

Diabetes and Mental Health Unit

Department of Psychological Medicine

King’s College London

Weston Education Centre

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**Patient information sheet**

**Title of project**: A mixed methods study to support insulin self-management for people with type 2 diabetes.

You are being invited to participate in a National Institute for Health Research (NIHR) funded study. Before you decide whether to take part in this study it is important that you understand why the research is being conducted and what is involved. Please take time to read the following information and feel free to ask if there is anything that is not clear or if you would like more information.

**1. What is the purpose of this study?**

This study is part of a research project in the department of Psychological Medicine at King’s College London. The purpose of this study is to test a newly developed group intervention to help insulin start for people with type 2 diabetes.

**2. Do I have to take part?**

No. It is entirely your decision as to whether you take part in this study. If you do decide to take part, further to reading this information, you will be asked to complete a consent form. However, you are still free to withdraw at any time during the study period without giving a reason.

**3. What will happen to me if I take part?**

If you decide to take part in the study, please fill out the consent form (attached). You will then we invited to by the research assistant for baseline assessment. The initial assessment will ask you about your life, how diabetes impacts on your life and questions about your psychological health. They will also access your record for more information about your diabetes. If you agree they will arrange for a blood sample to be taken which will test your HbA1c. This initial assessment will last around 60 minutes. After this visit, you will then be invited to a group (up to 10 people) intervention with others who have just started insulin. There will be 3 sessions (1-2 hours) one week apart to help initiate insulin and address any issues. The intervention will be delivered by a diabetes nurse. A follow-up session will take place 3 months following the first session, again this session will last around 1 hour.

**4. What are the possible disadvantages or risks of taking part?**

We do not forsee any disadvantages of participating in this study. You do not have to answer any questions you do not desire.

**5. What are the possible advantages of taking part?**

You will receive a newly developed, evidenced-based group intervention which is not currently available. This could result in improved outcomes following insulin initiation such as reduced hyperglycaemia. Participants attending the first treatment session following randomisation will receive a £10 high street voucher.

**6. Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practise and all information about you will be handled in confidence. We will also take measures to anonymise the data you give us. You will be given this information sheet and a signed consent form to keep, if you wish.

**7. Who has reviewed the study?**

The research proposal has been reviewed by staff in the Academic Department of Diabetes at King’s College London and by the local Research Ethics Committee at King’s College Hospital NHS Foundation Trust.

**Further information and contact details**

If you have any further questions or wish to know more information please do not hesitate to contact the researchers on:

kirsty.1.winkley@kcl.ac.uk, 02078485664 (Chief Investigator)

rebecca.j.upsher@kcl.ac.uk, 02078485666 (PhD student)

If you have any questions concerning your rights as a study participant you may wish to read the following leaflet: Getting Involved in Research: A guide for consumers, available at: <http://www.invo.org.uk/pdfs/guide_for_consumers.pdf> or contact the Consumers in NHS Research Support Unit, Tel: 01962 872247.

Thank you very much for taking the time to read this information.