

Participant Information Sheet

EXercise for Type 1 Diabetes (EXTOD) education

Supporting adults with Type 1 Diabetes to undertake exercise: Developing and piloting an education programme for exercise in Type 1 diabetes.

Invitation

We would like to invite you to take part in our research study which is being conducted by Taunton and Somerset NHS Foundation Trust, and will be run at Taunton and Somerset NHS Foundation Trust. The Chief Investigator is Professor Rob Andrews, and the Principal Investigator at University Hospitals Birmingham NHS Foundation Trust is Dr Parth Narendran.

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 with you so please ask if anything is not clear, or you need further information before deciding whether or not to join the study.

What is the purpose of this study?

We know that exercise is an important part of the management plan 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 in people with Type 1 diabetes. 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.

Studies have demonstrated that less than 40% of people with Type 1 diabetes participate in regular exercise. These studies found that common reasons people gave for not doing exercise were:

- worry that they will experience a 'hypo' (hypoglycaemia).
- not knowing how to adjust their insulin dose and diet in order to exercise.

The studies also showed that if people with Type 1 diabetes were given the knowledge and skills to manage their blood glucose levels safely and effectively while exercising, they felt encouraged to exercise more.

Whilst most adults with Type 1 diabetes felt it was important to be informed about diet adjustments for safe exercise, few felt they had received information about this. Healthcare professionals reported that they would like more knowledge to support people with Type 1 diabetes to manage exercise. So far however no approved education programme exists for

this subject, and no approved courses exist for healthcare professionals to learn how to manage and support patients around diabetes and exercise.

The EXTOD education study wants to find the best way of supporting safe and effective exercise for people with Type 1 diabetes. The first part of our study, which involved developing an education programme, is now complete. The second part, this pilot study, involves delivering the new education programme to people with Type 1 diabetes. People taking part in this pilot study will be placed by chance ('randomised') to receive either the new education programme or to continue their usual care. Health care professionals will be trained to deliver the new education programme. The pilot study will collect information that will help us design a full clinical trial in the future.

Why have I been invited?

You are being invited to take part in this study because you have Type 1 diabetes. You may have previously indicated to us that you would be interested in participating in research studies, or may have responded to one of our advertisements for this study. Taking part in this study will not affect your usual medical care for Type 1 diabetes.

Can anyone be involved with this research or are you looking for specific people?

For this study we are looking for people with Type 1 diabetes who are between age of 18-70, have knowledge about carbohydrate counting and have attended a DAFNE course and are doing more than 30 minutes of exercise twice a week or have signed up to do a sporting event (run or cycle event for example) that will take place in the next 3-6 months. We are unable to include people who are on insulin pumps or have problems in sensing when their blood sugars are falling too low (hypo unaware). In the future we to hope develop education programs for people who are not doing very much exercise or are on insulin pumps or have hypo unawareness.

What will I have to do if I decide to take part in the pilot 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 education study team will go through the consent process with you on your first visit and ask you to sign the consent form - please see an example of this form included with this information sheet.

Once enrolled in the study you will need to attend 6 or 8 appointments over a period of 32 weeks. These appointments will take place at a hospital or diabetes centre local to you and you will be reimbursed for travel and parking expenses. The total number of appointments you will need to attend will be decided after visit 2 and the information in the next few paragraphs explains the reason for this.

At **visit 1** after completing the consent form a member of the study team will review and record your medical history. This will include questions about your diabetes, family history, social history and medications.

A doctor will then examine you. This is done to check that you have no medical problems that would prevent you exercising. The doctor will check your body systems, measure your height, weight, body fat content, waist and take your blood pressure.

During this first visit you will have a blood sample taken, and will be given some health questionnaires to complete. You will be given diaries to keep a record of your blood glucose and insulin doses. You will also be offered a continuous glucose monitoring system to wear, which will track your glucose for 7 days. You will be given an activity monitor that is worn on your wrist or around your waist, which will record your activity for 7 days.

Finally at the end of the visit you will be given a booklet and written information to keep for the duration of the study. You and a member of the study team will go through the booklet confirming future study appointments and add these to your booklet before you leave. It can also be used as a reminder of what to expect at each appointment during the study.

At **visit 2**, you will return to the hospital/diabetes centre to hand in the activity monitor, continuous glucose monitor and the blood glucose and insulin diaries. The researcher will check if you are still willing to continue on to the next stage of the study called 'randomisation'. This is when a computer programme will be used to randomly allocate you to one of two groups in the study.

If you agree to continue in the study the researcher will arrange a date and time to ring you to explain which group of the study you have been allocated to and to clarify which dates you will need to attend for future appointments as group 1 and group 2 have different numbers of appointments.

At **visit 3** you will attend the education session(s) for the group you have been allocated to – group 1 or group 2.

Group 1

The people allocated to group 1 will be asked to go to a half day update (**visit 3**) of the local diabetes education course, such as Dose Adjustment for Normal Eating (DAFNE). This study session will recap DAFNE insulin dose adjustment, and glycated haemoglobin targets (HbA1c targets). The rest of the session is guided by the attendees' questions and could cover a variety of topics such as: exercise; sick day rules and ketone monitoring; eating out and alcohol; social aspects such as travel; driving; weight loss; and questions around kit such as insulin pens, blood glucose meters and insulin pumps. If you are in group 1 you will need to attend a total of six visits over the 32 weeks the study lasts for. You will not be required to attend visit 4 and 5.

Group 2

The people allocated to group 2 will be asked to attend the new education programme. The new education programme is divided into 3 half day sessions (**visits 3, 4 and 5**) which are outlined in the table below:

Day 1	Day 2	Day 3
Welcome and introduction	Welcome back	Welcome back
Where are you now?	Sharing stories	Sharing stories
Mechanics 1- Understanding how your body works	Mechanics 2	Advanced strategies
Staying safe	Fuel for exercise	

Strategies before and during exercise	Strategies after exercise	
Next steps	Next steps	Future planning

Day 1 will start with an introduction to everyone in the group. You will then be asked to identify and share with the group what you would like to achieve by attending the course and what you will gain by managing your exercise (in 'where are you now'). The session will then go on to provide a broad overview of: how the body controls blood glucose levels during different types of exercise in people who don't have type 1 diabetes and in people who have type 1 diabetes (in 'understanding your mechanics'); recommended exercise levels; top tips for exercise to keep you motivated and safe; exercising and diabetes complications; along with blood glucose levels and what these mean for exercise (in 'staying safe'). We will then explore with you three strategies that can be used to control glucose levels during exercise: by using carbohydrate; or by using quick acting insulin; or by choosing different exercises (in 'strategies before and during exercise').

At the end of day 1 you will be guided through a pre- and post-exercise planner for your chosen exercise so that you have the opportunity to try out some of the new skills you have learnt during the session by the time you return for day 2 (in 'next steps'). You will be provided with a personal folder which contains all the information provided in the three sessions, along with several exercise planners.

Day 2 will take place one to three weeks after day 1. You will be welcomed back and encouraged to share your experience of exercise planning with the rest of the group (in 'sharing stories'). The session will then build on the points from day 1 and see if some of the groups individual exercise questions have been answered. There will be a brief recap of the key principles from day 1 and you will learn how exercise can influence the body's sensitivity to insulin and how to use this to your advantage (in 'understanding your mechanics'). The session then moves on to explore the importance of food and fluid for exercise and the importance of carbohydrate and protein (in 'fuelling for exercise'). In the 'strategies after exercise' section you will learn three ways to control glucose levels after exercise; by adjusting quick acting and background insulin; by using carbohydrate; and by using exercise itself.

In the final part of day 2 you will again be guided through an exercise planner and learn to problem solve for exercise and then apply the skills you have learnt in during the session. You will be encouraged to try this plan out when you exercise over the following weeks before day 3.

Day 3 will take place three to five weeks after day 2, so that you have time to try out some of the new skills from the earlier sessions. The group will be welcomed back and encouraged to share their experience of exercise planning with the rest of the group (in 'sharing stories'). This will be followed by a brief recap of some of the options for managing glucose levels when exercising. You will then learn some alternative strategies around carbohydrate replacement and insulin adjustment using: your body weight; the length of time you are exercising for; and how hard or intense the exercise is for you (in 'advanced strategies'). In the final part of day 3 you will again be guided through an exercise planner and see how to apply the skills you have learnt in all the sessions. The study team will video record some of

the education sessions as they are delivered. Study participants and educators will be asked for their agreement prior to any video recording taking place. This will be in addition to your study consent and will not be a requirement for study participation. The camera will be focused and directed on the educators and not the participants. If participants are unwilling to take part, the course will be delivered without recording. The video footage will be viewed by the trainers and used to carry out quality assurance and provide feedback to the participants. The film will be stored on a secure drive and deleted when the study is finished.

If you are in group 2 you will need to attend a total of eight visits over the 32 weeks.

Group 1 and 2 will be required to attend visits 6, 7 and 8. At **visit 6** you will attend a joint appointment with specialist staff in diabetes, who delivered the education session you attended at visit 3. In this session the team see how you are managing glucose control around exercise and give you further tips and advice to improve this further if need be. The researcher will check and record any problems (or concerns) you have had since the last visit. A letter will be sent to your local consultant and to your GP stating any recommendations that came out of the visit.

At **visit 7** you will be seen by the researcher for your 6-month assessment.–The researcher will repeat all of the tests you had done during your first visit, and check to see if you have had any problems since your last visit or if you have any questions or anything that needs following up.

Your final visit will be **visit 8**, around 8 months after you started the trial. All equipment, such as the activity monitor, continuous glucose monitor and diaries must be returned during this visit. The information from your blood glucose monitor will be recorded, and the monitor returned to you. Again the–researcher will review if any problems have occurred since your last visit. Letters with a summary of the visit 7 and 8 and the study will be sent to your local consultant and to your GP. Any recommendations from the study team will be included in the letter.

At any time during the trial, if you experience any adverse event that may need following up, or experience any problems with managing your diabetes or if a trial test needs to be repeated (for example a blood test that should be taken as part of the trial instructions), then you will attend extra visits. These are known as ‘unscheduled’ (unplanned) visits. If you have to attend an unscheduled visit, it may include (for example) a physical examination, or a review of any changes to your medication or having a blood test.

Do I have to take part?

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, and be asked to sign a consent form, which will include an agreement to being contacted with details of future research. If you decide to take part you are still free to leave the group (withdraw) at any time and without giving a reason. If you decide not to take part then this will not affect the standard of care you receive. If you are unable to continue, we will keep the information we have collected up to that point.

What are the possible benefits of taking part?

You may not receive a direct personal benefit. However if you are assigned to receive the newly developed education programme, you may find that the education you receive whilst taking part makes it easier for you to keep your glucose in the ideal range during and after exercise.

If you are allocated to group 1, the half day update of your local diabetes education course, we will offer you the chance to attend the newly developed education programme at the end of the study.

We will use the results of this pilot study to help us plan a randomised controlled trial, from which we will obtain further information on the effects of delivering the new education programme to larger groups. We hope to eventually benefit all people with Type 1 diabetes by supporting them to safely increase their levels of exercise.

What are the possible disadvantages and risks of taking part?

Taking part in this pilot study will not affect the usual diabetes care you receive. Although we are not asking you to increase your exercise levels, you may well increase this across the course of the study. As mentioned above, exercise is associated with an increased risk of hypoglycaemia. To help minimise this risk we will provide further education about how you should manage hypoglycaemia and, if you wish, will provide training to your partner and/ or relatives on how to manage severe hypos (at visit 1). The education provided to both groups i.e. the update of your local education and the new education programme should also help to reduce this risk further.

We will provide you with daytime and out of hours numbers to ring if you are having frequent hypos and need advice on how to manage these. Please see the end of this patient information sheet for these numbers.

In line with normal clinical advice, if at any point during your involvement in this study you have a severe hypo that you or your partner/relative cannot manage, an ambulance should be called (999).

If you would like to discuss any aspect of being involved in this pilot study you should contact the study team using the details at the end of this sheet. They will be happy to discuss things with you.

Will my taking part in the study be kept confidential?

If you decide to take part, we will inform your GP. All information that is collected about you during the course of this study will be kept strictly confidential and handled according to the Data Protection Act. If the research team become aware of anything during the study that may put you at risk they will inform your care team. We will always try to discuss this with you first.

Only authorised persons such as researchers and regulatory authorities will have access to view data that can identify you. This will include Taunton and Somerset NHS Foundation Trust, the Sponsor and Leicester Clinical Trials Unit, in order to monitor the quality of the research being carried out.

After the pilot study has ended, any reports and publications will contain only anonymous data (which means that any details that might identify you are removed). It will not be possible to identify you in any presentation, report or publication. An anonymised copy of the computer file (with) will be retained and made available to other researchers for use in future studies.

Who has reviewed the study?

All research that involves NHS patients or staff, information from NHS medical records or takes place in NHS buildings must be approved by an NHS Research Ethics Committee before it goes ahead.

Approval does not guarantee that you will not come to any harm if you take part. However, approval means that the committee is satisfied that your rights will be respected, that any risks have been reduced to a minimum and balanced against possible benefits and that you have been given sufficient information on which to make an informed decision. This study has been reviewed and given favourable opinion by Coventry and Warwickshire Research Ethics Committee.

If you decide to participate in this study you will be given a copy of the patient information sheet and the signed consent form to keep.

What happens when the pilot study ends?

The results will be presented at scientific meetings and will be published in medical journals. It is not possible to identify you personally in any presentations or reports of the study. We can send you a summary sheet of the results, written in everyday language, when the study has finished.

The investigators expect that as a result of the pilot study, they will be able to plan a full clinical trial to test out the new education programme on a larger scale. This will benefit even more people who have Type 1 diabetes.

How do I take part?

If you would like to take part in our study please contact your local EXTOD education study team, below:

EXTOD education team Contact Details

You can contact a member of the EXTOD education study team using the following details:

Catherine Thompson, Lead Diabetes Research Nurse
Tel: 01823 344986
Email: Catherine.Thompson@tst.nhs.uk
Diabetes Research Office
Department of Clinical Research
Old Building
Musgrove Park Hospital
Taunton, TA1 5DA

Numbers to contact for advice on managing problems with diabetes control

Daytime Number

Please ring **01823 344986**

Out of hours number

Please ring **07554000172** and ask for the on-call medical registrar. This registrar will be able to contact the on-call diabetes consultant if advice is needed from them.