

PERSONAL CONSULTEE INFORMATION SHEET

STOP Diabetes

(Diabetes Screening Study for People with Learning Disabilities)

Introduction

We are inviting you to act as a 'personal consultee' for someone who is unable to make a decision for themselves. You are being asked to advise the researchers about this person's wishes and feelings as to whether they themselves would have wished to join this research. Before you decide, it is important for you to understand what it means to be a consultee. You also need to understand why the research is being done and what it will involve. Please take the time to read this information sheet carefully and talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide if you wish to be a consultee.

What does it mean to be a personal consultee?

A consultee is someone who knows a person with a mental incapacity well and is willing and able to offer an opinion as to what the incapacitated person's wishes would have been did they not have a mental incapacity. We are intending to recruit participants to this project who may not have the capacity to consent to their participation. This means that they may not be able to judge for themselves whether they should like to take part or refuse. You do not have to act as a consultee if you do not want to. If you decide to act as a consultee, you will be asked to sign a Personal Consultee Advice Form.

The project has been approved by an NHS Research Ethics Committee. We shall make sure that the project is safe for each participant and does not cause them unnecessary distress. To help with this, the researchers need information from people who have known the participant for some time.

Why have I been approached?

As a partner, friend or relative of a (potential) participant in the study, you will have an interest in the person's well-being and welfare. You may have been given a Lasting Power of Attorney to make personal welfare decisions on their behalf when they can't. You may be a deputy appointed by the Court of Protection.

Researchers in the project would like to discuss with you whether you think that your partner, friend or relative would like to take part. As you have known them for some time, you may be aware of any views they may have about taking part in such a project or whether they have made an 'Advance Decision'. If your partner, friend or relative has made an 'Advance Decision' this is important as it shows that they have ready made decisions for themselves. The researchers would like to respect the person's wishes.

Secondly, if you think that your partner, friend or relative may be interested in taking part in the project, you may be able to tell us about any possible difficulties they may have. You also may be able to tell us how they may communicate that they wanted to stop being involved. When thinking about the wishes and interests of your partner, relative or friend, it is important that you should set aside any of your own personal views about the project.

What is the study about?

Diabetes is an illness. People with type-2 diabetes have too much sugar (glucose) in their blood. This happens because the body can't use sugar (glucose) properly. People with type-2 diabetes may feel tired, thirsty and need to go to the toilet a lot. Some people have no symptoms at all. Type-2 diabetes can lead to health problems such as heart disease, stroke, and kidney disease. Lots of people have type 2 diabetes for many years before they are diagnosed and some of these people may have already developed health problems.

Why should people be screened (checked) for type 2 diabetes?

It is important to keep people healthy. Some people with learning disabilities find it hard to tell their doctor or nurse when they are poorly. A diabetes health check is a good way to identify people who have type-2 diabetes. If a person is found to have diabetes they can be given treatment to stop them feeling poorly and to help keep them healthy.

We can also identify people who may be at 'high risk' of developing diabetes in the future. This is called pre-diabetes. If people with pre-diabetes eat healthier foods and do more exercise this may help them not to get diabetes.

Why is this research being done?

Many people with learning disabilities have more health problems than the general population. We also know that health problems are more likely to go undiagnosed and untreated in people with learning disabilities.

We think people with learning disabilities may be more likely to get type-2 diabetes than some other people. We would like to find out if this is true and what the risk factors (things that make something more likely) are for type 2 diabetes in people with learning disabilities.

Does the individual have to take part?

No! Individuals can choose if they want to say yes and volunteer to take part or if they want to say no. Where individuals with a learning disability are unable to decide, we are asking advice from other people. If you volunteer to give advice, we will record your advice on a Personal Consultee Advice Form. You will be given a copy of your signed form for you to keep. Even if you say yes now, you (or the individual) can change your mind and stop at any time. The decision you both make will not affect the quality of the health care the individual receives.

What will be involved?

If you agree to help with the research, you will both be asked to attend 2 appointments for this study. The appointments will be held at a location that is convenient to yourself (e.g. day centre, general practice, community venue). You will both have the chance to meet the members of our team and to ask any questions you both might have.

Appointment 1

We expect that appointment 1 will last about 2 hours. During the appointment we would like to take some measurements (blood pressure, height, weight, waist, hips). We will also ask some questions about general health; such as any illnesses the person with learning disabilities has and any medications (tablets) they take. We will also give you some questionnaires to take away with you and bring back to the second appointment.

Appointment 2

We expect that appointment 2 will last about 1 hour. During the appointment we would like to test the person with learning disabilities urine (wee) and take a blood test. The blood will be taken from their arm using a needle and syringe. The blood will be tested for diabetes. We will check their liver and kidney function and measure how much cholesterol there is in the blood. We would also like to take some extra blood (optional) to be stored and tested at a later date. The total amount of blood we would like to take is about 10mls (2 teaspoonfuls). If

you agree that extra blood can be taken to be stored and tested in the future this will be about 20mls (4 teaspoonfuls).

On the evening before the second appointment, if appropriate, we may ask the person with learning disabilities to fast. This means having NO food or drink after 12 midnight and NO breakfast. They are allowed to have water to drink.

If you have any worries or questions about what will happen at the appointments please contact a member of the team to discuss how we can make it easier for you both to take part in the study. You can take a break at any time. If you prefer, some people may be allowed to have all the tests and measurements done together in 1 appointment but we would prefer you both to have 2 appointments.

Will I be asked to do anything else?

When you sign the Personal Consultee Advice Form there are some extra things we will ask you to think about. If the person with learning disabilities is found to be at high risk of getting diabetes we may want to invite you to take part in the next stage of our research. This is the development of a lifestyle education programme for people with learning disabilities. We are only asking if we can send you both the extra information, it does not mean you have to take part.

We would also like to take an extra sample of blood that will be stored for genetic analysis at the end of the study. You can both still take part in the diabetes screening study without agreeing to these extra things.

Might anything about the research be upsetting?

Individuals may suffer slight discomfort while the blood samples are being taken from their arm and some people do experience bruising after blood samples have been taken.

What are the possible benefits of taking part?

We might find out that the individual has diabetes or is at high risk of getting diabetes. This will mean that they can be given the right treatment by their GP (doctor). This may help prevent future health problems (keep them healthy).

The study will also help us understand if some people with learning disabilities are more likely to get diabetes and this may help us develop ways to prevent diabetes.

Will the persons GP be informed of the results?

Yes, their GP (doctor) will be informed of all the results of the tests and measurements taken as part of this study.

Will people be paid for taking part in the study?

If one or both of you have to pay for travel, we will pay you the money back up to the value of £15. Please keep all your receipts.

Will information that is given be kept confidential (private)?

Yes. All information that is collected from you both during the research study will be kept confidential (private). We will also ask your advice for permission to look at the persons medical records for information related to the research study (essential), and long-term follow-up (optional). Any information about them which leaves the hospital/surgery will have their name and address removed so that they cannot be recognised from it.

Some of the data collected as part of the study may be looked at by authorised people to check that the study is being carried out correctly.

What will happen to the results of the research study?

The results of the study may be published in a medical journal or presented at research seminars or conferences. People taking part will not be identified in any report or publication.

Who is doing this research?

The people who are doing the research study are:
Professor Khunti at the University of Leicester, and Dr Bhaumik at Leicestershire Partnership Trust.

Who is funding this research?

The funding (money) to do the research study has come from the Department of Health.

Who has reviewed this study?

Before a research study goes ahead it has to be checked by a group of people called a Research Ethics Committee. These people make sure that the research is ok to do. This study has been checked by an NHS Ethics Committee.

What do I have to do now?

If you think that your partner, friend or relative would be interested in taking part, please complete the reply form and return to the Diabetes Research Team. We have given you a pre-paid envelope with our address. The envelope does not need a stamp. The Diabetes Research Team will then contact you to arrange a time for a discussion.

If you are unsure or do not want to advise the researcher then please suggest who else we could ask. If you think that your friend, partner or relative would **NOT** be interested in taking part, please still complete and return the form.

If you would like to ask any questions before deciding, please feel free to contact the STOP Diabetes Research Team:



Prof Kamlesh Khunti
Professor of Primary Care Diabetes & Vascular Medicine
University of Leicester



Prof Sabyasachi Bhaumik
Medical Director,
Leicestershire Partnership Trust

Tel: XXXX

E-mail: XXXX

Or you can write to us:
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