notes) or interviews (audio recordings and written transcripts) will remain strictly confidential at all times. The information will be held securely on paper and electronically under the provisions of the 1998 Data Protection Act. Audio recordings will be deleted once transcribed. Data will be electronically stored on computers at University Hospitals Leicester, University of Leicester, De Montfort University and any cost data will be analysed and stored by the University of Sheffield. Access to any identifiable data (e.g. name and address) will be limited to select members of the study team, the Sponsor, Research Ethics Committee, NHS trust, Leicester CTU or from other regulatory authorities for auditing and monitoring purposes. You will be given a unique number, which will be used as a code to identify you on all research forms. All notes and transcripts will be anonymised; any information that could identify you (such as your name or where you work) will be removed.

Your personal details will be kept securely, away from the notes, recordings and printed transcripts, so that the research team can contact you during the study and tell you about the findings.

**What will happen to the results of the research study?**

Once completed, the findings of this study will be published in a written report. A summary of this report will be sent to each participating practice. Findings may also be used in journal articles and conference presentations. All information about participants will be anonymised in these publications.

**Do I have to take part?**

Even though the practice you work in, or with, is taking part in the study, it is still up to you to decide whether or not you would like to take part yourself. Taking part is entirely voluntary.

If you decide to take part and then change your mind, please just let us know. You are free to withdraw from the study at any time without giving a reason. However, please note any data collected prior to withdrawal may still be used.

**Who is organising and funding the research?**

This study is funded by the National Institute for Health Research, Programme Grants for Applied Health Research (PG-1212-20004) and sponsored by the University of Leicester.

**Who has reviewed the study?**

This study has been reviewed and approved by a group of independent people called Research Ethics Committee and by University of Leicester as Sponsor.

**For further information, please contact:**

[Research team contact detail to be inserted here]

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