**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 (EOI)**

**Version 2.0 (22/01/2018)**

We would like to invite you to take part in our research project. Before you decide please read this information leaflet about the study and contact a member of the study team if you have any questions (contact details below). Thank you for taking the time to read this leaflet.

**What is the study about?**

Diabetes education, you may hear it called ‘Structured Education’ (SE) is about supporting people to manage their own diabetes well. Although education programmes are available for people with type 2 diabetes the number of people attending is often very low. The aim of this study is to increase the number of people who are invited to, and who then attend education programmes.

**What does the study involve?**

The study involves taking part in one or more of the following activities:

1. **Taking part in an interview:** If you have been referred to or have attended diabetes education we would like to talk to you about the programme and how you were referred. This would involve you taking part in an interview that would last up to 30 minutes and would be audio recorded. Just you and the interviewer will be present. Interviews would take place at a time and location that is convenient to you (such as your home or your workplace), or by phone. The interviewer will also ask you to complete a short form with some basic details about yourself, such as age, ethnicity, etc.
2. **Taking part in an observation:** We would like to find out more about how people with type 2 diabetes are identified and referred to diabetes education in routine appointments. This might include observing consultations you have at your practice about your diabetes with your GP or practice nurse, or at any education sessions you may attend. A researcher would be present and would take notes about the process. Personal details would not be recorded during the observation and you, your doctor or nurse, or education provider can ask the researcher to leave at any time.

You do not have to take part in both of these activities; you can choose to take part in an interview or observation without having to take part in the other. Interviews and observations will take place between Feb 2018 and April 2020.

**Why have I been invited?**

You have been invited to take part because you are aged over 18 years, registered at a GP practice which has agreed to take part in the study, and have a diagnosis of type 2 diabetes.

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

If you are willing to take part in an **interview or an observation** during an appointment with your health care professional or during diabetes education, please complete the ‘Expression of Interest’ form making sure you tick the appropriate box or boxes and return it to the research team (details on the form). The research team will not contact everyone who responds but if you are selected they will contact you before April 2020.

**Is there any payment for taking part?**

There is no payment for taking part.

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

There may not be any direct benefits to yourself, but by taking part you will be helping to increase the number of people attending diabetes education. There are no anticipated risks involved.

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

If you have a concern about any aspect of the study you can speak to the lead researcher, (contact details below), who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information and Liaison Service (PILS) at: <<Enter local PILS contact details>>

In the unlikely event that something does go wrong and you are harmed during the research and this is due to someone’s negligence, then you may have grounds for a legal action for compensation against the University of Leicester. However, you may have to pay your legal costs as there are no special compensation arrangements for this study. The normal National Health Service complains mechanism will still be available to you.

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

If you consent to take part any records obtained during observations (written notes) or interviews (audio recordings and written transcripts) will remain strictly confidential. 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 stored on computers at University Hospitals Leicester, University of Leicester and De Montfort University. Access to any identifiable data (e.g. name and address) will be limited to select members of the study, the Sponsor, Research Ethics Committee, NHS trust, Leicester CTU or other regulatory authorities for auditing and monitoring purposes. All notes and transcripts will be anonymised; any information that could identify you (such as your name) will be removed.

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

Once completed, the findings of this study will be published in a written report for the National Institute for Health Research (NIHR). If you would like to receive a copy of this report please advise the research team and provide your contact details. Findings will also be used in journal articles and conference presentations. If possible we will print a study update in your practice newsletter. All information about participants will be anonymised in these publications.

**Do I have to take part?**

No, your practice is taking part in the study but it is still up to you to decide whether or not to you would like to take part. Taking part is voluntary and will not affect the care you receive in any way.   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. If you lose capacity during the duration of the study you will be withdrawn from any further involvement. However, please note any data collected prior to withdrawal may still be used.

**Who is organising and funding the research? How was it reviewed?**

This study is funded by the NIHR, Programme Grants for Applied Health Research (PG-1212-20004) and sponsored by the University of Leicester. The study has been reviewed and approved by a group of independent people called the Research Ethics Committee and by University of Leicester as Sponsor.

**For further information, please contact:**

[Research team contact details to be inserted here]

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