Friend/Relative's Information Sheet

Beyond education: A **H**ypoglycaemia **A**wareness **R**estoration **P**rogramme for people with type 1 diabetes and problematic hypoglycaemia persisting **d**espite **o**ptimised self-**c**are (HARPdoc)

Invitation

We'd like to invite you to take part in our research study.

One of our team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. We suggest this should take about 20 minutes. Please feel free to talk to others about the study if you wish.

What is the purpose of the study?

You have a relative or close friend who is participating in a research study comparing two different approaches to reducing the risk of hypoglycaemia (low blood sugar episodes) as a side-effect of the insulin they take to manage their type 1 diabetes. The two approaches are intended to help people with diabetes who can't always tell when their blood sugar is dropping to regain awareness of hypoglycaemia and most importantly reduce the number of times they have hypoglycaemia so severe that it has to be treated by someone else. One course, called Blood Glucose Awareness Training or BGAT for short) teaches new ways for people with diabetes to predict and feel what their blood sugar levels will be. This course has been successful in reducing severe hypoglycaemia in America, where it was designed and in some European countries. The other course, HARPdoc, is a completely new approach. As well as revising learning about hypoglycaemia and how to avoid it, HARPdoc explores thoughts and beliefs around hypoglycaemia that we have identified as possible barriers to regaining awareness of hypoglycaemia and reducing risk of severe episodes. It uses "talking therapies" to find new ways of thinking and worked very well in an early small test. We are making audiotapes of the sessions in order to ensure that the people leading the courses, who are diabetes nurses and dietitians, are delivering them as they are intended to be delivered. This is called "fidelity testing". We describe this in more detail below. We may also use the tapes to train new educators to deliver HARPdoc.

HARPdoc includes a session for the relatives and partners of the participants and includes relatives and friends in some of the main sessions and you will be invited to participate in these sessions. We are asking you to participate in the research by allowing the sessions you attend to be audiotaped.

Why have I been invited?

You have been invited to take part in the study because your friend/relative has been diagnosed with type 1 diabetes and with problems with recognising their own hypoglycaemia.

Do I have to take part?

It is up to you to decide. If you agree, we will then ask you to sign a consent form to show you have

agreed to take part. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care your friend/relative receives or their participation in the study.

What will happen to me if I take part?

We are asking for your participation in two ways. One is to help us understand exactly how much of a problem hypoglycaemia is for your relative/friend with diabetes. The people we have invited to take the BGAT and HARPdoc courses generally do not know when their blood glucose is falling, and they may have episodes that they do not remember clearly. We will be asking your relative/friend to describe the episodes they can remember over the previous 12 and 24 months at the start of the study and 1 and 2 years after they are allocated to a course. We will also ask them to give you a similar form to document your recollection of their hypoglycaemias at the same times for you to return to a researcher not involved in your friend's/relative's clinical care. The answers you give will be anonymised and entered into the study database by the researcher using the unique study number your relative/friend has been given.

Secondly, the HARPdoc intervention includes a session for the relatives/friends of the people with type 1 diabetes attending that course. This is an integral part of the intervention and not specifically a research session. After that session, you will be invited to join the rest of the course on that day. These sessions, with your relative/friend, are part of the course that is being audio-taped to assess fidelity (the accuracy with which the educators deliver the content of this session). We will therefore be asking all participants, friends and relatives on a course to allow us to make audio recordings of sessions. The recordings will be reviewed only by the researchers for assessing the accuracy with which each intervention is being delivered and for no other purpose. We will ask for your consent for recording to continue in the combined session that you and other relatives and friends attend.

Finally, we are also conducting a study to look at how best to implement either intervention into routine clinical care and seeking to understand the experiences of the people involved in the two courses through interviews and questionnaires. This research will be subject to an independent ethical approval, but we would like your permission for our colleagues conducting it to contact you about it.

Who is organising and funding this study?

The doctor in charge of this study is Prof Stephanie Amiel, diabetes consultant at King's. The study is funded by the JDRF (Juvenile Diabetes Research Foundation) and is being jointly sponsored by King's College London and King's College Hospital NHS Foundation Trust.

The research team are not receiving any financial reward for undertaking this study.

How have patients and the public been involved in this study?

Reducing the risk of severe hypoglycaemia and tackling impaired awareness of hypoglycaemia were topics listed as priorities for research in type 1 diabetes by a national exercise involving people with diabetes, their families and their health care professionals in 2012. People with type 1 diabetes

helped develop the HARPdoc intervention, both by participating in the original design of its curriculum and by providing feedback that has led to its present form. People with type 1 diabetes have also reviewed the questionnaire packs and this information sheet. One of them will continue to be involved in the study as part of the research team and will chair a group of people with type 1 diabetes who will assist in monitoring the progress of the study and the analysis of the data.

Who has reviewed this study?

The study protocol was reviewed by a research review committee of the JDRF and was developed with them. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favorable opinion by London-Dulwich Research Ethics Committee. It has also been approved by the Health Research Authority and each local hospital will also give confirmation that the study can go ahead. The American site will have been reviewed and approved by its own local Investigation Review Board, the US equivalent of the Research Ethics Committee.

Expenses and Payments

There are funds available for you to claim back travel expenses for attending the HARPdoc sessions described above and we will pay postage for questionnaires that you fill in.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to your study doctor (Prof Amiel, Dr Jacob or Dr Choudhary, 0207 848 5639) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints procedure by contacting your local Patient Advice Liaison Service (PALS) office. Details of your local office can be obtained by asking your study doctor, GP, telephoning your local hospital or looking on the NHS choices website. http://www.nhs.uk/pages/home.aspx

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

In the 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 King’s College Hospital NHS Foundation Trust. but you may have to pay your legal costs.

Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated by members of staff or about any side effects (adverse events) you may have experienced due to your participation in the study the normal National Health Service complaints mechanisms are available to you. Please ask your study doctor if you would like more information on this.

Will my taking part be kept confidential?

Information collected as part of the study protocol will be kept confidential. Only anonymised data will be kept in the research data base.

King's College London and King's College Hospital are the sponsors for this study based in the United Kingdom. We will be using information from you and/or your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. King's College London and King's College Hospital will keep identifiable information about you for 10 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information on https://www.guysandstthomas.nhs.uk/research/patients/about.aspx

HARPdoc sites will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from HARPdoc sites and regulatory organisations may look at your medical and research records to check the accuracy of the research study. HARPdoc sites will pass these details to Sponsor organisations, King's College London and King's College Hospital along with the information collected from you and/or your medical records. The only people in King's College London and King's College Hospital who will have access to information that identifies you will be people who need to contact you to discuss study related matters or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

Prof Amiel will be the custodian of the data collected in this study.

You have the right to access and withdraw information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correction, erasure, objection, and data portability.

Because we have an American centre in the study, your anonymized data will be merged with the US data and our US collaborators will be able to work with the data base for analysis purposes only. If this requires data to be sent to our American centre, a data transfer agreement will be made to ensure such data transfer complies with UK law. Your personal data will continue to be held in compliance with GDPR.

Your name will not be used in any reports about the study and all data is stored in accordance with the principles of General Data Protection Regulation (GDPR).

Thank you

Thank you for considering taking part and taking the time to read this information sheet.
If you decide to take part in the study, we will give you a copy of the information sheet and a signed consent form to keep.

Further information and contact details

If you would like more information about research participation you may wish to contact the organisation that advises on patient and public involvement in research listed below:

INVOLVE, Alpha House, University of Southampton Science Park, Chilworth, Southampton, SO16 7NS. Telephone: 023 8059 5628 Email: involve@nihr.ac.uk

If you would like more information about other research in type 1 diabetes funded by the JDRF, you may wish to visit their website: www.jdrf.org

In the UK, research into diabetes is also supported by the charity Diabetes UK (www.diabetes.org.uk)

If you have questions about this study, please contact your local research team.

Local Contact:
Your nurse: …….
E mail: …….
Tel: …….

Your doctor: …….
E mail: …….
Tel: …….

Trial Manager: …….
Email: HARPdoc@kcl.ac.uk
Tel: …….

Please remember your e mail and e mails that do not end "nhs.net" are not secure against hacking and should not be used for sensitive personal information.