Participant Information Sheet

Study: Improving treatment adherence in people with diabetes mellitus (INTENSE)

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please read the information in this leaflet before deciding whether to take part. Feel free to ask any questions and talk to others before making a decision.

What is the study about?

We know that all sorts of things can get in the way of taking medicines as prescribed. We want to know what gets in the way of taking medicines for diabetes and high blood pressure. We also want to find out if we can help people by using things like messages to their smartphone.

Who is doing this study?

The European Foundation for the Study of Diabetes is paying for the study. The University of East Anglia (UEA) together with the Amsterdam University Medical Center, University of Oxford, and NHS North Norfolk are doing the study.

Why have I been chosen?

You have been chosen because you are a registered patient with a medical practice and a community pharmacy that is involved in this study and you are prescribed medicines for diabetes. (A community pharmacy is the place where you go to get your medication(s)).

What if I want to take part?

Please let your usual community pharmacy team know, by either telephoning them or by completing the "Expression of interest" form that has been sent to you with this information leaflet, and taking it to the pharmacy. The pharmacy assistant will collect some details from you to make sure that you are suitable for taking part. If you are not suitable for the study (for example you only take insulin for your diabetes, or you do not have access to a computer or a smartphone), the pharmacy assistant will only keep details of your age, gender and reason for not being suitable. If you are included in the study, we will keep a record of your contact details, age and gender. We will also let your general practitioner (GP) know that you are taking part in this study.

What happens if I agree to take part?

We won't change any of your medicines and your doctor will provide your care in the usual way. The study happens in five stages:

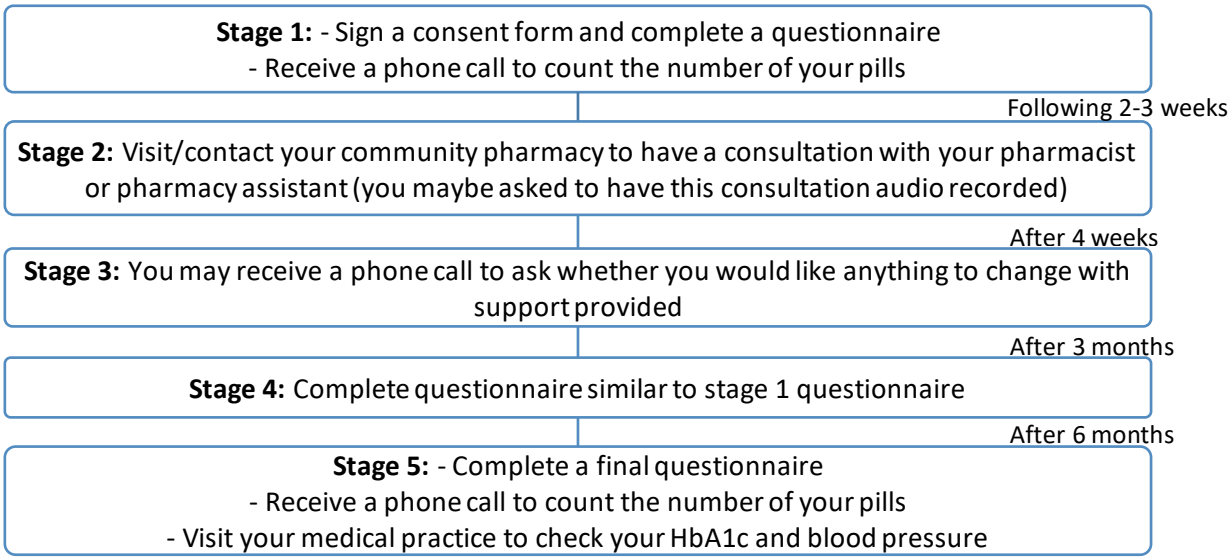
Stage 1 We will ask you to sign a consent form (this is so we know you understand the study and are happy to take part) and also to fill in a questionnaire which should take about 20 minutes. We will send you the consent form and questionnaire according to your preference, either by post (with a prepaid envelope) or by email (to complete and submit electronically). The questionnaire asks for information about your health and wellbeing and your thoughts on medicines. We are interested in people with diabetes who are finding that things get in the way of always taking their medicines as prescribed. You will then get a phone call from us to ask you to count how many of your diabetes and blood pressure tablets you have at home. This will help us to find out later whether we have been able to help you to better take your medicines. We will also ask you to visit/contact your community pharmacy for a consultation, which is stage 2.

Stage 2 We will decide randomly e.g. by flipping a coin, whether you have a discussion with your pharmacist or pharmacy assistant. They will help you with putting a link on your smartphone to a diabetes information website. You may also have a consultation about anything that makes it difficult for you to take your medicines as prescribed. Together you will decide what solutions might be best for you. This could be things like reminders to your smartphone to take your medicines, information about your medicines or a pill box. You will get this support whilst you are involved in this study which will be for 6 months. To help us monitor the performance of pharmacy staff, there is a small chance that you will be asked if it is ok to audio record your consultation, you are free to say no. Please note that consultations will be conducted according to practice employed at your community pharmacy, i.e. face-to-face, virtual or telephone consultation, whatever approach the community pharmacy is using at the time of conducting the study.

Stage 3 We might telephone you after four weeks of getting the extra help with taking your medicines. This phone call will be up to 10 minutes long. It will be to get your thoughts on the solutions that have been tried and to find out if you would like us to change anything.

Stage 4 After 3 months, we will ask you to fill in one questionnaire similar to the one in stage 1.

Stage 5 After 6 months, your part in the study will end. We will ask you to fill in one final questionnaire similar to those in stages 1 and 4. It is slightly longer so may take up to 30 minutes. This is to find out whether any things have changed for you regarding taking your medicines. We will telephone you to ask you how many of your diabetes tablets you have left. We will remind you to visit your medical practice to have your blood pressure and HbA1c (test for routine diabetes control) checked as part of your standard care. Finally, we may ask you if you want to be involved in a telephone interview about your opinions of being involved in the study. The next page has a flow chart summarising what will happen if you decide to take part in the study.



Are there any benefits to taking part?

We can't promise that the study will help you but the information that we get might help improve care for people with diabetes and high blood pressure. You will get an £8.50 electronic Amazon voucher to cover any internet and mobile phone costs during the study. We will send you this voucher by email or post at the end of the study.

Are there any disadvantages to taking part?

If you don't think that you have the time to fill in the questionnaires or you don't like using a smart phone then it might not be right for you.

What about confidentiality?

The UEA is sponsoring this study in the UK. We will collect information from you and your medical records. This information will include your name, date of birth, and contact details. We (i.e. study team) will use this information to do the study and to check your records to make sure that the study is being done properly. If you are interviewed by telephone, a member of the study team will type up the recording using a secure, password protected computer at the UEA. The UEA will keep any information that might allow you to be identified (name, date of birth, contact details) for one year after the study has finished. This is so that we can let you know how the study went. Paper copies of anything that might allow you to be identified will be kept in a locked filing cabinet at the School of Pharmacy at the UEA and only accessed by members of the study team. We will be the data controller for this study which means that we are responsible for looking after your information and using it properly. 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 study to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already collected. To safeguard your rights, we will use the minimum personally-identifiable information possible. People who do not need to know who you are will not be able to see your name or contact details your data

will have a code number instead. You can find out more about how the UEA manages Personal Data by contacting the UEA Data Protection Team (dataprotection@uea.ac.uk). Principles of the General Data Protection Regulations 2018 will be followed with respect to data storage, processing, and destruction. There will be no access to personally-identifiable data for audit or monitoring purposes. If you are offered and decide to use an online self-help program, information entered into this program will be stored on a secured third party data storage platform. After the end of the study, some of your information will be sent to the Amsterdam University Medical Center (VUmc) and the Academic Medical Center (AMC) in the Netherlands. They must follow our rules about keeping your information safe. We will only give them the study information for it to be analysed for the purpose of answering the study questions of this research. We will not give them any information that allows individuals to be identified. They will store the information for 15 years according to EU-regulations for protecting personal data. Research data will be stored in locked cabinets (paper data), and on the Vumc server (digital data). Data will only be accessible to researchers and other people who are according to Dutch law allowed to access the data.

What will happen if I don't want to carry on with the study?

If you change your mind, you can withdraw from the study at any time without giving a reason. Withdrawal from the study will not affect the ordinary course of your medical care or treatment.

What happens when the study ends?

Any solutions that involved your smart phone will stop so you will need to arrange a consultation with your pharmacist or GP to discuss alternative solutions. We will publish what we learn from the study in scientific journals and news articles for the public. We might use direct quotes from interviews but will remove any information that would allow a person to be identified such as names of people, community pharmacies or general practices. Instead we will use a reference number for each person, pharmacy and medical practice. The study findings might be used to help the NHS make decisions about better supporting people taking medicines for diabetes.

Who has reviewed the study?

This study has been reviewed and approved by NHS research Ethics Committee, which is committed to protect the rights, safety, dignity and wellbeing of research participants.

Complaints process and what to do if you want more information

Please telephone the lead researcher (Debi Bhattacharya) on 01603 593391. If your concern is about the lead researcher, or you have a complaint you would like to make, or you would like independent advice about being involved in research, contact the Patient Advice and Liaison Service (PALS) on 0800 5874132.

Thank you for taking the time to read this information