VERSION 5.1, 04/09/2012

TRUST LOGO

PATIENT INFORMATION SHEET FOR THE REPOSE TRIAL

Investigating whether insulin pumps are more effective in treatment of type-1 diabetes than multiple insulin injections when combined with diabetes education (Dose Adjustment for Normal Eating – DAFNE).

We are inviting you to take part in a research project to test the benefit of insulin pump treatment on people with Type 1 Diabetes. Before you decide whether to take part it is important to understand why the research is being undertaken and what will be involved. Please take time to read this information and discuss it with friends, family and your GP if you wish. Please feel free to ask questions if anything is unclear or if you would like more information.

What is the Purpose of the Study?

Insulin pumps, which are about half the size of a mobile phone and inject insulin continuously under the skin through plastic tubing, are becoming popular, particularly in the USA as a way of taking insulin in Type 1 diabetes. However, it is unclear whether they are better than insulin injections to control blood sugar and improve quality of life. Some professionals think that pumps have major advantages while others don't believe they offer much more than training in the skills of insulin adjustment, as offered by a standard DAFNE course using multiple daily insulin injections.

We already know that the standard DAFNE course, using multiple daily insulin injections, helps people to look after their own Type 1 diabetes more effectively. We now want to see if teaching people to use pumps as well as learning DAFNE, during the same week, helps people to get better glucose control and have less hypoglycaemia, than doing a DAFNE course and continuing on injections. In other words, do pumps offer added benefit over DAFNE alone to people with Type 1 diabetes.

The people who take part in the study need to be prepared to do either the course with standard injections or to do the course while using a pump instead of injections for 2 years.

Why have I been chosen?

We are asking you because you have Type 1 diabetes and may benefit from undertaking a DAFNE course. We are contacting all people in Sheffield, Harrogate, Cambridge, South London, Nottingham, Edinburgh, Dumfries and Galloway, and Glasgow who are already waiting to do a DAFNE course or who may benefit from a DAFNE course to see whether they might be prepared to join this study.

Do I have to take part?

No. It is for you to decide whether or not to take part in the study. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. You will be free to withdraw from the study at any time, without giving a reason. This will not affect the standard of care you receive from the hospital staff or delay your participation in a regular DAFNE course. The only difference in the study from the standard care you would usually receive through DAFNE, is that you may be asked to include using an insulin pump to deliver your insulin during and for 2 years after your DAFNE course.

What will happen to me if I take part?

Before the Course:

Before starting the course you will meet with one of the local DAFNE research team to discuss the course and the trial in detail. If you agree to participate we will ask you if you are happy to take part in various tests, such as checks of your weight, a HbA1c test obtained by blood sample and albumin creatinine ratio by urine sample. During this visit we will ask you to start checking your blood glucose regularly and you will also discuss your insulin treatment so that any changes to your usual dosing regimen can be agreed, as would happen on any standard DAFNE course. At this time you will be given your insulin pump if you were one of the participants allocated to have one.

We will also ask you to fill out a number of questionnaires. One of the questionnaires will be filled out at the visit with the member of the research team present and the rest will be given to you to take home and fill out in your own time. The other questionnaires will allow us to measure how you feel about your diabetes and how it affects your life and mood. These questionnaires will probably take about 15 minutes to complete. We ask you to return these questionnaires when you come to do the course. We will also ask you to keep a diary of any hypos (episodes of low blood sugar) for 2 weeks and to return this with the questionnaires.

The course:

Half the people who participate will have been allocated to do a standard 5 day DAFNE course and the other half will do a DAFNE course but will also be taught to use an insulin infusion pump. You will not be able to choose which therapy you are offered. You will find out which therapy you will receive approximately 2-3 weeks before the DAFNE course. People allocated to pump therapy will start using it immediately before the DAFNE course and be asked to continue to use pump for the following 2 years. You will receive support and advice in making sure you know how to adjust and keep to either treatment plan and you will be able to contact someone whenever you have a question or a problem on either treatment. The teaching on the pump course will be no different to a standard DAFNE course except for training on using a pump. The same educators who teach the standard DAFNE course will also deliver the pump course and it will be held in the same place.

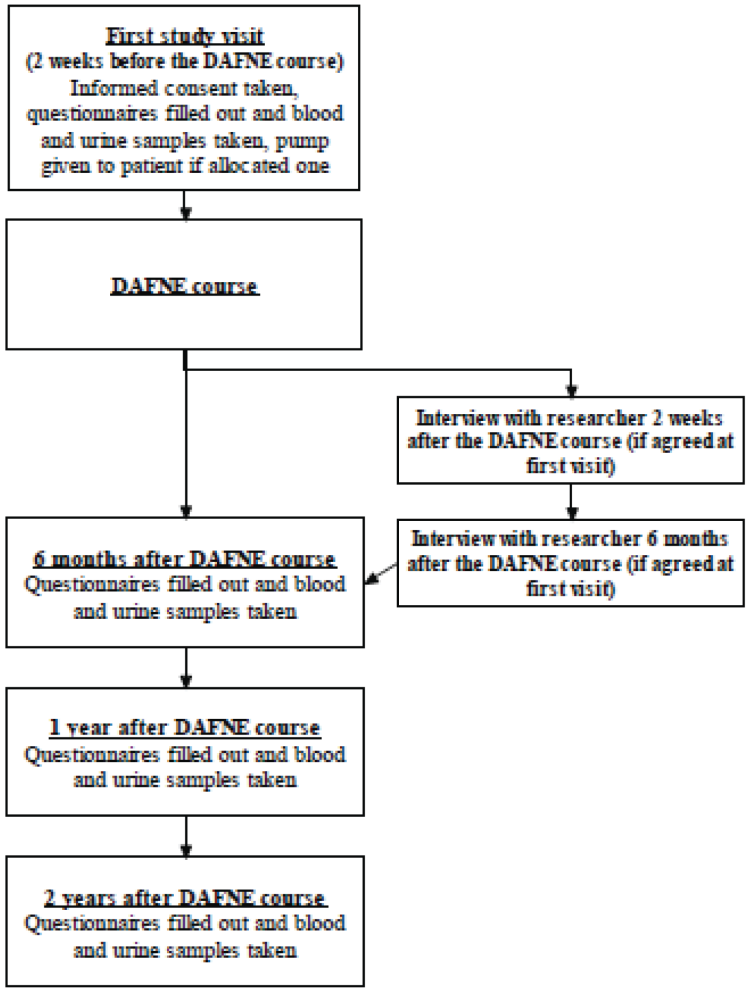
Ongoing evaluation after the course:
You will receive the usual support from the DAFNE team, the same as other DAFNE graduates and will continue to be able to contact someone whenever you have a question or a problem on either treatment. For 2 years after the course, we will evaluate both forms of treatment. We will ask you to keep a simple record of any hypos you have throughout this period and we will ask you to visit DAFNE staff 6 months, 1 year and 2 years after the course where you will have the same tests as before the course. The questionnaires will be sent out to your home address 2 weeks before you are due to visit in order that you would have time to fill these out and bring them back during your visit. As with the questionnaires at the start of the study, these should take about 15 minutes to complete.

As part of the REPOSE evaluation you can, if you wish, take part in an extra element of the study and agree to be interviewed. When you sign the consent form you will be asked whether you are happy for an interviewer to contact you regarding the interview element of the study, and to ask you whether you would like to participate. If the interviewer chooses to contact you for interviews then they will give you a patient information sheet to tell you all about this and there will be a separate consent form.

As part of the ongoing evaluation of DAFNE courses running within the UK, you will be invited to have your data included on a national database of DAFNE course participants. This would involve some of your data being copied and imported from the REPOSE database to the DAFNE database. There is also a separate patient information sheet and consent form for this.

After the 2 year evaluation:
Those who have been allocated to pump therapy will be asked to return the pump and we will provide you with the extra training you may need to transfer the skills in insulin management back to the use of injection therapy. If after 3 – 6 months of using DAFNE principles and injection therapy, you find your control less good than with the pump, we will tell the doctor responsible for your care. They will want to discuss this with you and may approach the people in your area who are responsible for funding and request finances for you to continue pump therapy. We cannot guarantee that this will be forthcoming but if you did achieve benefit on pump and DAFNE that is not sustained on DAFNE with injections, you may have a strong a case to have these funded permanently. For patients who were allocated to injection therapy at the start of the trial, the usual NHS criteria will apply for progressing to pump therapy (usually problems in achieving good overnight control without hypoglycaemia).

The flow chart below is a simplified diagram to explain the process that you would go through if you were to take part in the study.



What are the benefits?

There may not be any benefits over and above that anticipated from attending a standard DAFNE course. All those who complete a DAFNE course should feel more confident about managing their diabetes and be able to adjust their insulin dose correctly to suit their choice of food. This should mean greater freedom, improved quality of life and improved blood glucose control. The study will allow us to give the Department of Health a much clearer idea of who benefits from an insulin pump and who does not. This could mean that everyone in the country who would benefit from a pump will be able to try one.

Once you have decided that you would like to take part and would be happy to return for your data collection visits and to fill out the questionnaires, we will send you a £5

gift voucher after each follow up visit (6 month, 1 year, 2 years) in order to show our appreciation of your participation.

Are there any risks?
Previous experience shows that many people who use pumps prefer them, but this doesn't apply to everyone. Many trials have involved people who either wanted pumps or were advised by their medical teams to try them. It is often a matter of personal preference. There are small risks of infection with insulin pump use where the cannula is placed on the skin, but these are reduced by proper use of the device, which we will teach you. Because the pump only contains very short acting insulin which is given at a very slow rate between meals and at night, there is in theory, an increased risk of loss of diabetes control with high blood glucose concentrations and possibly even ketones in the urine (ketoacidosis). This means pump users do have to keep monitoring their blood glucose regularly, but this turns out to be no more frequently than the number of tests used to help DAFNE users achieve best outcomes. With modern pumps and methods of using them, this risk seems to be not much different than with standard treatment. Some people find wearing the pump intrusive or uncomfortable.

Will I be able to keep my pump at the end of the trial?
Since we are having to obtain the pumps especially for the trial, people will not be able to keep them at the end. The standard criteria the NHS uses in deciding who is given pump therapy will apply to you, whether or not you were allocated to a pump in the trial. It will be for your own GP (in England) or Health Board (in Scotland) to provide support if you decide you want a pump permanently and to obtain the necessary funding. We cannot guarantee that this funding will be forthcoming but if you did achieve benefit on pump and DAFNE that is not sustained on DAFNE with injections, you may have a strong case to have these funded permanently. In this instance every reasonable effort will be made to assist you.

What happens if I don't want to continue with the study?
You are free to withdraw from the study at any time. This will not affect your clinical care including the follow up support from the DAFNE team. If you have been using a pump, you will need to first contact your DAFNE educator to organise the switch from pump treatment and to receive advice and support concerning standard injection regime. We would ask you to consider completing the study questionnaires and having the blood test as you did at the beginning, but you are not obliged to.

Will it cost me any money?
No. Doing either course is free of charge and food will be provided each day. You will not have to pay for either the pump or the running costs.

What happens if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions (contact details below). If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed due to

someone's negligence then you may have grounds for legal action and compensation against the University of Sheffield or [XXX hospital] but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?
If you consent to take part in the research, some information may be taken from medical records, including details of the disease and treatment. We will inform your GP and usual diabetes care team that you are participating. All information that is collected about you during the course of this study will be kept strictly confidential and will be secure. When you sign the informed consent form we will ask you to provide your personal contact details. We ask for these so that we may contact you to arrange your visits. Information will only be accessed by the research team and regulatory authorities. All identifiable information will be destroyed 15 years after the end of the study.

What will happen to the results of the study?
We will publish the results in a scientific journal and produce a report that is freely available to anyone who wishes to read it. You will not be personally identified in any report or publication we produce. Please contact us using the details below if you would like to see a summary of the results when the trial is completed.

Who is organising and funding the research?
The research is organised by the University of Sheffield and funded by the Department of Health.

Who has reviewed the study?
This study was given a favourable opinion for conduct in the NHS by the Northwest 3Research Ethics Committee-Liverpool East

Contacts for further information:
If you have any further questions you may ask PI (details below) or the DAFNE lead educator, EDUCATOR You will be given a copy of this information sheet and a signed consent form for you to keep.

[local PI details] [local educator details]

If you wish to speak to somebody who has no involvement in the trial, and would therefore not influence you in taking part in the trial you may contact:

[local patient advice service details]

VERSION 01 07JAN2011

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Qualitative Study
Interview sub-study

Educator information sheet

What is the purpose of the research?
We would like you to take part in an interview study which is exploring people's experiences of the REPOSE trial. To do this, we are interviewing patients and educators who are taking part in the trial. This work is being undertaken in order to better understand the outcomes of the REPOSE trial and to improve future courses, information and support given to patients.

Why have I been chosen?
You have been chosen because you are the educator who is taking part in the REPOSE trial, and we would like to learn about your experiences of delivering courses during the trial.

What would taking part in the research involve?
If you decide to take part, you will be interviewed once in a place of your choosing and at a time most convenient to you. With your permission, your interview will be tape-recorded. We estimate that each interview will up to an hour, although this will depend on what you have to say.

Do I have to take part in the research?
It is entirely up to you whether you take part in this study or not. If you do decide to take part, you are still free to withdraw at any time without giving a reason.

Will my taking part in the research be kept confidential?
Yes. All information that is collected about you during the course of the research will be kept strictly confidential. All the information you provide will be kept in a locked filing cabinet and stored on a password-protected computer within a locked office at the University of Edinburgh, under the supervision of the research team. All personal information will be removed from these computer files and they will not be shown to anyone outside the research team. When we type up the recordings made during interviews and write about the results of the research, all your personal details will be removed so that no-one will know who you are.

What will happen to the results of the research?
The results will be published in scientific and policy journals and presented to key groups of health professionals, voluntary organisations and groups involved in the care of people with diabetes. The results will be used to help to develop and improve education courses for people with diabetes and the methods used to evaluate them.

Are there any benefits to taking part in the research?
Although there may be no direct benefits to you personally, we hope that you find the research an interesting experience. Taking part will help us develop and improve education courses for people with diabetes.

Are there any disadvantages to helping with this research?
Your interview may take up to one hour of your time.

Who is funding the research?
The research is funded by the HTA (Health Technology Assessment).

Who has reviewed the research?
The research has been approved by [name of] independent research ethics committee.

What do I need to do next?
If you agree to take part, the Research Fellow [name to be added] will contact you to arrange to interview you. You will be asked to sign a consent form at the start of the interview.

Thank you very much for taking the time to read this. In the meantime, if you would like more information or want to ask any questions about this research please contact:

[Name of researcher]
University of Edinburgh
Centre for Population Health Sciences
Medical School, Teviot Place
Edinburgh EH8 9AG
Tel:
Email:

Thank you for taking the time to read this information sheet.

Copies: 1 for participant, 1 for researcher

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REPOSE Qualitative Study
Interview sub-study

Patient information sheet

We would like you to take part in an interview study which is exploring people's experiences of taking part in the [name of trial]. Before you decide whether or not to take part in this interview research, it is important that you understand why it is being done, and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

Please ask if anything is not clear (contact details are given at the end of this form). Taking part in this interview research is voluntary and your medical care will not be affected if you decide you do not wish to take part.

What is the purpose of the research?

We are interviewing people about their experiences of taking part in the REPOSE trial. This is so that we can get a better understanding of what people like and dislike about the courses they attend during the trial. We also want to look people's experiences of managing their diabetes after they have attended their courses. The research will help us to understand the findings of the REPOSE trial and be used to improve future courses, information and support given to patients.

Why have I been invited?

You have been invited because you have agreed to take part in the trial. We would like to learn about your experiences of, and views, about your course, and how you manage your diabetes after you have been on the course.

What would taking part in the research involve?

You would be interviewed in a place of your choosing and at a time most convenient to you. With your permission, your interview would be tape-recorded. We estimate that each interview would last about an hour, although this would depend on what you have to say.

Do I have to take part in the research?

It is entirely up to you whether you take part in this interview study or not. If you do decide to take part, you will be free to withdraw at any time without giving a reason. You can take part in the trial without having to take part in the interview study.

Will my taking part in the research be kept confidential?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential. All the information you provide will be kept in a locked filing cabinet and stored on a password-protected computer within a locked office at Edinburgh University. This will be under the supervision of the research team. All personal information will be removed from these computer files and they will not be shown to anyone outside the research team. When we type up the recordings made during interviews and write about the results of the research, all your personal details will be

removed so that no-one will know who you are.

What will happen to the results of the research?
The results will be published in scientific and policy journals and presented to key groups of health professionals, voluntary organisations and groups involved in the care of people with diabetes. The results will be used to help to develop and improve education courses for people with diabetes.

Are there any benefits to taking part in the research?
Although there may be no direct benefits to you personally, we hope that you find the research an interesting experience. Taking part will help us develop and improve education courses for people with diabetes.

Are there any disadvantages to helping with this research?
Your interview may take up to one hour of your time.

Who is funding the research?
The research is funded by the HTA (Health Technology Assessment).

Who has reviewed the research?
The research has been approved by [name of] independent research ethics committee.

What do I need to do next?
If you agree to take part, a member of the research team will contact you to arrange to interview you. You will be asked to sign a consent form at the start of the interview.

Thank you very much for taking the time to read this. In the meantime, if you would like more information or want to ask any questions about this research please contact:

[Name of Research Fellow] Centre for
Population Health Sciences
University of Edinburgh
Teviot Place
Edinburgh, EH8 9AG
Tel & Email: to be added

If you wish to speak to somebody who has no involvement in the study, and would therefore not influence you in taking part you may contact.

[Insert Local Advisor Contact details here]

Thank you for taking the time to read this information sheet.
Copies: 1 for participant, 1 for researcher.