**Participant Information Sheet**

The **EX**ercise for **T**ype **1** **D**iabetes (**EXTOD**) 101 study

Exploring the risks and benefits of exercise in adults with Type 1 diabetes: a ‘real world’ study of patients with Type 1 diabetes undertaking the Swansea Half Marathon.

**Invitation**

We would like to invite you to take part in our research study which is being conducted by the Taunton and Somerset NHS Foundation Trust. The Chief Investigator is Professor Rob Andrews.

Before you decide whether you would like to take part it is important for you to understand why the research is being done, and what it will involve.

Please take time to read the following information carefully and discuss it with others, including your GP, if you wish. One of our team will go through the information sheet over the telephone with you so please ask if anything is not clear, or if you need further information before deciding whether or not to join the study.

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

In people with Type 1 diabetes regular exercise improves physical fitness and strength, reduces risks that are linked to developing heart disease and improves well-being. Based on this evidence, organisations that give advice on managing diabetes recommend that people with Type 1 diabetes should do at least 150 minutes per week of moderate to vigorous exercise.

People with Type 1 diabetes who exercise, particularly those who are training for endurance events such as half marathons or triathlons, can have problems managing their glucose around exercise. These problems include difficultly controlling blood glucose during and immediately following exercise and unexplained severe low blood glucose, particularly at night following exercise.

Although guidance exists on how best to manage these problems, these guidelines are based on experiments in which people with Type 1 diabetes have exercised in laboratories where conditions are closely controlled. As a result patients describe dissatisfaction with the quality and accuracy of the current exercise guidance when used in the “real world”.

This study aims to closely monitor glucose levels and other aspects relating to diabetes in people who are training for and running a half marathon. We hope this will provide us with data to adapt the current guidance to help people with Type 1 diabetes manage their glucose when doing exercise in the “real world”, and thus help people with Type 1 diabetes who are planning to undertake such events in the future.

**Why have I been invited?**

You have been invited to take part in the study because you have Type 1 diabetes and have signed up to run the Swansea Half Marathon on the 24 June 2018.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form, a copy of which you will also be given to keep. If you decide to take part you are still free to withdraw at any time without having to give a reason. This will not affect the standard of care you receive for your diabetes

**What will I have to do if I decide to take part in this study?**

If you decide you would like to take part, and you are satisfied that all your questions about the study have been answered, a member of the EXTOD 101 study team will go through the Consent process with you over the telephone, ask you to sign the consent form and then post or scan and email this to us. The consent form can be found at the end of this information sheet.

An overview of the study is shown below:

|  |  |  |  |
| --- | --- | --- | --- |
| 6-8 weeks before half marathon |  | 1 week before half marathon |  |
| Questionnaire |  | Questionnaire |  |
| Home urine and blood test |  | Home urine and blood test |  |
| Optional blood test at GP |  | Optional blood test at GP |  |
|  |  |  |  |
|  |  |  | Marathon |
|  |
| From 6 weeks before to 2 weeks after the Half marathon (total of 8 weeks) |
| Wear a continuous glucose monitor |
| Keep a training diary |

All of the tests will be done at home unless you opt to do the additional blood tests which will be done by your GP.

We will post you two research packs. One will be sent to you 6-8 weeks before the half marathon and the second one 1 week before the half marathon.

**First research pack**

This pack will contain a letter, a questionnaire, home urine and blood kit, a continuous glucose monitor with 4 glucose sensors a training diary and two prepaid packages. In addition if you agree to do the optional blood test the pack will also contain a blood form and bottles to take to your GP surgery and an additional prepaid package.

*Letter*

The letter will provide instructions on how to complete the questionnaire and training diary, perform the home blood and urine test and how to use the continuous glucose monitor and fit the glucose probes. If you have agreed to do the additional blood test at your GP surgery there will be instructions as to how to do this.

*Questionnaire*

The questionnaire will ask you to record the date you were diagnosed with Type 1 diabetes, how you control your diabetes (insulin pump or injections), what insulin you use and your dosage and whether your diabetes has affected your eyes, kidneys or feet. You will also be asked to record you height and current weight. Finally you will complete a series of questions to assess your current activity levels and hypoawareness (awareness of low blood glucose). On completion of this questionnaire you will post this to the researchers at Taunton and Somerset NHS Foundation Trust using one of the prepaid packages.

*Home blood and urine kit.*

We will ask you to collect a urine sample in the provided container 2 hours after breakfast having emptied your bladder before breakfast. In addition we will ask you to prick your finger with a lancet (small needle – like you use for checking your blood glucose) and put some blood into a blood collection tube and one spot onto a blood card. The urine specimen, blood tube and blood card will posted back to the Royal Devon & Exeter NHS Foundation Trust Blood Sciences Laboratory, for analysis, in one of the prepaid packages.

*Continuous glucose monitor and 4 sensors*

A key part of this study is to be able to monitor your glucose day and night for 6 weeks before the half marathon, during the half marathon and for 2 weeks after the half marathon (8 weeks in total). To do this we will use the FreeStyle Libre flash glucose monitoring system (<https://www.freestylelibre.co.uk/libre/>).

The FreeStyle Libre works by measuring blood glucose levels via a sensor which is applied to the skin. The sensor continuously records glucose level measurements and these results can be accessed by scanning a handheld reader against the sensor or a mobile phone. The device can therefore provide glucose level results without requiring finger-prick tests each time. Each sensor last for 2 weeks.

The pack will contain one FreeStyle Libre starter kit, which contains a FreeStyle Libre reader, a computer cable, instruction book and 2 FreeStyle Libre sensors, and 2 additional FreeStyle sensors. When setting up the FreeStyle Libre we will ask you to link your Freestyle Libre to an account set up by us in the company’s secure online cloud (<https://www2.libreview.com/>) so that we can see your data. This is the way in which data is shared with clinicians within the NHS and meets all the data governance and protection guidelines. Data from the site will be downloaded, anonymised and assigned an individual study code prior to storage on secure servers at Taunton and Somerset NHS Foundation Trust prior to analysis.

In October 2017 the FreeStyle Libre was made available on NHS prescription for some patients with T1DM. If you already have and are using a FreeStyle Libre we will simply ask you to link this to our account.

At the end of the study you will be able to keep the FreeStyle Libre reader, computer cable, and instruction book.

*Training diary*

For the last 6 weeks of your training before the half marathon and for 2 weeks after the half marathon we will ask you to keep a record of how much exercise you are doing. For this we will ask you to keep a record of when you exercise and for how long, what your glucose was before and after the exercise and what measures you took to control your blood glucose before, during and after the exercise. We will ask you to return this diary two weeks after the half marathon.

*Optional GP blood test*

Type 1 diabetes is caused by the immune system attacking and destroying the insulin producing beta cells. The immune system is made up of different types of cells, and we know that the T cells (about half the total immune cells in the blood), are the cells responsible for causing Type 1 diabetes. Recent research has shown that exercise can improve the activity of T cells, but this has not been examined in people with Type 1 diabetes. As part of this study we would like to explore how exercise affects T cells in people with type 1 diabetes.

We cannot look at T cell function in the blood taken from the finger prick test because we need 30 mls of blood (6 teaspoons of blood - three times the amount of blood that is taken for a standard blood test). This means that an additional blood test needs to be done at your GP surgery. We have thus made this an optional test.

If you consent to this additional blood test we will ask you to make an appointment with your GP surgery who will collect the blood using the labelled bottles. Once the blood is taken we will ask you to place the bottles into the stamped addressed envelope and take it to the post office (rather than a standard post box) for overnight posting. This blood will go to the laboratory at the Institute of Immunology and Immunotherapy based at the University of Birmingham. This blood test will need to be taken on Monday, Tuesday or Wednesday so that it arrives in the laboratory before Friday.

**Second research pack**

This pack will contain a letter, a questionnaire, home urine and blood kit, and two prepaid packages. In addition if you agree to do the optional blood test the pack will also contain a blood form and bottles to take to your GP surgery and an additional prepaid package.

*Letter*

The letter will provide instructions on how to complete the questionnaire and perform the home blood and urine test. If you have agreed to do the additional blood test at your GP surgery there will be instructions as to how to do this.

*Questionnaire*

The questionnaire will ask you to record whether there have been any changes to your diabetes treatment and whether you have had any problems during your training. You will also be asked your current weight. Finally you will complete a series of questions to assess your current activity levels and hypoglycaemic awareness (awareness of low blood glucose) and determine what your plans are for managing your glucose before, during and after the half marathon. On completion of this questionnaire you will post this to the researchers at Taunton and Somerset NHS Foundation Trust using one of the prepaid packages.

*Home blood and urine kit.*

We will ask you to repeat the home urine and blood test that you did for us 6 weeks earlier and post the specimens back to us using one of the prepaid packages.

*GP blood test*

If you consent to this additional blood test, we will ask you to repeat this and and post the specimens back to us, again using one of the prepaid packages.

**What will be done with the samples I provide?**

The two home urine tests will be used to measure the amount of insulin that you are producing (C-peptide). The two home blood tests will be used to measure your long term glucose control (HbA1c), levels of fat in your blood (cholesterol, HDL, LDL and triglycerides) and C-peptide. The blood cards will be used to measure C-peptide. These tests will be carried out at Royal Devon & Exeter NHS Foundation Trust Blood Sciences Laboratory. A small sample of each urine and each blood test will be saved for future research (if you consent to this). We will not store any of your DNA (the material from which genes are made).

Measuring C-peptide in the home blood test and the blood card and comparing this to the level found in the home urine test will enable us to determine if these two tests can accurately measure C-peptide.

The two blood specimens that are taken at your GP surgery will be used to analyse the number and function of the T cells in your blood. This will be through standard immunological techniques. We will compare the T cells taken 6-8 weeks before the half marathon with the T cells taken a week before the half marathon to see if any change has occurred. These tests will be carried out in the laboratory at the Institute of Immunology and Immunotherapy based at the University of Birmingham. A small sample of each blood test will be saved for future research (if you consent to this). We will not store any of your DNA (the material from which genes are made) or any live cells.

Any samples that you give permission for us to store will be kept in a secure location under a study ID number only, with no other identifying information. Access to samples or information related to samples will be restricted to members of the research team only.

With your permission, at the end of the study, your home blood and urine samples and data will be transferred to the Peninsula Research Bank at the University of Exeter and blood taken at your GP surgery transferred to the Research Bank at the University of Birmingham Human Biomedical Resource Centre, to ensure their safe use in the future. All personal identifying information will be kept separately and may only be accessed by the Peninsula or University of Birmingham Research Bank data management team.

The Peninsula or University of Birmingham Research Bank steering committee will approve the use of samples for research into common disease, healthy ageing and other relevant medical research. This research may form part of collaborations in the UK or overseas including collaborations with scientists within companies.

Specifically samples:

1. Will not be sold for profit
2. Will not be used in animal research
3. Will not be shared with non-research organisations, such as the police.

**What about privacy and confidentiality?**

If you are enrolled in the study you will be given a unique study ID number. All information that is collected about you will be held on a password-protected computer. Access to this data and samples will be available to the research team only. Tests your doctor would often request (such as HbA1c or lipids) will be copied to your GP and/or hospital diabetes team to avoid unnecessary repeat blood tests. In addition if there were other findings that suggest a change to your treatment is needed we would inform both you and your doctor.

**What are the potential risks and benefits of taking part in the study?**

We do not anticipate there being any significant risks to your health by taking part in the study. Doing the finger prick test and placement of the continuous glucose probe might cause some slight pain and bruising. Similarly having the blood test at your GP surgery may be uncomfortable and may result in bruising.

One benefit from being involved in the study is that you will be provided with a FreeStyle Libre monitor and 4 glucose sensors. This will enable you to closely monitor your glucose for 6 weeks before the half marathon, during the half marathon and for 2 weeks after the half marathon (8 weeks in total). In addition your participation in this study will provide us with “real world” data to update the current guidance that help people with Type 1 diabetes to manage their glucose when exercising.

**What if something goes wrong?**

We will address any problems that might occur during your participation in the study. The research team will be happy to discuss with you any concerns and our contact details are given at the end of this information leaflet. However, if you have concerns or complaints arising from your experience of participating in this study which you do not wish to discuss with the research team directly, the Patient Advice and Liaison Service (PALS) will provide independent advice, help address your concerns and liaise with the appropriate members of the Taunton and Somerset NHS Foundation Trust on your behalf. Contact details for the PALS service are given below. We do not anticipate any adverse events related to your health following your participation in this project, however if you experience any problems we would be happy to be contacted to discuss them with you.

**Will I be told the results?**

We will not routinely give participants their individual results; however any results that may impact on your health or treatment will be shared with you and your healthcare team. When the analysis of the samples has been completed, a summary of the results will be sent to you by post and we will offer you to attend an evening event where we go over the results. Results from the study will be submitted for publication, and when published, copies will be available on the <http://extodorg.ipage.com> website. You will not be identifiable in these publications.

**Ethical review**

This study has been reviewed and approved by the Research Ethics Committee. The members of the committee are satisfied that all ethical requirements have been met.

**How is this study funded?**

This study is funded by the Welsh Branch of Diabetes UK.

**Who can I contact to find out more about this study?**

If you have any questions please contact:

Catherine Thompson

Diabetes Research Nurse

Diabetes Research Office

Department of Clinical Research

Musgrove Park Hospital

TAUNTON Email: Catherine.Thompson@tst.nhs.uk

TA1 5DA Tel: 01823 344986/344738

If you would like to discuss this project with someone other than the researchers please contactPALS (Patient Advice and Liaison Service) by telephone, email or in writing at:

PALS Office

Musgrove Park Hospital

TAUNTON Email: PALS@tst.nhs.uk

TA1 5DA Tel: 01823 343536

**What do I do if I am interested in taking part in this study?**

If you would like to be involved with this study the next step is for a member of our research team to go over the study with you on the phone and answer any questions that you may have. To do this we would be grateful if you could either contact Catherine Thompson, the lead research nurse on this project, by email or by phone (details shown above) and let us have a contact number and the best time to ring you. Alternatively you could complete the form below and post it back to us using the cut out address label found below.

*Thank you for reading this information sheet and considering taking part*

**REPLY SLIP**

I am interested in taking part in this study.

|  |  |  |  |
| --- | --- | --- | --- |
| Name |  |  |  |
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| Address |  |
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| Post code |  |  |  |
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| Please complete the details below |
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| Daytime tel: |  |  |  |
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| Mobile tel: |  |  |  |
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| Email: |  |  |  |
|  |  |  |  |  |
| Best time to ring (please circle) | Morning | Afternoon | Evening |

Thank you very much for your time.

*Please print this and the envelope label and send back to us.*



**EXTOD 101 Study**

**Exploring the risks and benefits of exercise in adults with Type 1 diabetes: a ‘real world’ study of patients with Yype 1 diabetes undertaking the Swansea Half Marathon**

Attach Sample Barcode Set Label Here

**Consent Form** v1.1 (11/03/2018)

**Participant ID**

|  |  |  |
| --- | --- | --- |
| **CONSENT STATEMENTS** | **YES / NO** **(Please circle)** | **PARTICIPANT****INITIALS** |
| I confirm that I have read the information sheet **version no. 1.1** dated **11-MAR 2018** for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily  | YES / NO |  |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected  | YES / NO |  |
| I agree to undergo the tests and investigations described in the Patient Information sheet. The nature of the tests and investigations and any possible risks have been explained  | YES / NO |  |
| I am happy to provide information about my diabetes and other information relevant to my participation in the study.  | YES / NO |  |
| I am happy to allow the research team to contact my clinician/GP about my participation in the study and to provide them with clinical results relevant to my care. This information may be shared with you and your clinician both now and in the future.  | YES / NO |  |
| I understand that relevant sections of my medical notes and/or data may be looked at by Taunton and Somerset NHS Foundation Trust, Sponsor, the Research Ethics Committee or by regulatory authorities during the study for monitoring and audit purposes (to ensure proper conduct of the trial)  | YES / NO |  |
| I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers  | YES / NO |  |
| I agree to take part in the above study  | YES / NO |  |

|  |  |  |
| --- | --- | --- |
| OPTIONAL CONSENT STATEMENTS |  |  |
| I agree to have my blood taken at my GP practice on two occasions to look at the effect of exercise on T cell function. | YES / NO |  |
| I agree to gift samples and data, collected during this study, to the Peninsula Research Bank and the University of Birmingham Research Bank and understand that they may be used in future research. I understand that these studies will be approved by a steering committee and my samples will not be used for any of the following: Sold for profit, used in animal research, shared with non-research organisations such as the police. My samples may be provided anonymously to researchers from the UK and abroad including academic organisations and commercial companies. | YES / NO |  |
| I agree to being contacted with details of future research and my details to be stored on a computer database for this purpose  | YES / NO |  |

|  |  |  |
| --- | --- | --- |
| **PARTICIPANT NAME (PRINT)** | **SIGNED** | **DATE** |
|  |  |  |
|  |
| **RESEARCHER NAME (PRINT)** | **SIGNED** | **DATE** |
|  |  |  |

***Note to Consenting Researcher:***

*Please ensure that one signed copy of this consent form is sent to the participant, together with a copy of the participant information leaflet.*

*A further signed copy of this consent form will be placed in the study site file.*